



Legislation for plants produced by certain new genomic techniques

Public Consultation Factual Summary Report

Disclaimer:

This document should be regarded solely as a summary of the contributions made by participants in the public consultation on the initiative for Legislation for plants produced by certain new genomic techniques. It cannot in any circumstances be regarded as the official position of the Commission or its services. Responses to the consultation activities cannot be considered as a representative sample of the views of the EU population.

September – 2022



1. Introduction

The [public consultation](#) for **legislation for plants produced by certain new genomic techniques** collected views from the public and stakeholders in order to support the preparation of an impact assessment for this [initiative](#). The scope covers plants obtained by targeted mutagenesis and cisgenesis and their food and feed products. The relevant [inception impact assessment](#) outlined the problems to be addressed, policy objectives, potential impacts and key policy elements to be considered for the development of policy options.

The public consultation was accessible for 12 weeks on the Commission's [Have your Say Portal](#) from 29 April to 22 July 2022. The questionnaire featured an introduction, instructions, and a glossary section, and comprised 18 questions structured into three sections: Section A - 'Current situation' consulted on the adequacy of the current GMO legislative framework to address plants produced by targeted mutagenesis or cisgenesis, including specific problems of the current framework as identified in the inception impact assessment, as well as on positive or negative consequences of maintaining the current framework. Section B - 'The future' consulted on policy approaches to overcome the problems outlined in Section A, as well as on potential impacts of those approaches, based on the key policy elements identified in the inception impact assessment (risk assessment, sustainability, and information for operators and consumers). Section C - 'Other aspects' consulted on other relevant topics (e.g. future-proofing the legislation, co-existence with existing agricultural practices).

The questionnaire featured closed (multiple choice) and open questions. The policy approaches subject to the consultation reflected the full range of different views collected during the [inception impact assessment](#) feedback. Additional free-text fields as well as the possibility to upload supplementary documentation offered respondents the opportunity to raise any other issues or provide further information.

This factual summary provides an overview of the number of responses, the type of respondents, the contributors' views on the main consulted issues, and reports on contributions that could constitute campaigns. A full analysis of the public consultation, together with all other consultation activities, will be included in the Synopsis report that will be published with the Impact Assessment.

2. Overview of contributions

Overall, 2300 contributions were submitted, out of which **2196 individual contributions** were analysed (duplicates have been identified and analysed once within individual contributions, while contributions that could constitute campaigns are analysed separately below).

The bulk of the contributions (Figure 1, Annex) came from 23 EU Member States (MS), with three-quarters of total consultation respondents coming from Germany (599; 27.3%), (Italy 515; 23.5%), France (335; 15.3%), and Spain (194; 8.8%). There were no responses from stakeholders from Cyprus, Luxembourg, Malta or Slovenia. The 105 respondents from outside the EU account for 4.9% of the total. They came from Switzerland (33), the United States (17), the United Kingdom (15), and 40 contributions from 25 other countries.

Most respondents self-identified (Figure 2, Annex) as 'EU citizen' (1491; 65.1%), followed by academic/research institutions (206; 9.0 %), company/business organisations (179; 7.8%) and business associations (122; 5.3%), non-governmental organisations (NGOs - 81; 3.7%), non-EU citizens (38; 1.7%), public authorities (35; 1.5%), environmental organisations (20; 0.9%), trade unions (14; 0.6%), consumer organisations (5; 0.2%), and others (5; 0.2%). Out of the companies/business organisations, 30.2% (54) self-identified as large companies and 69.8% (125) as Small and Medium Sized Enterprises (SMEs), comprised of medium companies (28; 15.6%), small companies (33; 8.4%), and micro-companies (64; 35.8%).

Out of all the respondents, 89 (4%) are registered in the EU Transparency Register, and 141 (6.4%) provided additional documentation.

Figure 3 (Annex) illustrates the distribution by economic sector of the respondents who self-identified as business associations, company/business organisations and trade unions (506); their field of activity is farming (103; 20.4%), plant breeding/seeds (97; 19.2%), organic sector and food processing/manufacturing (each 54; 10.7%), trade (46; 9.1%), biotechnology/bio-based industry (28; 5.5%), GM-free sector (24; 4.7%), feed (21; 4.2%), plant protection products/fertilisers (20; 3.9%), ornamental plants (15; 3.0%), other sectors (15; 3.0) and forestry (6; 1.2%).

Among the 31 respondents that self-identified as a public authority, 5 (16%) were international authorities (3 from the EU, 2 non-EU), 18 (58%) were public authorities at national level (16 from the EU, 2 non-EU), and 8 (26%) were public authorities at regional or local level (all from the EU).

Originally, 62 respondents classified themselves as "Other". After manually assessing the information related to the respondents in this group, 57 were reassigned to existing stakeholder categories.

3. Overview of responses

The following overview of the responses is based on the structure of the questionnaire and reflects the policy approaches put forward in the consultation for key policy elements, i.e., adequacy of existing framework, risk assessment, sustainability and traceability and provision of information; finally, additional points of interest on co-existence, SMEs and uptake of technologies are also summarized.

Adequacy of existing framework:

Overall, four out of five (1732; 79%) participants in the consultation found that the **existing provisions of the GMO legislation are not adequate for plants obtained by targeted mutagenesis or cisgenesis**. This view was expressed by the large majority¹ of EU and non-EU citizens, academia/research institutions, business associations, companies/business organisations, and public authorities, as well as the majority² of trade unions. Among the economic sectors, this view was expressed by the large majority of operators from biotechnology and bio-based industry, farming, feed, ornamental plants, plant breeding and plant protection and fertilisers, and by the majority of operators from trade and food processing/manufacture.

17% (375) of the total consultation respondents found the **current GMO provisions adequate for plants produced by targeted mutagenesis or cisgenesis**; this view was expressed by a large majority of environmental organisations, and by the majority of NGOs and consumer organisations. Among the economic sectors, this view was expressed by a large majority of operators in food retail/service, organic, GM-free and forestry.

61% of the total consultation respondents (1329) believed that **maintaining plants produced by targeted mutagenesis and cisgenesis under the current framework is expected to have short-, medium- or long-term consequences in their activity or sector**. Out of those, a large majority mentioned negative consequences, relating to loss of tools to tackle climate change, develop more resilient crop varieties, reduce the use of phytosanitary products and, in general, achieve the goals of the Green Deal and the Farm to Fork Strategy, as well as obstacles to research and development of improved crops and loss of competitiveness. Around one fifth mentioned positive consequences, mainly referring to non-GM agriculture in general and the organic farming/sector in particular, which relies on the current strict traceability and labelling provisions of the GMO legislation. Some respondents mentioned both positive and negative consequences.

¹ For the purposes of this summary, the term large majority means >65%.

² >50%

Risk Assessment

61% (1331) of total respondents supported a risk assessment approach different from the current one in the GMO framework: 34% (738) of total respondents believed that **risk assessment should have requirements adapted to the characteristics and risk profile of a plant** and 27% (593) believed that **risk assessment is not needed when these plants could have been produced through conventional plant breeding or classical mutagenesis**. The adapted risk assessment approach was the most selected³ reply by public authorities, academic/research institutions, EU and non-EU citizens. The approach that no risk assessment is needed when these plants could have been produced by conventional plant breeding or classical mutagenesis was supported by the majority of business associations; it was also the most selected reply of trade unions, companies/business organisations. This view was expressed by the majority of operators in ornamental plants and the large majority of the operators in plant protection products/fertilisers, plant breeding/seeds and biotechnology/bio-based industry; it was also the most selected reply among the farming, feed and trade sectors.

The view that the **risk assessment requirements of the current GMO legislation should be maintained** was expressed by 22% (480) of total respondents. It was expressed by the majority of NGOs and the large majority of environmental and consumer organisations. Among the economic sectors, this view was expressed by the majority of organic and GM-free operators and the large majority of food retail/services and forestry sectors; it was also the most selected reply of the food processing/manufacturing sector.

13% (289 responses) of total consultation respondents believed that **no risk assessment is needed at all** for these plants.

Sustainability

51% (1111) of total consultation respondents found that **specific regulatory provisions for sustainability should be included in this initiative**; this view was expressed by the majority of academic/research institutions, EU and non-EU citizens and almost half of public authorities. Their views were approximately equally split between including sustainability provisions in the form of regulatory incentives or in the form of requirements.

41% (903) of total consultation respondents believed that there is **no need to introduce sustainability provisions in this initiative**. This view was expressed by the large majority of business associations, NGOs, environmental organisations and trade unions, as well as the majority of companies/business organisations and consumer organisations. As regards economic operators, this was the view expressed independently of the sector of activity (the large majority of biotechnology/biobased industry, feed, food processing/manufacture, food retail/services, GM-free, organic, ornamental plants, plant breeding/seeds, plant protection products/fertilisers, trade and the majority of the farming and forestry sectors).

Concerning the **potential contribution of specific traits to sustainability**, the majority or great majority of respondents strongly agreed/tended to agree that better use of natural resources, tolerance/resistance to biotic stresses (e.g., to plant diseases) or abiotic stresses (e.g., climate change or environmental conditions in general), yield or other agronomic characteristics, better composition (e.g., better content of nutrients or lower content of toxic substances/allergens), better storage performance, and production of substances of interest for the food and non-food industry, are traits that could contribute to sustainability. Those that strongly disagreed/tended to disagree ranged from 11 to 24% as regards those traits. Views are approximately equally split on whether quality related (e.g. colour, flavour) or tolerance/resistance to plant protection product traits could contribute to sustainability.

³ i.e., the top-ranking response, without being a majority view (<50%)

Traceability and provision of information

Replies were split on **how to best ensure effective traceability for plants produced by targeted mutagenesis and cisgenesis**; the most selected responses were 'Public databases and registries' (32%), 'documentation transmitted through the chain of operators' (27%), and 'digital solutions, e.g., block chain' (19%). In most cases, the distribution of replies among the different stakeholders and economic sectors followed the above pattern.

As regards **what should be required when reliable analytical methods that can both detect and differentiate a product cannot be provided for** plants produced by targeted mutagenesis and cisgenesis, 63% of respondents considered that requirements should be adapted (with different replies chosen, see below), while 30% considered that the product in question should not be allowed to be placed on the market.

Concerning adapted requirements, 27% answered that operators should not be asked at all for an analytical method. This has been selected by almost half of the business associations and is the most expressed view among academic/research institutions, companies/business organisations and non-EU citizens; it was expressed by the great majority of the plant protection product/fertiliser, plant breeding/seeds and biotechnology/bio-based industry sectors, and was the most selected response among the trade, farming and ornamental plant sectors. Another 20% of respondents answered that operators should be asked to provide a detection method, but without the need to differentiate, if they can justify that the latter would be impossible. This response was the most selected among public authorities. Finally, 16% answered that operators should not be asked to provide an analytical detection method at all, but under the condition that they can justify this would be impossible.

The response that products should not be allowed in the market when reliable analytical methods cannot be provided was selected by the great majority of consumer and environmental organisations and the majority of NGOs; it was also the most selected view among citizens and trade unions. Among economic operators, half of the forestry sector, the majority of the food retail/services sector, as well as the great majority of the organic and GM-free sector also expressed this view.

Views also varied on **how transparency for consumers and operators can be ensured for plants produced by targeted mutagenesis or cisgenesis**. The most selected responses were that transparency can be achieved via physical label on the final product (29%); transparency is not necessary for those plants that could also have been produced through conventional breeding or classical mutagenesis (22%); transparency can be achieved via information available elsewhere e.g., a website or public database/register (20%); and that transparency can be achieved via a digital label accessible through the final product, e.g. link to a website or a QR code (18%).

Achieving transparency via a physical label was the majority view of the NGOs, consumer and environmental organisations; it was also the most selected response among trade unions, EU-citizens, non-EU citizens and public authorities. This view was also expressed by the majority of organic, food retail/services and forestry sectors and the great majority of GM-free and organic sectors; it is also the view most expressed among food processing/manufacturing. The view that transparency is not necessary was the most selected one among academic/research institutions, business associations and companies/business organisations, as well as the sectors of farming and plant breeding/seeds. 'Transparency can be achieved via information available elsewhere, e.g., a website or public database/register was the most selected response among the feed, ornamental plant, trade and plant protection product/fertilisers sectors

Other aspects

On co-existence with other types of agriculture, including organic, diverse points were raised, including: co-existence measures should benefit all levels of agriculture,

especially for organic farming; measures safeguarding coexistence should be strengthened at EU level, e.g. labelling, traceability, seed purity and protection against contamination, as well as the protection of organic and GM-free agriculture and food production; measures must encompass the entire chain from seed production to the finished product; a public register with information on the breeding techniques to produce plant varieties would allow freedom of choice for farmers and other parts of the food supply; the whole GMO-free sector, including organic and biodynamic farming, is at risk with the development of NGTs; if GM free and conventional plants are infiltrated by NGTs, then the economic burden is entirely on the GM free/conventional farmer without any possibility to get damage compensation; need to implement clear liability rules and a 'polluter pays' principle; genetically modified varieties that allow a reduction in pesticides, fertilizers, etc., would be compatible with organic agriculture; conventional-like NGT plants should be treated the same as conventional plants and therefore be suitable for all kind of agriculture, without the need of applying any specific coexistence measures.

On measures to facilitate access to technologies/plant genetic resources, respondents expressed diverse views, including on the need or not to put in place such measures. Points raised mainly revolve across the notions of 'access' and 'transparency', and include: access to plant genetic resources is essential and should be free from any kind of intellectual property rights; access to these technologies must be guaranteed to prevent a concentration of power in the hands of a few; public databases provide transparency with respect to information on the protection of intellectual property; non-regulatory measures can facilitate access to biological material for further reproduction e.g. providing transparency in terms of intellectual property protection.

On measures to facilitate the uptake of these technologies by SMEs, points raised include: avoid excessive regulatory/administrative burden requirements that are obstacles to access and which only large companies can afford; establish criteria whether plant products obtained by NGTs are conventional-like or result in GMOs; regulation of these techniques should be aligned with the main international standards not only to facilitate the use of these techniques by SMEs but would allow them to remain competitive; protection for SMEs that work on genetic traits for minor crops, in order to continue to guarantee the existence and sustainability of these plants; provide specific funding support through research funding and public-private partnerships.

4. Information on campaigns

Similar sets of replies that could potentially constitute campaigns were identified using a combination of statistical software and manual analysis of responses, based on the identification of more than 10 identical contributions to closed questions and at least one open question. Overall, five such groups were identified from 109 respondents (4.7% of all consultation responses, Table 1). Their main messages were:

Groups 1, 2, 4 and 5: current provisions of the GMO legislation are adequate; risk assessment using the current GMO legislation requirements; no need for specific regulatory provisions on sustainability. Groups 1, 2 and 4: effective traceability can be ensured via documentation, public databases/registries and digital solutions, while Groups 1, 2 and 5 stated that transparency can be achieved via a physical label.

Group 3: current provisions of the GMO legislation are not adequate; no need for risk assessment when plants could have been produced through conventional breeding or classical mutagenesis; no need for specific regulatory provisions on sustainability; effective traceability can be ensured via public databases/registries; transparency for operators and consumers is not necessary, when these plants could have been produced through conventional breeding or classical mutagenesis.

5. ANNEX – Lists of figures and tables

Figure 1 - Contributions by country of origin

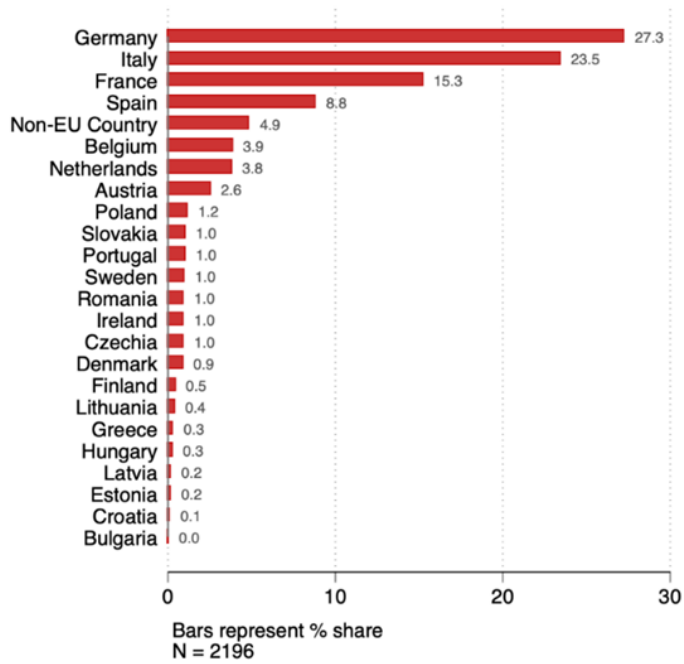


Figure 2 - Contributions by stakeholder category

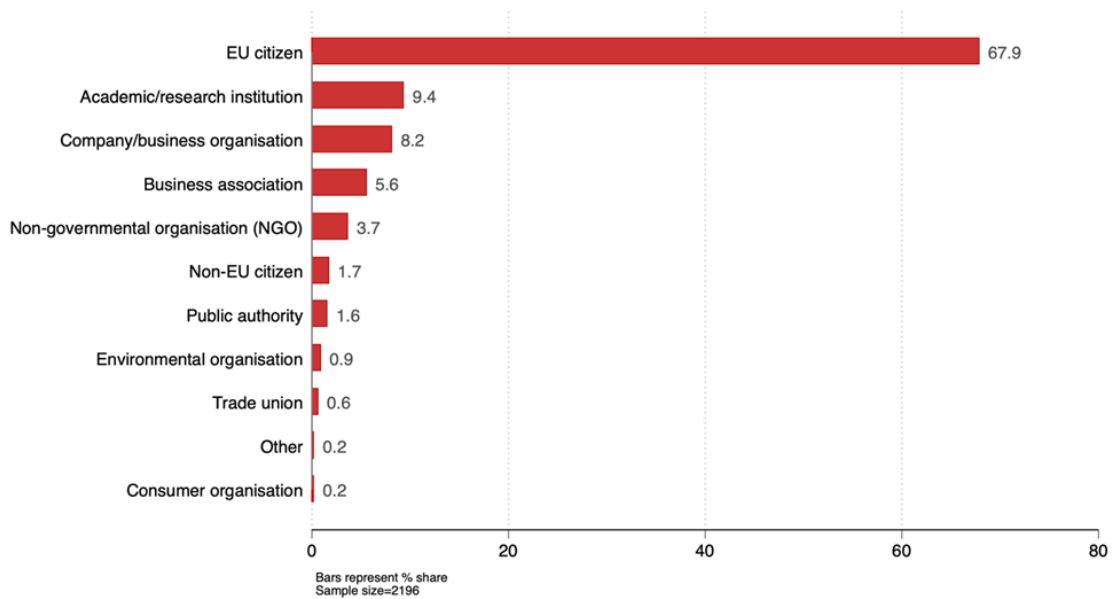


Figure 3 - Contributions by economic sector for company business organisations, business associations and trade unions

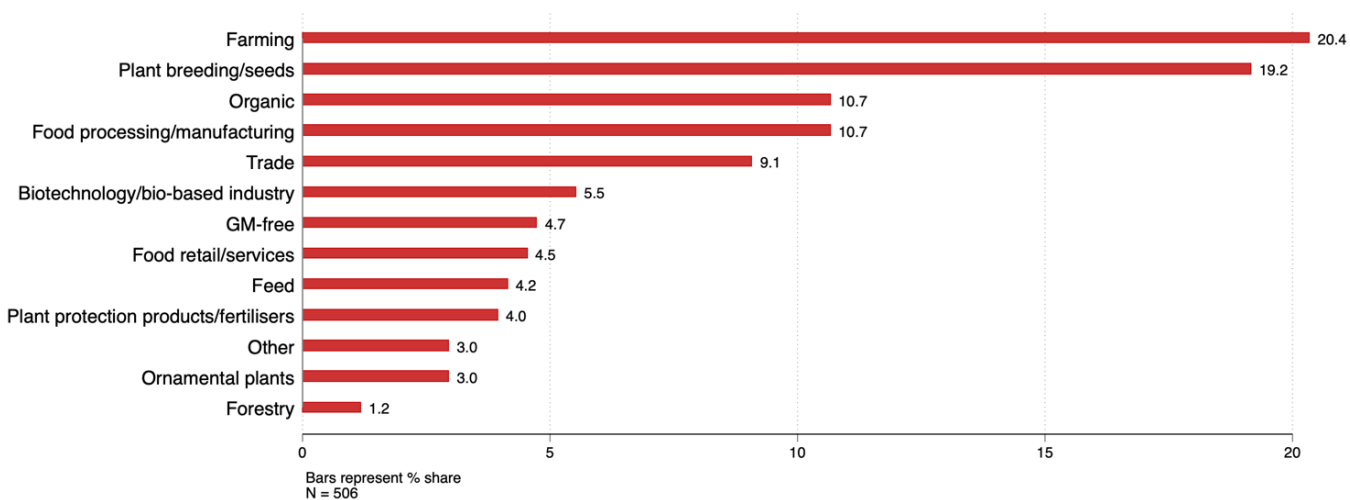


Table 1 Overview of campaigns

Group	No/% of respondents*	Stakeholder types						
		Business association	Company/business organisation	NGOs	EU citizen	Environmental Organisation	Non-EU citizen	Other
1	13 / 0.6%			2	2		8	1 (consumer organisation)
2	18 / 0.8%	4	2	5	3		4	
3	20 / 0.9%	5	7	4	4			
4	48 / 2.1%	1		7	34	5	1	
5	10 / 0.4%	1		1	7	1		
TOTAL	109 / 4.7%							

* Out of total responses: 2 300