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Stakeholder consultation on new genomic techniques to contribute to a Commission study requested by the Council

questionnaire

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Background

The Council has requested[1] the Commission to submit a study, by 30 April 2021, regarding the status of new genomic techniques under Union law.

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 altering the genetic material of an organism and which have emerged or have been developed since 2001[2].

The questionnaire concerns plants, animals, micro-organisms and derived products obtained by NGTs for agri-food, medicinal and industrial applications.

Please document your answers with explanations and concrete data as well as with practical examples, whenever possible. In case you wish to differentiate between different techniques, please clarify this in your reply.

Please indicate which information should be treated as confidential in order to protect the commercial interests of a natural or legal person.

Fundamentals of the NGTs according to footnote 2

MIV remark:

[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.

In the understanding of MIV, NGTs have to be considered in a differentiated way. Especially with CRISPR/Cas, TALEN, Zin-finger nucleases etc. the range of applications and the possibilities of changes on DNA level is very large. It ranges from small deletions and insertions to the insertion of large new DNA- sequences or even entire new gene constructs.

All our answers and comments relate exclusively to the organisms and products resulting from the modification of genetic information from small deletions or insertions (SDN 1, SDN 2) as they can also occur naturally.

Draft questionnaire

- Name of the stakeholder: **Association of the German Dairy Industry (MIV)**
- Interests represented by the stakeholder: **Information and application on NGTs**
- If your organisation includes other EU-level entities as members, please list all the contributors to the questionnaire.

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/products obtained by NGTs?

   no If no, please explain why not.

   MIV: As an association we and our individual members do not perform own research work on the area of NBTs. This is done outside of MIV. But MIV and our individual member observe very carefully the scientific research work and possible applications in the area of milk and feeds, which will come on the market in the near future and will influence our interests e.g. hornless cattle, feed and feed ingredients derived from gene edited plants and microorganisms. In the moment MIV can not estimate whether products derived from gene edited organisms will be used or not.

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

   MIV: we expect legal clarification, see above

3. Are you aware of initiatives in your sector to develop, use, or of plans to use NGTs/products obtained by NGTs?

   MIV and its individual members are generally aware of joint public and industrial research efforts world-wide to use genome editing in plants and animals. We are not only interested on the research work but also on the regulations world-wide and the possible resulting implications on the trade.

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

   MIV: See question 2

5. Are your members taken specific measures to comply with the GMO legislation as regards organisms obtained by NGTs?

   Yes

   MIV: The main problem will be if gene edited organisms (SDN1, SDN 2) will be regulated to comply with labelling and traceability requirement. Until now it will be not possible if products arrived on the market. In the moment the only way is to exclude products from countries where gene edited organisms or products are regulated in another way than in EU. We expect severe restrictions in the international trade.

6. Has your organisation/your members been adequately supported by national and European authorities to conform to the legislation?

7. Does your sector have experience on traceability strategies, which could be used for tracing products obtained by NGTs?

   MIV: only paper certificats up to now, but tracebility in general is well established in our sector

8. Are your members taking specific measures for NGT-products to ensure the compliance with the labelling requirements of the GMO legislation?
   MIV: see above

9. Do you have other experience that you can share on the application of the GMO legislation concerning products obtained by NGTs?

   Yes

   MIV: In Europe the stigma that is attached to a GMO product is such that no entity, public or private, would develop a GMO product for cultivation in the EU market today.

B-Information on research on NGTs:

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

    MIV: not applicable

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

    Yes

    MIV and its individual members observe the scientific literature and there we found examples of genome-edited plants that could fall under the exclusion as mentioned (question 29). Several of those examples originated in European research centers

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12. Has there been any immediate impact on NGT-related research in your sector following the Court of Justice of the EU ruling[3] on mutagenesis?

    MIV: Professor Klaus-Dieter Jany (Wissenschaftlerkreis Grüne Gentechnik e.V) conducted a survey on this question, the results of which he assembled in the first quarter of 2019. Those results can be made available to the Commission

13. Could NGT-related research bringing benefits/opportunities to your sector?

    Yes

    MIV: In the literature are many examples of edited plants that should be excluded from the Directive, the benefits are clear in respect of ecology, economic and sustainability but also on health effects for consumers.

14. Is NGT- related research facing challenges in your sector?

    MIV: No, not that we are aware of. The development in the milk area is not yet very advanced.

15. Have you identified any NGT-related research needs/gaps?

    MIV: currently unknown

C-Information on potential benefits and opportunities of products obtained by NGTs:

16. Could products obtained by NGTs bring benefits/opportunities to your sector/field of interest?

    Yes

    MIV: See above 13

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

    Yes

    MIV: See above 13

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

    Yes

    MIV: Our knowledge derives mainly from literature data and we found only two products associated with a large company. All others come from public research or SMEs.

19. Do you see benefits/opportunities from patenting or accessing patented NGTs/products obtained by NGTs?

    Yes

    MIV: Whether the products are patented or not is not an issue. There cannot be a return on investment on an innovation that is not patented.

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D-Information on potential challenges and concerns on products obtained by NGTs:

20. Could NGTs/NGT-products raise challenges/concerns for your sector?

    MIV: see no harm or danger associated with organisms (plants, animals) modified in the range of SDN1 and SDN2. Therefore we propose that they should be treated in the same way as organisms (plants, animals) obtained by conventional breeding (mutation) techniques.

21. Could NGTs/NGT-products raise challenges/concerns for society in general such as for the environment, human, animal and plant health, as well as social and economic challenges?

    no

    MIV: As far as we know from products present on the market or in the pipeline, the products derived from organisms modified in the range of SDN1 and SDN 2 have the same "risk" profile as organisms (plants and animals) derived from conventional breeding techniques.

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

    Yes

    MIV: The challenges exist if and only if all NGTs are treated as GMOs. If they are, these products will not be developed in the EU for the reasons stated in the response to question 9.

23. Do you see challenges/concerns from patenting or accessing patented NGTs/products obtained by NGTs?

    no

    MIV: European SMEs will patent their inventions to the same extent as SMEs originating in other parts of the world. No SME to our knowledge has been blocked from developing an NGT product as a result of a patent in Europe or elsewhere.

E - Safety on NGTs/NGT-products

24. What is your view on the safety of products obtained by NGTs?

    MIV: the products derived from organisms modified in the range of SDN1 and SDN2 are indistinguishable from conventionally bred plants or animals. They contain genes (alleles) that either exist in their gene pool or are well known in another plant species. Because of their natural origin these genes (alleles) can be considered to have a history of safe use that is as long as humanity's use of products derived from plants/animals containing such genes (alleles).

25. Do you have specific safety concerns on products obtained by NGTs?

    No

MIV: related exclusively to the organisms and products resulting from the modification of genetic information from small deletions or insertions (SDN 1, SDN-2) as they can also occur naturally.

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F - Ethical aspects NGTs/NGT-products:

26. What is your view on ethical aspects related to products obtained by NGTs/NGT-products?

MIV see no ethical question raised by their use as the genes (alleles) occur naturally, are well-known and have a functionality that is understood.

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

no

See above

G – Consumers right for information/freedom of choice

28. What is your view on the labelling of products obtained by NGTs?

MIV: There is no need to label products derived from gene edited organisms. (see lower and our statement at the beginning).

29. Do you have specific concerns on labelling of products obtained by NGTs?

Yes

MIV has concerns on a general labelling of products derived from gene edited organisms. We see problems to differentiate products derived from "classical" mutagenesis procedures and from identical products derived from SDN-1 or SND-2 organisms. In the first case the product is legally not derived from a GMO and must be not labelled whereas in the second case it must be labelled as a GMO as it is derived from a GMO, since it is classified as gene engineering according to the EUGH judgment.

A modification can be demonstrated, but not through which this result came about.

Or more specific: There is no need or justification to label a genome edited plant if the modification that has been made corresponds to the following:

the plant has a native allele that has been edited to reproduce a functionality associated with a known allele present in its natural gene pool;

the plant has a native allele that has been edited to reproduce a functionality associated with a known allele present in a plant species that is outside the plant's natural gene pool;

the plant has a native allele that has been edited to reproduce a new functionality, of which the sequence modifications obtained by genome editing are of the same type as those which be obtained by spontaneous or induced mutagenesis;

or the plant possesses a gene known and present in its natural gene pool which has been inserted into a targeted site of its genome.

Therefore we have a special concern on labelling "ohne Gentechnik "(without gene engineering). It is possible to detect changes on the DNA-level, but it can not prove on which way this (these) modification (s) are occoured.

Our concerns would be alleviated if organisms or products modified by SDN1 and SDN2 were excluded from the scope of The Directive and related GMO regulations in Europe.

H - Final question

30. Do you have other comments you would like to make?

Yes/no - If yes, please provide your comments here.

MIV would like to ask the Commission to contact [redacted]@biotech-gm-food.com) for more informations.

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