Position paper

5th November 2023

SAFE's reaction to the Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625

Introduction

The European Commission's (EC) Green Deal Communication and the Farm to Fork Strategy lay the foundations for a new sustainable food production system.

Within the Green Deal (GD), the Commission calls upon Member States' governments to implement national strategic plans for agriculture that develop the use of sustainable practices like precision farming, organic farming, agroecology, and agroforestry.

Research stands as a crucial tool for achieving the objectives of the Green Deal.

According to the Farm to Fork Strategy (F2F), more emphasis should be placed on researching on the microbiome, marine food, urban food systems, and increasing the availability and sources of alternative protein natural resources. In addition, research should focus on the link between agriculture, fisheries, aquaculture, and the environment, as well as the use of digital technologies and nature-based solutions in the agri-food sector. Furthermore, European food health policies should aim to develop solutions to restore soil health and functions, while promoting agro-ecological approaches.

The Green Deal and the F2F introduced various new tools methods to improve for increasing the sustainability of agri-food systems and enhance food security. However, these methods and measures do not include New Genomic Techniques (NGTs).
There is no explicit promotion of NGTs in research and development projects.

The reference to using NGTs to reduce pesticide use is found in a document[1] addressing the recent economic crises caused by the Commission's response to the war in Ukraine -which has nothing to do with the Green Deal and the Farm to Fork Strategy.
The claim that NGT development is in line with GD and F2F is a debatable statement.

[1] Safeguarding food security and reinforcing the resilience of food systems. COM (2022) 133 final

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Concerns regarding the proposed Regulation

Misleading information to consumers

The use of the term NGT instead of GMO is inaccurate and can mislead consumers.

One key issue with the proposed regulation is the potential for misleading information being provided to consumers. Specifically, the use of the term NGT instead of GMO can inaccurately lead consumers to believe that the product does not contain genetically modified ingredients. This misrepresentation is problematic as it goes against the definition of genetically modified organisms (GMOs) established by Directive 2001/18, which remains valid for products generated using new genetic techniques (NGTs). Despite NGTs not being explicitly listed in the Directive's annexes, they are still covered within the scope of the general definition, as clearly stated by the European Court of Justice in its judgment (Grand Chamber) of 25 July 2018 (case C-528/16).

Ignoring the Court's reasoning that NGTs should be considered mutagenesis techniques within the current legislation would be irresponsible.

Furthermore, a recent ruling of the European Court of Justice of 7 February 2023 confirms the need for a thorough analysis of the nature of the changes produced by CRISPR/Cas9 and SDN-1 induced mutagenesis. According to Directive 2002/18, the exemption provided for in Directive 2002/18 for the genetic modification techniques listed in Annex IB only applies if the genetic modifications produced by the mutagenesis technique used are different (in nature or in the rate at which they occur) from those normally used over time. The study[2] funded by the German Federal Agency for Nature Conservation (BfN) from the UFOPLAN of the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety clearly states that the CRISPR/Cas9 and SDN-1 techniques produce mutagenesis that differs in nature and timing from traditional techniques.

Moreover, as these techniques have been in use for less than 10 years, it is evident that the plants produced through these methods have not undergone sufficient field testing for an appropriate duration, and there is inadequate data available to conduct a thorough risk assessment for humans. Consequently, the EC's proposal to abandon the current GMO definition must be strongly disapproved.

[2] The Generic Risks and the Potential of SDN-1 Applications in Crop Plants *Plants 2021, 10, 2259. doi: 10.3390/plants10112259*

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Finally, the use of the acronym NGTs deceives consumers by leading them to believe that the product does not contain GMO ingredients, which is misleading.

Lack of traceability obligation and loss of consumer information

For most new GM crops, the European Commission is planning to abolish compulsory labelling, which means that consumers, as well as farmers and retailers, will no longer be able to know whether or not their food contains GMOs.

It is important to note that traceability of GMOs is legally required under EU Reg 1830/2003, and this requirement can still be met. The European Court of Justice has expressly classified NGTs as GMOs, emphasizing the need for traceability and information regarding NGTs. The "Study on the Status of New Genomic Techniques under Union Law and in Light of the Court of Justice Ruling in Case C-528/16 Traceability and information requirements for GMOs therefore apply to NGTs. This study[3] (page 27 -29) reports that many Member States have suggested that traceability systems can be used without the possibility of a downstream analytical system Moreover, some Member States have recommended the use of analytical methods to identify the presence of NGTs in the market. It is crucial to emphasize that the cost of implementing traceability and analytical systems should not be used as an excuse to compromise consumers' right to information and food safety.

Despite these efforts, the EC's proposal includes a derogation that excludes the obligation to declare GMO presence on labels for NGT1. This derogation undermines consumers' ability to make informed choices. However, it is still possible to trace these products until they are sold, which has been the case thus far.

Lack of transparency of the authorisation procedure for NGT

It is imperative to dispel the notion that NGTs are equivalent to plants hybridized with non-GMO techniques.

This assertion is unacceptable. All new breeding techniques (NGTs) encompass cisgenesis and intragenesis, both of which introduce foreign genetic material, such as promoter and terminator sequences, into the plant. Consequently, NGTs cannot be distinguished from transgenic genetically modified organisms (GMOs) unless all foreign material has been entirely eradicated from the plant DNA.

The European Food Safety Agency (EFSA), in its 2021 opinion[4] on the use of cis- and intragenic NGTs, stated that "*in order for the final product to be considered non-transgenic, molecular characterisation should be performed to demonstrate that no exogenous DNA is retained*." By

[3] https://ec.europa.eu/food/system/files/2021-04/gmo_mod-bio_ngt_eu-study.pdf
[4] https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2021.6314

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addressing the lack of traceability obligation, protecting consumer information, and ensuring transparency in the authorization procedure for NGTs, we can uphold consumers' rights, facilitate informed choices, and enhance food safety.

NGTs cause visible mutations only in specific environments. Deviating from risk assessment is hazardous.

Mutations resulting from NGT techniques have potential to alter different sections of DNA or restructure plant chromosome. s, However, the full impact of these mutations may not be apparent until they are evaluated in the field under diverse agronomic and agro-climatic conditions, as well as in conjunction with indigenous species. In a 2021 study conducted by Katharina Kawall[5], and co-funded by the German Federal Agency for Nature Conservation (BfN)[6], it was found that NGTs (especially SDN-1) can generate many uncontrolled genetic changes that do not occur naturally. In particular, the study concludes that" *about half of the market-oriented plants developed by SDN-1 applications contain complex alterations in their genome (i.e., altering multiple gene variants or using multiplexing). It also illustrates that data on both the process and the end-product are needed for a case-by-case risk assessment of genome edited plants. The broad range of genetic alterations and their corresponding traits reflects how diverse and complex the requirements are for such a risk assessment.*

Regarding cis- and intra-gene NGTs, EFSA itself states in its opinion[7] in 2021 that "*Although it might be expected that the use of a native promoter is more likely to result in an expression pattern like the donor plant, this is not guaranteed. For example, the length of the cis regulatory elements transferred as part of the cisgene to the recipient plant will probably affect the expression pattern. On the same topic, EFSA also noted that intragenesis offers considerably more options for modifying gene expression and trait development than cisgenesis, since genes and their promoters and regulatory elements are interchangeable within the intragenes*".

In addition, in its document on *'Criteria for the risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis* (2022)"[8] EFSA points out that it is necessary to assess "*certain aspects that require further discussion, particularly relevant for complex products, and their safety evaluation*". This is particularly relevant in cases where's introduce multiple

Commented [GU1]: maybe rephrasing with: . The study highlights that around half of the market-oriented plants developed through SDN-1 applications had complex alterations in their genome, such as multiple gene variants or multiplexing. It emphasizes the importance of having data on both the process and the end-product for a case-by-case risk assessment of genome edited plants. The study also underlines the broad range of genetic alterations and corresponding traits, highlighting the complexity and diversity involved in conducting such risk assessments.

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[5] The Generic Risks and the Potential of SDN-1 Applications in Crop Plants *Plants 2021, 10, 2259. doi: 10.3390/plants10112259*

[6] Grant number 3519840300

[7] https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2021.6314

[8] doi: 10.2903/j.efsa.2022.7618

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genetic modifications into the plant simultaneously. As highlighted in the German government study and other scientific studies, this is a common case in NGTs, which cannot be compared to traditional mutagenesis techniques.

According to EFSA, these mutagens not only modify several endogenous plant genes, but can also produce numerous new proteins. However, EFSA recognizes that "*the assessment all these new proteins would also be challenging according to the current regulatory framework (EFSA GMO Panel, 2022b,c*)".

EFSA concluded that the comparative analysis may not always be applicable to some genome-edited plants with complex traits for which a comparator cannot be identified (EFSA GMO Panel, 2021, 2022b).

In such cases, the current EFSA guidelines on risk assessment, although adequate, are not sufficient for these plants. It may be necessary to conduct a comparative analysis against multiple comparators or develop a specific for a stand-alone assessment [see Case Study 4 in EFSA GMO Panel (2022b)].
Finally, EFSA refers to the consideration already included in previous Opinions regarding the analysis of the potential off-targets induced by the application of targeted mutagenesis techniques (EFSA GMO Panel, 2012b, 2020), highlighting the real possibility of off-target hazards and the necessity to consistently assess them.

The requests made by EFSA and the risks associated with promoting these plants in the market, which it has highlighted, are undoubtedly clear. Nevertheless, these have not been factored into the preliminary draft of the regulation, as NGT1 methods are deemed equivalent to the conventional techniques currently employed.

Considering these data and the epigenetic interactions that new plants can have even after many years, the absence of an environmental and human health risk assessment of NGT 1 and 2 in the draft regulation is very worrying.

Application for authorisation lodged in one Member State does not ensure consumer protection.
Under the proposed regulation, a single notification to the competent authority of an EU Member State is required. This notification shall be shared with the other EU Member States before the Standing Committee on Plants, Animals, Food, and Feed (PAFF) begins the comitology procedure.

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Confidentiality of the information is imperative. The complete authorisation process should not exceed three months.

This statement fails to consider the varying agronomic and agro-climatic conditions and the impact of native species in the regions of the different Member States, which have the potential to influence the manifestation of mutated genes, governed by epigenetic principles.

Derogation of human health risk assessment for NGT2 poses a hazard.
NGT2 gains exemption from the human health risk analysis mandated by existing regulations, potentially compromising food safety and increasing risk for consumers.

Facilitations or incentives for NGT2
In addition to not complying with the rules set under the new regulation, NGT2 producers can benefit from incentives (e.g. fast track risk assessment procedure, pre-submission advice) from the European Commission provided that their plants and products contribute to a sustainable agri-food system.

The use of the precautionary principle shall also be applied when data and information for assessment are incomplete.

What does SAFE ask?

- There is no equivalence between new genetic techniques (NGT) and conventional plants. Therefore, the term NGT should be removed and replaced with genetically modified organisms (GMOs) in Directive 2001/18. The two suggested classifications should be GMO Type 1 for cisgenic and GMO Type 2 for intragenic and transgenic modifications.
- Prior to authorisation for both GMO Type 1 and GMO Type 2, environmental and human risk assessments should be carried out.
- Additionally, an application for authorisation must be submitted in each Member State where the genetically modified plant is intended to be released into the environment.

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- Environmental and human health risk assessments are required for all agronomic and agro-climatic conditions as well as any interactions with native species in the area where the plant will be introduced.
- The risk assessment data should primarily come from independent institutions in ample numbers to ensure a range of research sources and authors.
- No pathways or financial support should be provided, even indirectly, for GMO 1 and 2 producers.
- Continue tracing GMOs 1 and 2 throughout the food chain, as mandated by EU Reg. 1830/2003, and demand disclosure of utilising GMOs 1 and 2 in the product.
- Specify on the label the enhancement that GMOs 1 and 2 provide towards meeting the F2F objectives on the label, like reducing water consumption.

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