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Impact Assessment on New Genomic Techniques – Why Participation of Non-GMO Producers and Marketers Matters

The purpose of this briefing is to inform companies in advance so that they can prepare to participate in the impact assessment (IA). The impact assessment itself (and, therefore, the opportunity to contribute) will be launched at beginning of April 2022 at the earliest.

Executive Summary

As part of the legislative process the EU Commission (EC) has announced an **impact assessment (IA) for New Genomic Techniques, expected to start at the beginning of the second quarter of 2022.** Stakeholders affected by the envisaged new GMO legislation will be invited to comment on policy options during a **12-weeks consultation period**.

Active and wide-scale participation of conventional and organic Non-GMO food producers and marketers is of utmost importance: **The Non-GMO sector will need to actively stand up for its business interests.**

On the basis of an IA the EC decides whether to submit a new legislative proposal (or not) and its content. The more companies from the food and feed sector pro-actively speak out in favour of strict regulation of new GMOs, the more powerful the signal to the EC, member states and the European Parliament - as political decision makers on this issue - will be.

Non-GMO producers and marketers need to have full transparency throughout the whole value chain; products consisting of, containing or are produced from GMOs need to be identifiable and traceable. This is guaranteed by the current EU GMO legislation with its traceability and labelling requirements for old as well as for new GMOs – but would be severely threatened in case of deregulation or a substantial lowering of regulation standards. Without this knowledge the conventional and the organic Non-GMO business operators will run the risk of selling their customers (B2B as well as B2C) unwittingly and unintentionally new GMOs. They will be the first that will be confronted with the anger of consumers, not the politicians, nor the biotech industry.

A loss of control over the value chains will lead to a loss of consumer confidence. Any Non-GMO label needs to be able to fully guarantee "production without the use of genetic engineering" – including old as well as new methods of genetic engineering. Without such a comprehensive claim any label would become implausible – and consequently invalid to both producers and consumers. This also applies to the organic sector. EU regulation excludes the use of GMOs for organic products. Consequently, with a deregulation a major selling point would be at stake. **Massive economic setbacks for the conventional and organic Non-GMO producers and marketers loom.**

The EC justifies its effort for deregulation of new GMOs with their alleged contribution to sustainability – without being able to provide clear criteria what sustainability means and how a proof of claim should be carried out. **The labelling of new GMOs as sustainable is under discussion. Whether such labelling would replace a GMO label or be used in parallel is an open question. This idea could undermine the whole concept of sustainability, as consumers don't acknowledge GMOs as sustainable.**

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In order to:

- **protect your freedom to conduct Non-GMO business;**
- **avoid disrupting the booming conventional and organic Non-GMO markets**, which are widely seen as strong markets of the future;
- **meet consumer expectations for food free from GMOs**

please **use the opportunity to pro-actively raise your voice against deregulation of new GMOs** via participating in the IA. **ENGA will advise and assist** (more details on this laid out below). Please get in touch with us if you are interested or if you have any questions.

1. Starting point: Why Is an Impact Assessment Taking Place?

1.1 European Court of Justice: New GMOs are GMOs

In its landmark judgment in July 2018 the European Court of Justice (ECJ)[1] ruled that new GMOs (produced with techniques like CRISPR/Cas) have to be regulated in the same manner as old GMOs - that is they are subject to the current EU GMO legislation. In accordance with the precautionary principle they must undergo environmental and food safety risk assessments before receiving permission to enter the EU market. Their producers must provide detection methods, economic operators must ensure traceability throughout the entire value chain, and authorities are responsible for effective monitoring methods. GMO labelling is compulsory for genetically engineered feed and food.

1.2 EU Commission on a Course of Deregulation

Contradicting the ECJ's judgment (and thus giving in to massive lobby pressure), the EU Commission (EC) announced in April 2021 that the current EU GMO legislation is "*no longer fit for purpose.*"[2] Consequently, the EC "*will aim at a proportionate regulatory oversight for the relevant plant products by adapting, as warranted by the future impact assessment, the risk assessment and authorisation procedures and the labelling/traceability requirements*."[3]

Even if phrases like "*proportionate regulatory oversight*" and "*adapting (…) the risk assessment and authorisation procedures and the labelling/traceability requirements*" sound neutral, in fact **the EC is striving to lower or even abolish food safety assessment and transparency standards for most new GMOs.**

In its letter to the Portuguese presidency[4] in April 2021 the EC states: *"As concluded by the European Food Safety Agency (EFSA), plant products with similar risk profiles can be obtained with conventional breeding techniques, targeted mutagenesis and cisgenesis. Thus, a different regulatory oversight for similar products would not be justified in these cases*."

This is a clear confirmation that the EC suggests that products derived from targeted mutagenesis and cisgenesis (these are GMOs without the integration of DNA from other species) are to be treated like those derived from conventional breeding techniques. As a logical consequence in a future GMO legislation, the precautionary principle would not be applied any more for plants produced with targeted mutagenesis and cisgenesis techniques. Thus, risk assessment and authorisation procedures would not be seen as compulsory, nor would labelling and traceability requirements.

[1] https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-07/cp180111en.pdf
[2] https://ec.europa.eu/commission/presscorner/detail/en/ip_21_1985
[3] https://ec.europa.eu/food/system/files/2021-04/gmo_mod-bio_ngt_letter.pdf
[4] https://ec.europa.eu/food/system/files/2021-04/gmo_mod-bio_ngt_letter.pdf

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1.3 National Authorities: Why a Strict Regulation of New GMOs is Necessary

Good arguments why such deregulation is inappropriate are provided by a study published in 2021 by experts from various national safety authorities. Their "Considerations for a Focused Case-Specific Risk Assessment in the EU" paints a very different picture for a method as well as trait-related risk assessment for new GMOs.[5]

In its viewpoint from October 2021 the German Agency for Nature Conservation (BfN) explains why the current GMO regulation in the EU is suitable and also necessary for new GMOs to protect humans, animals and the environment from potential dangers, as well as to support possible sustainability goals established in the framework of European strategies.[6]

2. What is the Impact Assessment on New Genomic Techniques About?

2.1. Impact Assessment with Focus on GMO Plants

The Impact Assessment (IA) on New Genomic Techniques will focus on plants obtained by targeted mutagenesis and cisgenesis. New Genomic Techniques is a term invented by EU institutions, avoiding the legally correct term GMOs (as confirmed by the ECJ). Plants created by targeted mutagenesis and cisgenesis are GMOs without the integration of DNA from other species.

2.2. Outcome of Impact Assessment Decides on Future Regulation of New GMOs

Initiated by the EC, an IA is part of the legislative process in the EU. Stakeholders affected by an envisaged new legislation can comment on policy options during a 12-week consultation period. **On the basis of an IA, the EC will decide whether to submit a new legislative proposal (or not), and about its content.** The IA for New Genomic Techniques has been announced for the second quarter 2022. An evaluation will be carried out by the Biotech Unit of DG SANTE by the end of 2022. As a rule, the EC publishes the results of an IA together with a legislative proposal. This is expected in the second quarter of 2023.[7]

The IA mainly will take place via questionnaires. How exactly they will be designed is still open, as are the guidelines for answers. Answers can be very general ("agree, agree to some extent, disagree") or allow individual statements ("What should a future labelling regime look like?"). In such a variant, there will be a limit on the number of characters and the possibility to upload additional documents. An additional survey for certain stakeholders in workshops or meetings is also possible.

3. Why is Participation in the Impact Assessment of Utmost Importance for Non-GMO Producers and Marketers?

The more individual companies and associations that represent Non-GMO business operators pro-actively participate, the better.

With the IA, the EC will determine which policy options are politically feasible and how much resistance or support it can expect in the legislative process. **From the stakeholder input the EC can see how far it can go with its plans to weaken or abolish risk assessment and labelling for new GMOs.** It will also assess whether a sustainability claim for new GMOs will gain acceptance.

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[5] https://www.mdpi.com/2673-6284/10/3/10
[6] https://www.bfn.de/en/latest-news/bfn-viewpoint-new-genetic-techniques-and-their-regulation
[7] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en

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3.1. Pro-Deregulation Business Lobby Needs a Strong Non-GMO Business Counterpart

Much will depend on - individual - voices and inputs from the business sector. Civil society alone is too weak to prevent deregulation of new genetic engineering. The pro-deregulation business lobby needs a strong counterpart. Unlike seed developers from biotech companies who sell GMOs to farmers, food producers and retailers will be the ones who will have to face the direct judgement of consumers – and market research throughout Europe shows that the majority of them are sceptical towards old and new GMOs.[8]

A clear and unambiguous positioning of Non-GMO producers and marketers during the IA has the power to make a difference!

4. Why is the Impact Assessment about Freedom to Conduct Non-GMO Business?

4.1. Deregulation of New GMOs Will Harm Non-GMO Business Operators

The Inception Impact Assessment (IIA)[9] from October 2021, as a preparation for the IA, made very clear that business interests in the field of GMOs are at least contradictory or even exclude each other. Under the heading "*Likely impacts on fundamental rights"* it states:

"Adapting legal requirements for plants obtained by targeted *mutagenesis and cisgenesis in accordance with their risk levels may bring new opportunities for agri-food system and biotechnology operators, as well as researchers, and SMEs, enhancing their freedom to conduct their business. Organic and GM-free operators have expressed concerns that their freedom to conduct business might be negatively affected."*

While an **adaption of legal requirements (a lowering or abolishing of standards)** will expand the freedom to conduct business for agri-food system operators (such as commodity traders and some farmers) and biotechnology operators (such as Bayer and Corteva as the major patent holders for New Genomic Techniques)[10], it **will massively threaten the freedom to conduct business for the conventional and organic Non-GMO producers and marketers.**[11]

4.2. Increased Costs, Risks to Sell Unwittingly New GMOs

This applies to both regulated and deregulated new GMOs. **For regulated new GMOs costly and complex systems are needed to separate the flow of goods**. Since there is no polluter-pays principle in the EU, **the Non-GMO producers would have to bear the costs for product segregation, analysis and monitoring**.

For deregulated new GMOs traceability and labelling requirements would be eliminated. However, **to credibly label "Non-GMO", food and feed producers need to know which products consisting of, containing or are produced from GMOs. Without this knowledge they run the risk to unwittingly and unintentionally sell new GMOs.**

[8] https://www.greens-efa.eu/en/article/news/opinion-poll-on-the-labelling-of-gm-crops
[9] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en
[10] https://www.testbiotech.org/sites/default/files/Patents_on%20new%20GE.pdf
[11] See Retailers' Resolution Against Deregulating New GMOs
https://www.enga.org/fileadmin/user_upload/pdf/Retailers_Resolution_03_11102021.pdf

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5. Deregulation of New GMOs: What is at Stake for Conventional and Organic Non-GMO Producers and Marketers?

- **Loss of control over *all* value chains** due to lack of GMO labelling: After a deregulation, new GMOs can be present everywhere in agriculture and in food and feed production, not only in Non-GMO and organic value chains.
- **Loss of consumer trust:** Any Non-GMO label needs to be able to fully guarantee "production without the use of genetic engineering" – including "old" as well as "new" methods of genetic engineering. Without such a comprehensive claim any label would become implausible – and consequently invalid to both producers and consumers. This is just as valid for the organic sector: EU regulation foresees that for organic products the absence of GMOs is compulsory. Consequently, with a deregulation or lowering of standards, a major selling point would be at risk for the organic sector. The EU Commission's own target in its Green Deal, to raise the share of organic production to 25% by 2030, will be in jeopardy.
- **Loss of investments** throughout the whole Non-GMO value chain. To be able to credibly label Non-GMO, feed and food producers substantially invested in changing recipes and formulations, developing quality management systems, establishing segregation in production and transport, installing certification systems by external certification bodies, and informing consumers of the advantages of Non-GMO food with widescale marketing campaigns. Who will be liable if these investments turn out to be in vain?
- **The need to develop fully segregated value chains** (from seeds to agriculture to feed to food production to retail) would be highly complex and expensive, hardly feasible or even impossible.
- **Massive setbacks for the conventional and organic Non-GMO markets** – despite the fact that they have been booming throughout Europe for more than ten years and commonly are considered to be strong future markets. Market research all over Europe clearly shows: **Consumers want to be able to buy food free from GMOs – and expect from their retailers and food producers to credibly fulfil this expectation.**

6. Which Policy Options is the EU Commission Likely to Present in the Impact Assessment?

The EC will probably present 4 policy option for comments.

Option 1: Maintaining the status quo. No change to existing legislation.

Option 4: Complete deregulation. All plants produced with targeted mutagenesis and cisgenesis will be removed from GMO legislation. With such a deregulation, the vast majority (about 95 per cent) of new GMOs currently in the pipeline[12] would enter the market without any risk assessment and labelling.

[12] https://publications.jrc.ec.europa.eu/repository/handle/JRC123830
Modrzejewski D, Hartung, F., Sprink, T., Krause, D., Kohl, C., Wilhelm R. (2019) What is the available evidence for the range of applications of genome-editing as a new tool for plant trait modification and the potential occurrence of associated off-target effects: a systematic map. Environ Evid 8 (27). doi:10.1186/s13750-019-0171-5

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Option 2 and Option 3: Deregulation according to risk levels. Under the heading of "*proportionate risk assessment*", risk classifications of GMOs with corresponding criteria are likely, combined with data requirements for an authorisation. The variant "no risk, no regulation, no data collection" for certain (or the majority of) new GMOs is also likely to come into play. If a risk classification were to be linked to the question of labelling and traceability, proposals could be conceivable that for certain GMOs classified a priori as safe and exempted from risk assessment, the obligation for labelling and traceability could be deleted.

Options 2 and 3 will differ in terms of the scope of exemptions from regulation, the extent of data requirements and transparency.

6.1. Two Legislative Variants Likely to Be Presented by the EU Commission

In addition to the options, the EC is likely to present two legislative variants for deregulation: firstly, an amendment of the current Directive 2001/18 (e.g. amendment of the GMO definition, extension of the mutagenesis exemption to include targeted mutagenesis, etc.), and secondly a new legislation that exclusively regulates plants produced with targeted mutagenesis or cisgenesis.

6.2. Sustainable New GMOs?

It is also possible that the EC will integrate the sustainability topic into a new legislation for new GMOs. One main reason for deregulation is the alleged contribution of new GMOs to sustainability. Currently it is completely unclear whether the EC will oblige the GMO developers to submit a proof of claim according to precisely defined criteria. This lack of clarity is increased by the fact that the legislative proposal for a sustainable food systems framework (which should contain sustainability criteria) is not expected before the fourth quarter 2023[13] – half a year later than the legislative proposal for new GMOs.

Should new GMOs be classified as sustainable (as has been done recently for nuclear energy), this is likely to be perceived as "greenwashing", as consumers see "sustainable" as a synonym with environmentally friendly, without GMOs and pesticides, and local.[14]

7. What is the Objective of Non-GMO Producers and Marketers in the Impact Assessment?

Our overarching goal is to prevent deregulation – thus to stop the deregulation process initiated by the EC. In the best case, the EC will not present a proposal to change GMO legislation (= Option 1: maintaining the status quo). In the second-best case, it will submit a new legislative proposal that strictly regulates plants produced with targeted mutagenesis and cisgenesis.

After some public pressure, the responsible Commissioner Stella Kyriakides stated at the EC's High-Level Conference on New Genomic Techniques on 29 November 2021 **that maintaining the current legislation could be a possible outcome of the IA and the legislative process**.[15]

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[13] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13174-Sustainable-EU-food-system-new-initiative_en

[14] https://www.beuc.eu/publications/consumers-and-transition-sustainable-food-executive-summary-and-recommendations/html

[15] https://webcast.ec.europa.eu/high-level-event-on-new-genomic-techniques-the-way-forward-for-safe-and-sustainable-innovation-in-the-agri-food-sector

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8. ENGA's Services for Your Contribution to the Impact Assessment

Our service is meant for companies that want to maintain and secure their conventional and/or organic Non-GMO portfolio.

- **Please feel free to contact ENGA proactively!**
- In addition, ENGA will contact companies individually to inform them about the impact assessment and its relevance for maintaining strict regulation of new GMOs.
- After the launch of the impact assessment in the second quarter of 2022: ENGA's provisional assessment of the policy options will follow within a week.
- Within three weeks after the launch: ENGA will support you with a comprehensive assessment and recommendations for answers. Individual advice is also on offer.
- And please be advised: ENGA is attempting to mount an EU-wide information and activation campaign to motivate as many Non-GMO producers and marketers as possible to participate in this important endeavour. This requires significant commitment, substantial know-how – and funds. Not all of the suggested services are covered yet by the existing budget. ENGA is still in need of additional members and supporters – please show your commitment and join our cause with financial support.

9. Which ENGA Toolkits Can You Use During the Impact Assessment?

In April, ENGA will start providing toolkits you can use for your communication. You can:

- share content prepared by ENGA (and posted via LinkedIn) within your company and feed internal communication channels with information about the deregulation process and its threat for your Non-GMO business;
- use ENGA content for communication with customers;
- attend a webinar which explains the political process (dates will be published on the ENGA website and in the regular ENGA newsletter – see: www.enga.org)
- inform your customers about the NGO petition to safeguard the current EU GMO legislation (starts in March 2022 via national NGOs, addressees will be the Commission, the European Parliament and national governments).

10. Prepare Your Company Input for the Impact Assessment

- Please prepare data that show the relevance of Non-GMO and organic production for your company (turnover, market share, product categories, costs to keep your value chains GMO-free, investments to label Non-GMO, customer expectations, economic setbacks in case of a deregulation etc.) by the end of April.

11. Official Political Timetable

- April 2021: EU Commission's Presentation of a study on New Genomic Techniques, main message: current legislation "*no longer fit for purpose*"[16]

[16] https://ec.europa.eu/food/plants/genetically-modified-organisms/new-techniques-biotechnology/ec-study-new-genomic-techniques_de

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- October 2021: Deadline for participation in the Inception Impact Assessment[17]
- 2nd quarter 2022 Impact Assessment (12-week consultation period)
- 2nd quarter 2023: Legislative proposal by EC, presented together with results of IA (announcement made by EC, not binding, could be earlier)
- After presentation of a legislative proposal co-decision procedure: Member States and European Parliament negotiate and adopt legislation with EC
- Spring 2024: EU elections (EC aims to have the legislative process finalised by the end of 2023, this is during its mandate; newly elected EC and European Parliament are too unpredictable)

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[17] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en