

Commission proposal on plants obtained by certain new genomic techniques

Summary report of the feedback received ⁽¹⁾

The feedback period ran from 7 July to 5 November 2023 and intended to gather views from stakeholders on the proposal for a 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 ⁽²⁾.

The Commission received 3763 ⁽³⁾ replies, of which, according to respondents' self-identification, 3421 came from EU citizens, 98 from company/business organisations, 81 from business associations, 40 from non-governmental organisations (NGOs), 26 from academic/research institutions, 14 from non-EU citizens, 13 from public authorities, 9 from environmental organisations, 4 from consumer organisations, 3 from trade unions and 54 from 'others'. Position papers or letters were attached for 123 replies.

Contributions originated from 38 countries, including 20 Member States and 18 non-EU countries. Most contributions from respondents in Member States, accounting together for over of 93% of the responses, came from France (72.4%). Germany (12.8%), Belgium (3.6%), Spain (2.6%) and Slovakia (2.2%).

5 contributions from public authorities were from EU Member States and 3 were from third countries. In addition, there were 5 responses from entities self-identifying as public authorities which were found not to hold this status.

Based on identical or near identical wording of replies, 97 replies were identified belonging to five different campaigns.

A spike in the number of responses occurred from 14 October to 16 October 2023: 1545 on the first day, followed by 344 and 253 respectively. Out of these 2142 responses, 1969 were from citizens and originated in France. Another spike, though smaller, emerged from 2 November to 5 November, with daily responses totalling 111, 264, 172, and 154. Both these spikes in feedback are distinct from the average response rate of 40 per day. These deviations from the average response rate indicate events which may require specific analysis. In the first case, the 1969 responses shared a small number of identical or similar themes, although they did not use identical wording. Given the high number of responses received in a short time window, the similarity of themes, their origin in one Member State and from citizens, the 1969 responses are treated as a coordinated action. In the second case, no pattern can be identified from the substance of the replies or their origin, and therefore these responses are not treated as a coordinated action. One potential explanation for the increase in activity in the latter case could be that it coincided with the final days of the open feedback period for the proposal.

The following analysis treats the campaigns and the coordinated action separately from the other contributions.

⁽¹⁾ 'Have Your Say' webpage where all feedback responses are published: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en

⁽²⁾ COM/2023/411 final

⁽³⁾ This total number excludes 3 responses which were removed through moderation as they were not related to the initiative.

1) CONTRIBUTIONS NOT BELONGING TO CAMPAIGNS OR COORDINATED ACTIONS

1.1. General comments

A majority of respondents from academia welcome the proposal (18 out of 25) arguing that the EU should be able to reap the benefits of new genomic techniques (NGTs) for food security, climate change adaptation and rural development, ensuring sustainability of agri-food production. The 7 remaining respondents expressed concerns about environmental and human health, genetic diversity and monocultures, and called for stringent risk assessments and adherence to the precautionary principle.

Among respondent business associations and companies, 64 (out of 81) and 41 (out of 92), respectively, welcome the proposal. Respondents active in the organic sector generally do not support the proposal, questioning, for example, the potential benefits of NGTs), the equivalence of category 1 NGTs to conventional varieties and stressing the risks of patenting for breeding progress. Farmers' organisations representing conventional farmers and individual conventional farmers and growers are generally positive towards the proposal.

Among respondent NGOs, a majority (25 out of 40) do not support the proposal. They stress a possible environmental, biodiversity or health threat of NGTs or their unintended consequences. Many call for the proposal to adhere to the precautionary principle with thorough risk assessment. NGOs welcoming the proposal (15 out of 40) underline the need to reap NGT benefits in order to respond to challenges from climate change and other abiotic and biotic stresses, and to ensure sustainability.

Among respondent environmental organisations, almost all (8 out of 9) do not support the proposal. They underline the need for freedom of choice for consumers and consider that NGT plants pose risks and should be thoroughly risk assessed. One environmental organisation welcomes the proposal underlining that NGTs can have environmental benefits.

All 5 responding public authorities from within the EU underline the need for a new regulation on NGTs. Two of them highlight the global usage of NGTs and the necessity for the EU to align its regulations with international trade partners. They raise concerns about potential trade disruptions due to international asymmetry in regulatory approaches. Emphasis is also given to the significance of NGTs in addressing global challenges like food security and climate change. One underlines the need to support the EU's competitiveness. However, concerns are raised from another about the scope of the Commission proposal, particularly its limitation to specific techniques and the number of modifications allowed.

Respondents from third country authorities (3) welcome the proposal, but they also voice certain concerns about the criteria used to define category 1 NGTs. One business association from a third country expresses concern about the possible lack of detection of category 2 NGT plants and products and about how this might impact international trade.

The 4 responding consumer organisations do not support the proposal, stating that it is not in line with the precautionary principle and that freedom of choice for consumers is not respected. Two out of three responding trade unions welcome the proposal stating that NGTs are indispensable solutions for farmers facing challenges of climate change and for sustainable production. One trade union disagrees with the proposal advocating for the preservation of nature and the abolishment of chemical compounds in agriculture.

A large majority of responding EU citizens (1375 out of 1527) do not support the proposal. A majority considers that NGTs should continue to be regulated as genetically modified organisms (GMOs) according to the current requirements, with risk assessment for all NGTs. The main concerns expressed are potential threats to the environment, health, biodiversity, seed diversity and, to a lesser extent, to animal welfare. Some responding citizens believe that there is not enough scientific evidence supporting the proposal. Responding to EU citizens that welcome the proposal (152 out of 1527) underline the importance of NGTs to address challenges related to climate change, pests and food sovereignty. Some respondents emphasise the importance of retaining EU competitiveness by adopting the proposal, while others mention the need to align EU legislation with third countries.

14 non-EU citizens provided replies, raising concerns about the proposal, mentioning environmental and health threats and supporting the view that NGTs should be regulated as GMOs.

A majority of respondents self-classifying as ‘others’ do not welcome the proposal (47 out of 54). They believe that NGTs should be classified as GMOs, underline a potential health threat or concerns about biodiversity and the environment. The precautionary principle and possible unintended effects are also mentioned by several respondents. Several respondents in this category welcome the proposal, emphasising the benefits of NGTs.

Two NGOs and one business association call on the Commission to extend the proposal to microorganisms, and one of them also to animals.

1.2. Category 1 NGT plants

A majority of respondents from public authorities, business associations and companies active in the biotechnology, breeding and crop protection sectors as well as traders, conventional farmers and farmers associations, as well as public authorities and business associations from third countries, welcome the proposed categorisation of NGT plants. They view the creation of category 1 NGT plants (those comparable to plants occurring in nature or obtained by conventional methods) as an important pillar of the proposed Regulation. These stakeholders consider that the proposal reflects scientific consensus on NGT plants and that these plants should be assessed according to their characteristics, not according to the way they are produced. Traders welcome the proposal regarding category 1 NGT plants arguing it follows a regulatory approach taken by many EU trade partners. Conventional farmers and farmers’ associations emphasise that farmers need a wide range of tools to face the challenges of climate change and to remain competitive at the international level.

Several business associations, especially from the biotechnology and breeding sectors, are of the view that the proposed verification procedure must be science-based and harmonised in order to avoid a politicisation of the procedure. Some business associations express the view that the proposal takes a very cautious approach in defining how many genetic changes an NGT plant would entail before it can no longer be considered equivalent to a conventional plant, drawing attention to polyploid crop species, which have multiple copies of the same gene. Third country respondents are of the view that further work is needed on the criteria to determine the equivalence of NGT plants with conventional ones to broaden the equivalence criteria to go beyond specific techniques or the number of modifications. A number of NGOs supporting the proposal also advocate for more flexible

criteria of equivalence. One respondent from academia states that the verification process needs to be described in more detail.

Among business associations and companies, different views exist on the proposed labelling of seeds and plant reproductive material for category 1 NGT plants. Several stakeholders from the breeding and farming sectors, welcome the labelling of seed, while several associations from the food processing sector, one third-country association from the seed sector and also one farmers' association from a Member State see such labelling as unnecessary and burdensome, with some of them claiming that the public database of NGT plants offers sufficient transparency. Business associations and companies from the organic sector generally do not consider that the labelling of seeds and plant reproductive material is sufficient and advocate the labelling of all NGT products throughout the entire value chain. A third-country respondent expresses the opinion that the proposed labelling could affect trade.

A public authority from a Member State expresses the position that NGTs, and also transgenic plants, offer possibilities to develop pest resistant species, when conventional plant breeding is insufficient. Two public authorities from Member States emphasise the need for pest-resistant NGT plants.

A majority of NGOs and environmental organisations contest the view that certain NGT plants are equivalent to conventionally bred plants, expressing the view that gene editing has the potential to alter gene functions and properties of plants in ways that would not be expected through conventional breeding and that, even without inserting additional genes, the use of gene editing can result in intended and unintended changes that go beyond the known characteristics of the individual species. These stakeholders conclude that all NGTs should be subject to risk assessment, traceability and labelling. The majority of respondent EU citizens who advocate for the application of the existing GMO requirements to all NGTs are aligned with this view.

One NGO supports the need for a database containing information on the used technique.

1.3. Category 2 NGT plants

A majority of respondents from public authorities, business associations and companies active in the biotechnology, breeding and crop protection sectors, traders as well as conventional farmers and farmers' associations support a specific regulatory regime for category 2 NGT plants. However, some of these stakeholders consider certain elements of the proposed regulatory regime for category 2 NGT plants to be inadequate (see below for more details). A majority of NGOs and environmental organisations as well as the majority of responding EU citizens support the application of the existing GMO legislation to all NGTs and thus do not support a specific regulatory regime for category 2 NGT plants.

Several business associations and companies from the biotechnology, breeding and trading sectors state that the proposed regulatory regime for category 2 NGT plants is too burdensome, in particular for SMEs, and that it is likely that not many companies will choose to bring such plants to the market. Furthermore, the absence of a similar category in third countries and the lack of detection methods is seen by several business associations and companies from the trading sector as an obstacle to international trade. Several business associations, from the breeding sector and from sectors representing breeders, growers, traders and processors of specific crops, claim that the proposed incentives would contribute little to making this category more attractive for applicants. One business

association representing farmers welcomes the incentives, especially for small sectors, citing ornamentals as an example.

One business association from the agrochemical sector is of the view that category 2 NGT plants for which a detection method cannot be developed should also be exempted from traceability, labelling, and coexistence requirements as a GMO.

Several business associations, in particular farmers' organisations, express concerns that compulsory coexistence measures for category 2 NGT plants could be made so extensive and burdensome that cultivation of these plants would become practically impossible. A number of NGOs raise the issue that coexistence between organic and conventional cultivation cannot be guaranteed and state that there is the need to allow Member States an opt-out ⁽⁴⁾.

A public authority from a Member State suggests that Annex III of the proposal, listing the traits justifying incentives, should be supplemented with 'traits used for nature conservation'. Another authority from a Member State expresses concerns on unresolved details regarding the registration of Category 2 plants and their products in national plant variety catalogues.

Two third-country respondents note that provision is made for a case-by-case authorisation procedure for category 2 NGTs with an adapted risk assessment and that it is therefore not clear how adapted or shortened the risk assessment will actually be. One third-country respondent does not welcome the labelling of category 2 NGTs as GMOs.

1.4. Organic production

Business associations and companies from the organic sector, in particular farmers' organisations, individual farmers, traders and retailers underline that NGTs go against the principles of organic production. These stakeholders welcome the ban of all NGT plants and products in organic production and argue that for operators to be able to guarantee the absence of NGT plants and their products throughout the production process, traceability and labelling for NGTs along the entire value chain must be ensured. This view is shared by the majority of responding NGOs. One national NGO representing actors from the organic sector points out that organic farming strongly depends on conventional crop varieties and that a more careful analysis of the possible role of NGTs in organic agriculture is needed.

Some NGOs and business associations representing both conventional and organic farmers do not agree with the ban of using NGTs in organic agriculture, arguing that this sector needs the technology to adapt to the challenges of climate change and pest pressure.

A small number of the responding NGOs advocate that the ban in organic agriculture should be re-assessed in order for the sector to benefit from NGTs as well. This view is shared by three respondents from academia. Two respondents from academia argue that coexistence rules are unnecessary.

Several business associations, representing either crop-specific sectors or the entire value chain, propose that category 1 NGT plants and products should be allowed in organic

⁽⁴⁾ Opt-out measures would allow Member States to ban or to restrict cultivation of authorised NGTs on their territory or parts of their territory.

production, while other associations state that the use of NGTs in organic agriculture should not be addressed in the NGT proposal, but regulated in the Organic Products Regulation ⁽⁵⁾.

Two third-country respondents do not agree with the prohibition of NGTs in organic agriculture, with one underlining the possibility of disruptions in trade.

The view that there should be traceability and labelling for NGTs along the entire value chain, so that the absence of products from NGT plants can be guaranteed, is widely shared by a large majority of responding EU citizens. In the view of some responding EU citizens, stronger rules on coexistence should be applied for the protection of all agricultural cultivation practices. A small number of responding EU citizens support the idea that the organic sector should have the freedom to utilise NGTs to take full advantage of their benefits.

A public authority from a Member State expresses the need for adequate traceability and labelling and highlights the absence of detection methods that could result in endangering the integrity and reputation of the organic sector.

1.5. Intellectual property rights and SMEs

Business associations from the breeding and farming sector draw attention to intellectual property rights, arguing that, in order to promote innovation and to stimulate the introduction of improved varieties, it is crucial to maintain breeder's exemption and that the breeding sector should continue to rely on Plant Variety Rights and not on patents.

Concerns on the intellectual property and patents of these plants and their products were also raised by two respondents among Member State authorities. They refer specifically to licensing costs of the technologies and the regulation of intellectual property of genetic materials based on their phenotypic characterisation and the relationship between patents and Plant Variety Rights.

Three NGOs are calling on the Commission to address potential gaps regarding patents and intellectual property rights. Two respondents from academia support a prohibition of patenting of NGTs.

Some responding citizens state that the proposal only serves the interests of large agricultural corporations, ignoring the needs of small and medium-sized enterprises (SMEs) and farmers. Other EU citizens raise concerns about patents and intellectual property, supporting the view that NGTs should be freely available with no restrictions.

1.6. Other comments

A public authority from a Member State expresses the view that rules should be adjusted to make it possible in practice to approve also plants modified with transgenesis, also noting that it needs to be taken into account that not only companies can be applicants for approval of a modified plant, but also other actors, such as research institutes. A regional

⁽⁵⁾ Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products, OJ L 150, 14.6.2018, p. 1–92

authority from a Member State expresses concerns about effects and impacts on food sovereignty, biodiversity and health.

Monitoring is raised by public authorities from two Member States, with one expressing the need to ensure monitoring and the other advocating for reduced monitoring.

2. CAMPAIGNS/COORDINATED CONTRIBUTIONS

All identified campaigns originated from a single country or at most two countries: Campaign 1 from France with 12 replies, Campaign 2 from Slovakia with 12 replies, Campaign 3 primarily from Germany with 44 replies, including one from Austria, Campaign 4 from France with 13 replies and Campaign 5 primarily from Germany with 14 replies, including one from Austria. The majority of the 97 participants in the campaigns self-identified as citizens (95) with the exception of two replies in Campaign 3 self-identifying as company/business organisation.

2.1. Campaign 1

Campaign 1 disagrees with any regulation that would, in the respondents' view, allow certain NGTs to undermine current European food safety standards. The respondents assert their right to produce and consume non-GMO products. The campaign demands that all NGTs remain strictly prohibited in organic agriculture and calls for mandatory traceability and labelling of these products from 'seed to plate'.

2.2. Campaign 2

Campaign 2 views the Commission proposal as contradictory to the precautionary principle and as a threat to environmental and human health. They argue that it undermines the autonomy of European agriculture and the freedom of choice for consumers. The campaign argues that NGT plants should be subject to existing legislation, including comprehensive risk assessments and mandatory labelling to ensure informed consumer choices. They express concerns about the lack of detection methods, risk assessments, and labelling, which could obscure the risks to agriculture, the environment, and the food chain. Additionally, they highlight the economic impacts on the GM-free sector and challenge the proposal's potential to undermine the decision-making authority of the EU member states.

2.3. Campaign 3

Campaign 3 advocates that all plants produced with NGTs should be subject to risk assessment and labelling requirements.

2.4. Campaign 4

Participants in Campaign 4 express their view by stating: "I am against" (the Commission's proposal).

2.5. Campaign 5

Campaign 5 asks the Commission to maintain existing rules for NGT plants. They emphasise the necessity to ensure the continuation of GMO-free agriculture and food production, highlighting the lack of solutions for coexistence issues. The campaign stresses the economic impact and the high costs associated with maintaining GMO-free production

in the EU. They advocate for the enforcement of the polluter pays principle, where those profiting from GMOs should bear the responsibility for any resulting damages. Campaign 5 underlines the importance of safeguarding GMO-free food production, from ‘seed to plate’.

2.6. Coordinated response from France between 14 – 16 October 2023

A large number of responses in this coordinated action insist that, following the ruling of the European Court of Justice in case C528/16, NGT plants should be regulated according to the requirements of the existing GMO legislation. Many responses also express concerns about health risks of NGTs, and the lobbying influence of large corporations. A considerable number of the respondents also highlight the benefits of organic farming practices for biodiversity and human health and advocate for more robust support for organic agriculture as a preferable alternative to GMOs and NGTs. Emphasis is also placed on the application of the precautionary principle for all NGTs. Transparency and effectiveness of detection methods are a recurring theme, and many respondents support labelling in all cases. Support for stricter coexistence measures and stringent, effective monitoring of GMOs and NGTs is also frequently expressed. Many of the comments are also critical of the expected intellectual property regime for NGTs. Other recurring topics are ethical considerations and potential unforeseen consequences, and the need for more inclusive decision-making processes, taking the views of citizens better into account.