

# 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

NATRUE AISBL, The International Natural and Organic Cosmetics Association

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

Cosmetics: specifically finished cosmetic products made from raw materials isolated and derived from natural (non-GMO) and organic agricultural products.

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

A list of NATRUE members can be found here: <https://www.natrue.org/our-members/>. Memberships are NATRUE label users but membership is not mandatory to use the NATRUE label. Label users can be found here: <https://www.natrue.org/our-standard/natrue-certified-world/>. The NATRUE standard set verifiable criteria for natural and organic cosmetics in the absence of an official regulatory definition. Criteria is aligned with consumer expectations.

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)

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\* 1. Are your members developing, using, or planning to use NGTs/NGT-products?

- Yes  
 No  
 Not applicable

\* Please explain why not

The voluntary NATRUE standard (<https://www.natrue.org/our-standard/natrue-criteria-2/>) setting label criteria to carrying the NATRUE label, which is used by our label users and members for the purposes of third-party certification of finished products and selection of compliant raw materials, prohibits the use of raw materials from GMO origin as described in Section 1.2.3. The definition of a GMO used in the standard is that referred to in Directive 2001/18/EC.

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

- Yes  
 No  
 Not applicable

\* Please provide details

Currently, for non-organic raw materials the independent control bodies approved by NATRUE rely on EU legislation (Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003) conformity for traceability and labeling of plants origin and raw materials including non-food building blocks for derivatives used in cosmetics. Our control system relies on the stringency of the current legal framework. (Un)intentional contamination with NGTs (GMOs) will impact the compliance of the raw materials used, and hence the finished product's ability, to match our standard. Although there is no official regulatory definition European consumers expect natural and organic cosmetics to be non-GMO. For organic cosmetics, which may use natural grade ingredients for certain functionalities, the presence of these natural ingredients from NGTs (GMOs) would undermine consumer trust and also the validity of the claim organic, which is often associated with organic food where GMOs are prohibited under Art. 9 of the EU Organic Regulation. Whilst we are not aware of natural or organic raw materials for cosmetic end use that have been impacted by NGTs there is a risk to the integrity of the non-GMO supply chain, and so the validity of the consumer and sector demands for such non-GMO claims for natural and organic cosmetics where the same transparency and traceability afforded to existing GMOs is not extended and guaranteed for NGTs (also GMOs).

\* 2 bis. Have you encountered any challenges?

- Yes  
 No

\* **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

Since there is no opportunity to put a response in the 'no' section, we would like to emphasise that since there is no official definition or harmonised criteria at EU level for natural or organic cosmetics, there is always the reality that outside the scope of certified products with non-GMO criteria, cosmetic products are free to use raw materials from GMO, non-GMO or a mix of the two in both natural and organic cosmetics. The natural and organic sector is outpacing the cosmetic industry in terms of growth by ca. 5-7 times, and this growth is based upon a number of factors including trust and raw material transparency - even for non-certified products.

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

- Yes  
 No  
 Not applicable

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

- Yes  
 No

\* Please provide details

Transparency about crops using and positive testing for NGTs remains inadequate to be sure that all crops will remain without testing should these crops be used to isolate natural substances for cosmetic products. Without details to confirm a crop is GMO, then there is a risk for inclusion in products that would ordinarily prohibit them impacting the consumers' right to know, right to choose.

**\* 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

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

- Yes  
 No  
 Not applicable

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

- Yes  
 No  
 Not applicable

**\* 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

**\* 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**

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

- Yes
- No
- Not applicable

\* Please explain why not

NGTs (GMOs) are banned from use in certified natural and organic cosmetics under the NATRUE standard. NATRUE label users, who include all NATRUE members, do not use GMOs.

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

- Yes
- No
- Not applicable

\* **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 explain why not

So far as we are aware we have not witnessed changes to the available raw materials that may impact compliance with the non-GMO in the NATRUE standard for natural and organic cosmetics. Neither have we seen new raw materials on the market that, to our knowledge, stipulate that they specifically use NGTs (GMOs). This does not mean though that there are not products on the market where raw materials may be sourced or future sourced from NGT (GMO) origin without proper declaration as a GMO or adequate testing to maintain transparency and traceability throughout the supplier chain for cosmetic ingredients from natural or organic origin.

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

- Yes
- No
- Not applicable

\* Please explain why not

Due to the fact that consumers do not expect natural and organic cosmetics to contain GMOs in Europe, and use of GMOs or products from GMOs in an organic cosmetic is fundamentally opposed to the consumer and legal understanding of this term from the food sector.

\* **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 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

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

- Yes
- No

\* Please explain why not

As mentioned before, consumer expectations and perceptions of natural and organic cosmetics are diametrically opposed to the use of raw materials manufactured from GMOs like NGTs. For certified cosmetics (natural or organic) non-GMO is a criterion for conformity. For non-certified cosmetic products, manufacturers will still pursue due diligence in traceability in order to support claims like non-GMO.

**\* 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 explain why not

Independent of substance origin, all cosmetic raw materials and products must be safe and in a position to demonstrate this safety. The principle concern for NATRUE is the authenticity, transparency and traceability of natural and organic raw materials to ensure the integrity of the claim (natural or organic) on finished cosmetic products, and therefore avoid greenwashing and misleading claims for these two terms. The accuracy and transparency of these claims in order to meeting consumer expectations overlaps with the consumers own right: the right to know and right to choose. Within the scope of the standard GMOs are excluded for their inconsistency with consumer expectation of these claims, natural and organic; we cannot comment outside this scope.

**\* 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 to NATRUE's scope given the prohibition of GMOs under the NATRUE standard.

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

- Yes  
 No

\* Please explain why not

Not applicable to NATRUE's scope given the prohibition of GMOs under the NATRUE standard.

*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**

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**\* 20. Could NGTs/NGT-products raise challenges/concerns for your sector/field of interest?**

- Yes  
 No

\* Please describe and provide concrete examples/data

As mentioned previously consumer expectations are for natural and organic cosmetics to be made from non-GMO raw materials in Europe. Hence, the origin as non-GMO must be confirmed. Private standards setting label criteria for independent certification of natural and organic cosmetics prohibits GMOs. Whilst there is no harmonised criteria at EU level for natural and organic cosmetics to prohibit the use of NGTs in the future, the non-GMO claim is a baseline consumer demand given their familiar with the criteria already set by private standards, like NATRUE, in this regard.

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

- Yes  
 No

\* Please explain

Please see above.

**\* 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

For consumers, please see previous comments.

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

For third-party certification to natural and organic private standards, as well as companies who may choose not to certify and who are moving into the natural/organic sector of the cosmetic industry, there is a need to confirm the origin of raw materials to support claims. This is particular true of organic cosmetics.

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

- Yes
- No

- \* Please explain

Please see the points highlighted above.

- \* **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 to NATRUE's scope given the criteria in the NATRUE standard prohibiting GMO use.

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

- Yes
- No

- \* Please explain why not

Not applicable to NATRUE's scope given the criteria in the NATRUE standard prohibiting GMO use.

*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

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

All uncertainty must be reviewed scientifically by rigorous testing and not assumed by analogy to historical methods in use for long periods of time. Risk assessment and adequate downstream testing to identify and risk manage such GMOs is crucial.

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

- Yes  
 No

\* Please explain why not

Products from existing GMO crops for cosmetic use will be safety assessed in Europe by law. However, the integrity of the subsequent claims natural (non-GMO) and organic will be effected if NGT/NGT-products are used.

*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

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

NATRUE members support increased biodiversity and social and environmental sustainability efforts without use of GMOs. Consequently, any negative impact to these factors would be view as unethical.

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

- Yes  
 No

\* Please explain

Environmental impacts of premature use of these products without appropriate, rigorous and thorough risk assessment and adequate testing for traceability and transparency in the supply chain.

*Please upload any supporting documentation for this section here*

The maximum file size is 1 MB

## G - Consumers' right for information/freedom of choice

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

As for all products from GMOs under existing EU legislation (cf. Regulation (EC) No. 1829/2003 and 1830 /2003), NGT-products must be labelled. Without labeling, without traceability there is a decisive risk to undermine the integrity, trust and transparency of the supply chain ultimately leading to consumers who have the right to know and the right to choose.

*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

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

- Yes  
 No

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### Contact

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