

JULY 2022

POLLINIS CONTRIBUTION TO THE PUBLIC CONSULTATION ON PLANTS PRODUCED BY CERTAIN NEW GENOMIC TECHNIQUES

DISCLAIMER : Pollinis didn't answer a certain number of questions, as these questions were strongly oriented in favor of the new genomic techniques, which therefore did not allow POLLINIS to bring an answer in agreement with its convictions and its expertise. The list of these questions can be found in ANNEX 1.

INTRODUCTION OF THE PUBLIC CONSULTATION (EUROPEAN COMMISSION)

In the last decades, advances in biotechnology have led to the development of new genomic techniques (NGTs), i.e. techniques capable of altering the genetic material of an organism that have emerged or have been developed since 2001, when [Directive 2001/18/EC](#) on the deliberate release of genetically modified organisms (GMOs) into the environment was adopted. The Court of Justice of the EU in 2018 clarified that organisms produced by targeted mutagenesis are GMOs subject to the requirements of the [EU GMO legislation](#). Targeted mutagenesis techniques are new genomic techniques, as opposed to random mutagenesis techniques. Based on the reasoning followed by the Court, the GMO legislation also applies to organisms produced by other NGTs, including cisgenesis techniques.

In November 2019, the Council [requested](#) the Commission to prepare a study on the status of NGTs under EU law, and submit, if appropriate in view of the outcomes of the study, a proposal accompanied by an impact assessment, or otherwise inform of other measures required.

The [study](#), published in April 2021, confirmed that NGTs have developed rapidly in many parts of the world and are expected to continue to do so. There is significant interest both in the EU and globally for plant applications of NGTs, and some of their applications are already on the market outside the EU; this trend is likely to continue.

The study also concluded that plants obtained by NGTs have the potential to contribute to the objectives of the European Green Deal and in particular to the Farm to Fork and Biodiversity Strategies and the United Nations' Sustainable Development Goals (SDGs) for a more resilient and sustainable agri-food system. The study also reported concerns, e.g. on potential safety and environmental impacts, including on biodiversity, coexistence with organic and GM-free agriculture and on consumers' right to information and freedom of choice.

Concerning safety, the European Food Safety Authority (EFSA) has concluded that plants obtained by targeted mutagenesis and cisgenesis can have the same risk profile as plants produced with conventional breeding. EFSA has not yet assessed the safety of targeted mutagenesis and cisgenesis in microorganisms or animals, nor the safety of other techniques.

The study concluded that the GMO legislation has clear implementation challenges and requires contentious legal interpretation to address new techniques and applications, and that there are strong indications that it is not fit for purpose for some NGTs and their products, needing adaptation to scientific and technological progress.

POLLINIS CONTRIBUTION

POLLINIS is a non-profit organisation that aims at stopping the extinction of bees and other pollinators on which all biodiversity depends. We pressure public authorities to urgently restore a favourable environment for all arthropods and we demonstrate how this restoration can be achieved. It is imperative to preserve the environment for future generations, is the transition to an agricultural model that does not use pesticides or other synthetic chemicals contaminating our environment. We base all of our actions for environmental conservation and transformation of public policy on scientific opinions and reports.

In the first stage of the consultation, POLLINIS represented **12 European organisations:**

1. SICAMM Holland-Marleen Boerjan and Alan Forskitt;
2. University of Galway - NIU Galway Ireland - Keith A. Browne (Researcher in Molecular Evolution in honey bees);
3. Division of Apiculture - Hellenic Agricultural Organization "DEMETER" Greece - Fani Hatjina;
4. APIMONDIA -Bee Health Scientific Commission Greece - Fani Hatjina;
5. Norsk Brunbiesenter Norway - Anja Laupstad Vatland (Prosjektleder);
6. OGM Dangers France - Hervé Le Meur;
7. Wild Bees Project France - Rosa Maria Licon Luna;
8. Norsk Brunbielag Norway: Lars Andreas Kirkerud (Biology of honeybees, morphometrics);
9. Friends of the Earth Malta - Alexei Pace;
10. Faculty of Ecological Agriculture, University Educons from Sremska Kamenica Serbia - Slađan Rašić;
11. Aurelia Stiftung Germany - Johann Lütje Schwienhorst and Jan Hellberg;
12. Asociación de Apicultores de Gran Canaria, ApiGranca Spain - Antonio Quesada Quesada.

PART A. REGULATING PLANT PRODUCED BY TARGETED MUTAGENESIS AND CISGENESIS - CURRENT SITUATION

INTRODUCTION (EUROPEAN COMMISSION)

The EU [GMO legislation](#) applicable to plants includes Directive 2001/18/EC on the deliberate release into the environment of GMOs, Regulation (EC) No 1829/2003 on GM food and feed and Regulation (EC) No 1831/2003 concerning the traceability and labelling of GMOs and their food and feed products. The 2010- 2011 [evaluations](#) of the GMO legislation and the 2021 Commission [study](#) on NGTs have indicated that, as regards plants obtained by some NGTs and their products, the current legislation is no longer fit for purpose and needs adaptation to scientific and technological progress. On the basis of these evaluations and the study, the [inception impact assessment](#) has identified the following problems associated with the application of the current legislation to plants produced by targeted mutagenesis and cisgenesis:

- Legal uncertainties in Directive 2001/18/EC (and other legislation based on it) have been intensified by developments in biotechnology, with unclear or undefined terms and notions;
- Current regulatory oversight and requirements are not adapted to the resulting diverse risk profiles, and in some cases can be disproportionate or inadequate;
- The GMO legislation includes authorisation, traceability and labelling requirements that raise implementation and enforcement challenges;
- The current legislative framework does not take into account whether products have the potential to contribute to sustainability.

These problems could impact operators across the agri-food system, including in agricultural biotechnology innovation and research, non-food/feed bio-based and biotechnology industries, operators in EU trade partners, organic and GM-free operators, EU and national authorities, and EU citizens and consumer organisations. The issues are of interest to a broad spectrum of stakeholders, including NGOs active in the environmental protection, agri-food system, biotechnology and consumer protection areas.

POLLINIS CONTRIBUTION

POLLINIS states that existing provisions of the GMO legislation for plants produced by targeted targeted mutagenesis and cisgenesis are adequate, **(question 1)** because, the GMO legislation is sufficiently clear : risk assessment rules of the GMO legislation are appropriate for these plant products ; authorisation, traceability and labelling requirements are appropriate for these plant products ; sustainability can be taken into account under the existing GMO legislation.

Question 2 regarding consequences for you/your activity/sector was not applicable to POLLINIS

PART B. REGULATING PLANTS PRODUCED BY TARGETED MUTAGENESIS AND CISGENESIS - THE FUTURE

INTRODUCTION (EUROPEAN COMMISSION)

The envisaged policy action on plants obtained from targeted mutagenesis and cisgenesis will aim at an appropriate regulatory oversight for the concerned plant products, ensuring a high level of protection of human and animal health and the environment, and enabling innovation and the contribution of plants developed by safe NGTs to the objectives of the European Green Deal and the Farm to Fork Strategy. This section aims at identifying potential impacts and possible ways to address the problems acknowledged in the [inception impact assessment](#) and mentioned in section A above. Your views will assist us in defining whether the current situation should be changed and the possible way forward.

RISK ASSESSMENT : In the current GMO legislation, risk assessment requirements are to a large extent the same for all GMOs. However, [EFSA has concluded](#) that plants produced by targeted mutagenesis and cisgenesis generally pose lower risks than plants obtained with transgenesis (1). EFSA has also concluded that, in some cases, plants produced by targeted mutagenesis and cisgenesis do not pose new hazards compared to plants produced with conventional, non-GM breeding techniques, or compared to classical mutagenesis techniques, which are considered as GMOs outside the scope of the legislation, and not subject to risk assessment. Finally, EFSA has concluded that off-target mutations potentially induced by targeted mutagenesis are of the same type as, and fewer than, those mutations in conventional breeding.

POLLINIS CONTRIBUTION

Currently, plants produced by targeted mutagenesis and cisgenesis are risk assessed as any other GMOs. POLLINIS believes that plants produced by targeted mutagenesis and cisgenesis need to be risk assessed using the current GMO legislation requirements (**question 3**).

In **question 4** regarding potential economic, social, environmental or other impacts POLLINIS is also concerned that the current Public consultation :

1. Assumes or claims benefits of new methods or products put forth without much room for actual risks; and the problems in applying existing legislation (see question 1) where it assumes the problems are correct and question 2 assuming that all stakeholder would like to introduce NGT plants);
2. Another assumption made by this consultation is that a future regulation of *"plants by NGTs have the potential to contribute to the objectives of the Green deal and in particular to the farm to Fork and Biodiversity strategies and the United Nations' Sustainable Development Goals (SDGs) for a more resilient and sustainable agri-food system"*. Even if the EU Commission is prudent with its wording, it does not mention that these NGT plants are still only hypothetical in regards to their seemingly positive effects on the Green deal, F2F and the like. Currently, there are only three crops on the market with no link to sustainability.

POLLINIS thinks that any future legislation concerning plant products of targeted mutagenesis or cisgenesis should take sustainability into account by other means than the one listed in the current public consultation (question 5). There should be no release of NGT products in the wild until our governments develop a strong regulatory framework to understand the risks to the biological environment by NGTs, as well as the “real” benefits.

We also remind EU Commission that the processes to develop NGT plants are highly complex and could have off-target mutations. In fact, we ask the EC to refer to a previous EFSA consultation on synthetic biology, when offering a case study on best known advances identified in the horizon scanning exercises: “While plants with a small number of mutations have already reached the market, the large number of mutations required to achieve gluten-free wheat is far beyond any plan previously assessed” (pg.11) EFSA. 2020 Evaluation of existing guidelines for their adequacy for the molecular characterisation and environmental risk assessment of genetically modified plants obtained through synthetic biology”.

The current PC also seems to put aside the Court of Justice ruling of 2018 where it ruled that all products stemming from new genetic modification methods, including CRISPR/Cas, TALENs must be classified as GMOs (even if this PC mentions this ruling in the introduction) and thus ignoring the risks of new genetic modification methods and the application of the PP.

We encourage the EU Commission to uphold the current legislation (European Court of Justice ruling 2018 and under the framework of Directive 2001/18, Regulations 1829/2003 and 1830/2003). There should be no release of any kind of NGTs products until we have a better understanding of risks to the plants, animals and ecosystems. Otherwise, the safety of the biological environment will be threatened and the precautionary principle not upheld.

SUSTAINABILITY (EUROPEAN COMMISSION) : The Commission NGT study has concluded that plants obtained by NGTs have the potential to contribute to the objectives of the European Green Deal and in particular to the Farm to Fork and Biodiversity Strategies and the United Nations’ SDGs for a more resilient and sustainable agri-food system. Examples of potential benefits include plants more resistant to pests, diseases and the effects of climate change (e.g. notably increasing severity and frequency of extreme heatwaves, droughts and rainstorms) or environmental conditions in general, or requiring less natural resources and fertilisers. NGTs could also improve the nutrient content of plants for healthier diets, or reduce the content of harmful substances such as toxins and allergens. Regarding questions 6 & 7, POLLINIS wonders why is the EU Commission feel responsible to create incentives for GMO products? It is not the EU Commission’s responsibility to create incentives. If there are benefits, like sustainability related to new GMOs, there must be proof and not merely assumptions of sustainability benefits.

POLLINIS CONTRIBUTION

In question 5.1 regarding sustainability in future legislation concerning plant products of targeted mutagenesis or cisgenesis, POLLINIS states that there should be no release of NGT products in the wild until our governments develop a strong regulatory framework to understand the risks to the biological environment by NGTs, as well as the “real” benefits.

In question 6 regarding most relevant trait for contributing to sustainability, POLLINIS strongly disagree with the following proposals :

- Tolerance/resistance to biotic stresses (e.g. plant diseases caused by nematodes, fungi, bacteria, viruses, pests)
- Tolerance/resistance to plant protection products such as herbicides or insecticides

In question 7 regarding best incentives to encourage the development of plant products of targeted mutagenesis or cisgenesis with traits contributing to sustainability, POLLINIS strongly disagree with the following proposals :

- Measures to facilitate the approval process (waiving of fees, faster procedures)
- Allowing sustainability-related claims to appear on the final product

POLLINIS also ask why is the EU Commission feel responsible to create incentives for GMO products? It is not the EU Commission's responsibility to create incentives. If there are benefits, like sustainability related to new GMOs, there must be proof and not merely assumptions of sustainability benefits.

POLLINIS didn't express opinion in questions 8 and 8.1 (See Annex 1).

In question 9 regarding potential economic, social, environmental or other impacts , POLLINIS recalls that EFSA states: "*Together with our Member States partners, we build the European food safety knowledge ecosystem, ensuring safe food as the basis for healthy diets and sustainable food systems*"; and reports on existing and emerging risks associated with the food chain. Safety and the precautionary principle (EU Treaty and 2018 ECJ Decision) must be protected.

The potential benefits of sustainability should not put the safety of the biological environment at risk.

The EU Commission must take into account the potential risks of the techniques on the products but also beyond its applications. There might be unintended consequences or interactions to the NGT plants, especially to organisms in its environment. The concept of the holobiont is a relevant concept here: ecosystems cannot be seen and evaluated merely by investigating one part (e.g. one plant or one organism) of the ecosystem. The ecosystem is made up of many parts and pieces living together. They are known as larger units called holobionts or hologenoms (Richardson 2017; Rosenburg & Zilber-Rosenberg 2016) taking into account that all species in the same habitat interact and influence each other (Then 2020). We must consider all the interactions (some of them unknown and too complex) to understand the effects on the biological environment in its entirety.

INFORMATION FOR OPERATORS AND CONSUMERS (EUROPEAN COMMISSION)

Under the GMO legislation, GMOs are traced (documentation with declaration of presence of GMO, GMO unique identifier for all transactions along the food chain, obligation to keep information for each transaction for a number of years and labelled as such.

The GMO legislation includes an obligation for applicants for a GMO authorisation to provide a quantitative detection method that is specific to the product, i.e. it can both detect it and

differentiate it from other products. In some cases of plants produced by targeted mutagenesis or cisgenesis, analytical methods might be able to detect the product but might not be able to differentiate it from similar plants produced by conventional, non-GM breeding techniques or by classical mutagenesis. This means that in these cases analytical methods might be able to detect the presence of a modified product, without being able to prove that the change was the result of a technique regulated under the GMO legislation. Question 12 of the PC does not propose the answer “can not be achieved”. The EU Commission seems to assume that NGT products will reach the market, and does not take into consideration the issues of traceability and gene transfers (Xia et al. 2021) or gene pollution/gene contamination (that will make it challenging if not impossible to achieve transparency for customers).

POLLINIS CONTRIBUTION

POLLINIS didn't answered **question 10** (See Annex 10).

In **question 11** regarding market introduction for plants produced by targeted mutagenesis or cisgenesis when reliable analytical methods to detect and differentiate a product cannot be provided, POLLINIS that operators should not be allowed to place the product in question on the market.

POLLINIS didn't answered **question 12** (See Annex 10).

In **question 13** regarding other aspect the respondent would like to mention, POLLINIS underlines that question 12 of the public consultation does not propose the answer “can not be achieved”. The EU Commission seems to assume that NGT products will reach the market, and does not take into consideration the issues of traceability and gene transfers (Xia et al. 2021) or gene pollution/gene contamination (that will make it challenging if not impossible to achieve transparency for customers).

PART C. OTHER RELEVANT ASPECTS OF A NEW FRAMEWORK

In **question 14**, POLLINIS strongly disagree with the following statements :

- Improving legal clarity in the legislation would be necessary for future-proof legislation on plants produced by targeted mutagenesis or cisgenesis
- Putting in place mechanisms that facilitate easy adaptation to scientific progress would be necessary for future-proof legislation on plants produced by targeted mutagenesis or cisgenesis
- Risk assessment that takes into account the characteristics and risk profile of a final product would be necessary for future-proof legislation on plants produced by targeted mutagenesis or cisgenesis

POLLINIS believe the European Court of Justice 2018 ruling did not see any legal unclarity in the current GMO legislation.

In **question 15** regarding measures that would be most relevant to co-existence with existing agricultural practices, POLLINIS underlines that currently, the EU does not currently have any co-existence measures with existing agricultural practices (e.g. conventional, organic). The EU must develop comprehensive transparent co-existence measures for all Member states to abide by,

including strict regulation measures for new GMO plants (e.g. approval, risk assessment, traceability, physical labeling, detection, constant monitoring and evaluation strategies). The EU must also address the problem of gene contamination or pollution, which is known to exist.

In question 16 regarding access facilitation to targeted mutagenesis or cisgenesis technologies/plant genetic resources, POLLINIS wonders why the EU Commission has evaded the discussion on patents related to NGTs. There are a wide number of patents related to plants, organisms and agricultural practices existing already (UN Development Programme 2000). The discussion of regulatory measures without discussion of patents seems incomplete almost implying that the EU Commission might be biased and in favour of stakeholders with a stake to sell their products (patent holders).

ANNEX 1

QUESTION 5

Should the potential contribution to sustainability of the modified trait of a product be taken into account in new legislation on plants produced by targeted mutagenesis or cisgenesis?

QUESTION 8

Do you think information about the sustainability contribution of a modified trait of a plant produced by targeted mutagenesis or cisgenesis should be made available to the consumer?

QUESTION 8.1

How should the information be provided?

QUESTION 10

When analytical methods are not available or reliable, effective traceability of plants obtained by targeted mutagenesis or cisgenesis, and of their food and feed products, can be ensured via:

- multiple answers possible
- documentation transmitted through the chain of operators public databases/registries
- digital solutions, e.g. block chain
- other means

QUESTION 12

Transparency for operators and consumers, on plants produced by targeted mutagenesis or cisgenesis:

- can be achieved via a physical label on the final product
- can be achieved via a digital label accessible through the final product (e.g. link to a website, QR code)
- can be achieved via information available elsewhere (e.g. a website, a public database/register)
- is not necessary for plants produced by targeted mutagenesis and cisgenesis,
- when they could have been produced through conventional plant breeding or classical mutagenesis
- is not necessary for any plant produced by targeted mutagenesis and cisgenesis