

European Ombudsman rejects environmental advocacy group claims that European Commission mishandled favorable impact assessment of gene-edited crops, and closes case

Background to the complaint

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1. Releasing genetically modified organisms into the environment and placing them on the EU market as food or feed is subject to authorisation under EU legislation.^[1] Organisms produced by means of 'mutagenesis'^[2] do not require authorisation as they were considered safe when the EU legislation was adopted.^[3]

2. On 25 July 2018, the Court of Justice of the EU ruled^[4] that only organisms produced by means of conventional mutagenesis techniques, which had a robust safety record at the time the EU legislation was adopted in 2001, could be exempted from the authorisation procedure.^[5] However, organisms produced by means of 'new mutagenesis techniques', which have been developed since then, require authorisation as they differ from the earlier, conventional techniques.

3. On 8 November 2019, the Council of the EU asked the Commission to carry out "a study in light of the Court of Justice's judgment... regarding the status of novel genomic techniques under Union law".^[6] The Commission presented the study on 29 April 2021.^[7]

4. The Council also asked the Commission to submit a legislative proposal accompanied by an impact assessment, if appropriate in view of the outcome of the study, or otherwise to inform the Council about any other measures potentially required based on the study's findings.

5. Based on the results of the study, the Commission carried out an impact assessment concerning how plants obtained by new genomic techniques should be regulated in the EU, in view of the risks they pose. The process included publishing an 'inception impact assessment', holding a public consultation,^[8] updating relevant scientific opinions of the European Food Safety Authority (EFSA),^[9] and the consideration of further evidence by the Joint Research Centre (JRC),^[10] among other elements.

6. The complainants in this case, two environmental organisations, have been involved in the Commission's impact assessment process since 2020. During that time, they raised various concerns about the process, but considered that the Commission did not respond to these concerns appropriately.

7. On 17 February 2023, the complainants turned to the Ombudsman.

8. On 5 July 2023, while this inquiry was ongoing, the Commission published a legislative proposal accompanied by an impact assessment report concerning new genomic techniques.^[11]

The inquiry

9. The Ombudsman conducted an inquiry into the following aspects of the complaint:

- the evidence that the Commission had sought and how it addressed the complainant's concerns regarding the safety and impact on the environment of organisms produced by means of new genomic techniques and possible applications of these techniques;
- whether the Commission had observed its 'Better Regulation' rules regarding the publication of the envisaged 'policy options' ahead of the public consultation;
- whether the information on its dedicated website was complete; and
- whether it had ensured that the public consultation was transparent and inclusive.

10. The complainants furthermore mentioned several other issues regarding the impact assessment process on new genomic techniques, such as whether the range of participants in the targeted stakeholder consultation was sufficiently balanced, whether the stakeholder contributions and the consultation strategy were published in good time, and whether the Commission appropriately referred to the risks presented by genetically modified organisms to obtain reliable results of the stakeholder consultation. The Ombudsman did not find sufficient grounds to inquire into those issues.

11. In the course of the inquiry, the Ombudsman received the reply of the Commission and the comments of the complainants in response to the Commission's reply.

12. Subsequently, the Ombudsman inquiry team held a meeting with the representatives of the Commission to obtain further clarifications. The meeting report was shared with the complainants, who provided comments on it.

Arguments presented to the Ombudsman

Evidence on which the impact assessment was based

13. According to the **complainants**, the Commission failed to obtain sufficient evidence regarding the impact on the environment of organisms produced by means of new genomic techniques.

14. The complainants argued that EFSA's scientific opinions did not form a sufficient basis for the Commission to propose that plants obtained through new genomic techniques, which are comparable to conventional plants, should be exempted from any risk assessment.

15. They also argued that the Commission based its study, published in 2021, on a survey conducted among stakeholders but it did not assess the responses and background material critically.

16. According to the **Commission**, its impact assessment was based on evidence. It involved a broad consultation of Member State authorities and relevant stakeholders, and was supported by scientific opinions of EFSA and studies prepared by the JRC, among others.

17. In its reply to the Ombudsman's further questions, the Commission emphasised that EFSA had concluded that there were no new risks specifically linked to the application of the new genomic techniques addressed by the legislative proposal as compared to conventional breeding or established genomic techniques. Moreover, the Commission summarised findings of expert groups and the JRC, according to which new genomic techniques are becoming increasingly precise and, as such, result in fewer unintended genetic modifications.

18. The Commission noted that, in its impact assessment report, it had acknowledged that some organisations and agencies disagreed with its conclusions. These organisations were concerned that new genomic techniques lead to genomic changes beyond those resulting from conventional breeding. They were also concerned that these techniques can result in multiple modifications and alter the genome to a much greater extent than any previous breeding method. However, according to the Commission, EFSA had evaluated the scientific literature provided by these organisations and, based on that, considered that it did not provide new evidence which would alter the validity of its scientific opinions.

Validating data regarding possible applications of new genomic techniques

19. The **complainants** argued that the Commission failed to verify declarations made by industry representatives regarding possible applications of new genomic techniques.

20. The **Commission** explained that the data on possible applications of new genomic techniques came from online sources and a survey of public and private technology developers. Subsequently, the Commission invited experts from relevant government agencies to verify the information and gathered other sources of information.

Failure to publish policy options in the 'inception impact assessment'

21. The complainants were concerned that, prior to the public consultation, the Commission had failed to publish 'policy options' under consideration in its inception impact assessment to enable the participants in the public consultation to provide specific comments on them. Instead, the Commission merely indicated more general 'policy elements', which the complainants contended is at odds with the Commission's 'Better Regulation' rules.[\[12\]](#)

22. The Commission argued that the inception impact assessment was conducted and published under the Better Regulation Toolbox of 2017 (applicable at the time), which – according to the Commission – did not require the publication of policy options in the inception impact assessment prior to the public consultation. During the meeting with the Ombudsman inquiry team, the Commission representatives clarified that the development of 'policy options' is an iterative process. While they acknowledged that inception impact assessments should be sufficiently detailed to allow stakeholders and the public to

provide meaningful comments, fully-fledged policy options are not always available from the start. In some cases, policy options are developed through engagement with stakeholders. Consequently, the level of detail varies across inception impacts assessments.[\[13\]](#)

23. In the case at hand, the inception impact assessment provided ‘policy blocks’ rather than concrete ‘policy options’. This was a deliberate choice of the Commission as the issue of new genomic techniques is highly controversial. The Commission thus sought to gather feedback from stakeholders *before* outlining concrete policy options.

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Whether the information on the Commission’s dedicated website was complete

24. The complainants argued that some exchanges between the Commission and Member States were not disclosed.

25. The Commission argued that summary reports of the meetings of the Joint Working Group, which met in preparation of the study and the legislative proposal, are always published in full, although with a delay, as the reports need to be drafted and then approved.

26. The Commission acknowledged that some information about bilateral exchanges with Member State authorities and stakeholders is not proactively published on its dedicated website[\[14\]](#), but that relevant meeting reports are regularly disclosed following requests for public access to documents.[\[15\]](#) In the relevant time period, there was no request made that related to documents specifically concerning bilateral meetings with Member State authorities. However, the Commission received some broader requests (mostly from the complainants), which it interpreted to include minutes of bilateral meetings with Member State authorities.

Transparency of consultation activities by an external contractor

27. The complainants contended that the activities performed by an external contractor, which the Commission had contracted to carry out consultations with stakeholders, had not been sufficiently transparent, in particular with regard to which stakeholders had been consulted. The complainant also argued more generally that the Commission had failed to disclose its consultation strategy.

28. The Commission described in detail how it ensured, through contractual arrangements, that the contractor would seek input from a broad range of stakeholders. It also listed other material showing that, in its view, measures had been put in place to ensure broad and representative participation of stakeholders throughout the impact assessment process.

The Ombudsman's assessment

Evidence on which the impact assessment was based

29. The Commission's 'Better Regulation' rules are intended to ensure evidence-based and transparent EU law-making informed by the views of those impacted.[\[16\]](#)

30. The European Ombudsman is not a scientific body, and does not have the remit to question policy choices made by EU bodies based on scientific evidence. The Ombudsman can verify only whether the Commission sought reliable evidence, as required by its rules, and whether conclusions drawn by the Commission from the scientific opinions were not manifestly unreasonable.

31. In the legislative proposal on new genomic techniques, the Commission proposed new verification or authorisation procedures, intended as less burdensome than the existing procedures, for plants produced by means of certain new genomic techniques.[\[17\]](#)

32. The Commission described to the complainants in detail how it sought reliable information regarding the safety of these techniques. This information came mainly from EFSA, which is the main scientific advisor of the Commission on matters of food safety.[\[18\]](#) Also, the JRC provided further information on the development of new genomic techniques.

33. The Ombudsman notes that the Commission's proposal concerns specifically targeted mutagenesis [\[19\]](#) and cisgenesis[\[20\]](#) involving new genomic techniques. According to EFSA and other expert bodies cited by the Commission, these techniques present no new risks as compared to established techniques and conventional breeding. They may even reduce the likelihood of off-target mutations. As EFSA concluded,

no new risks are identified in cisgenic and intragenic plants obtained with NGTs [new genomic techniques], as compared with those already considered for plants obtained with conventional breeding and EGTs [established genomic techniques]... The use of NGTs reduces the risks associated with potential unintended modifications of the host genome. Thus, fewer requirements may be needed for the assessment of cisgenic and intragenic plants obtained through NGTs, due to site-directed integration of the added genetic material... On a case-by-case basis, a lesser amount of data might be needed for the risk assessment of cisgenic or intragenic plants obtained through NGTs. [\[21\]](#)

34. The complainants contend that, based on EFSA's scientific opinions, the Commission should not propose allowing the release into the environment of certain genetically modified organisms without any risk assessment. In particular, they pointed out that, while EFSA had concluded that a "*lesser amount of data might be needed*" for the risk assessment on a case-by-case basis, EFSA did not conclude that no risk assessment is necessary at all. The complainants expect more robust scientific evidence regarding the absence of risk that these techniques pose to the environment.

35. During the inquiry, the Commission explained why it proposed to exempt some cases of genetically modified plants from the full risk assessment and how this proposal is supported by EFSA's opinion. The Commission relied on information it said showed that new genomic techniques present no new risks as compared to established techniques and conventional breeding.

36. In their comments on the meeting report that was shared with the complainants in the course of this inquiry, the complainants insisted that, in many cases, plants produced with new genomic techniques are different if compared to results from conventional breeding and present new risks. However, the complainants provided no material or reference in support of these statements. Therefore, the arguments by the complainants do not indicate a manifest error of the Commission.

37. That said, there is clearly a heightened public interest in the regulation of genetically modified organisms. In this context, and as a matter of good administration, the Commission should openly engage with the substance of scientific and other arguments raised by the public questioning its policy choices. It may also request specialised EU bodies advising it, such as EFSA, to engage with any substantial concerns.

38. In its reply to the Ombudsman's written questions and in the impact assessment report, the Commission acknowledged that some organisations had disagreed with its assessment regarding the absence of new risks posed by new genomic techniques. However, it did not explain why exactly the scientific arguments of these organisations had not cast doubt on the opinions of EFSA.

39. During the meeting with the Ombudsman inquiry team, the Commission representatives pointed to a public Q&A document published by EFSA, [\[22\]](#) which provides some replies to the commonly expressed doubts about the safety of novel genomic techniques. [\[23\]](#) It is not clear, however, whether the Commission had referred the complainants to this document before this inquiry.

40. Against this background, the Ombudsman will make a suggestion to ensure that, where it is preparing legislative proposals in the future, the Commission should do more to explain how exactly the concerns raised by the public or stakeholders have been considered.

Validating data regarding possible applications of new genomic techniques

41. The complainants also argued that the Commission's description of the process for validating the data regarding possible applications of new genomic techniques is incomplete. According to the complainants, there is no detailed information on the specific criteria for the selection of experts asked to validate the

data, nor are there clear criteria and methodology for assessing the reliability of information made available by companies about these technologies.

42. During the meeting with the Ombudsman inquiry team, the Commission stated that the JRC combined and cross-checked information from different sources. It did not only review information from industry sources. As the Commission explained, the JRC also reviewed the information available online. Moreover, it prepared case studies of potential impacts of applications of new genomic techniques.^[24] On top of that, the Commission sought information from public or non-industry sources on the applications of new genomic techniques.^[25]

43. In the Ombudsman's view, the Commission's explanations regarding how it had systematically verified information from industry sources about the potential applications of new genomic techniques were not entirely clear. This was particularly so regarding the criteria for selecting governmental experts asked to validate the data.

44. The Ombudsman trusts that, in the future, the Commission will ensure there is clarity and transparency concerning the criteria and methodology for validating data used in its impact assessments. This is particularly important concerning issues for which there is uncertainty or disputes about the research.

Publishing policy options in the inception impact assessment

45. Under the rules applicable at the time of this impact assessment process, the 'inception impact assessments' were the basis for public consultation on the Commission's initiatives. This is why the complainants believe that the Commission should have published the specific 'policy options' under consideration already in the 'inception impact assessment'. Knowing the specific 'policy options' being considered by the Commission would have allowed the participants in the public consultation to provide more concrete and meaningful comments.

46. The Commission's position that it could publish more general 'policy blocks' and that it took an "iterative" approach to developing policy options appears reasonable. The Commission contended that its approach was consistent with the internal rules on impact assessments applicable at the time, that is, the 2017 'Better Regulation Toolbox'. While 'Tool #8' of the Toolbox mentions 'policy options' among the contents of inception impact assessments, Tool #17 on 'How to identify policy options' recommends asking for "*stakeholders' ideas and opinions*" and considering "*those options that can count on considerable support among stakeholders, experts, policymakers, member States and other EU institutions.*" It also recommends not to "*exclude a priori options with little support or facing strong opposition by some groups*".^[26] Against this background, it is reasonable that, in some cases, the Commission chooses to gather feedback from stakeholders before outlining concrete policy options.

47. At the same time, as the Commission pointed out, the content of stakeholders' replies demonstrates that they were in fact able to provide meaningful feedback in the context of the impact assessment process. During the public consultation, stakeholders could share their view on: the adequacy of the existing framework; the consequences of maintaining this framework for plants produced by targeted

mutagenesis and cisgenesis; whether a risk assessment should have requirements adapted to the characteristics of a plant; whether a risk assessment is needed when plants could have been produced through conventional plant breeding or classical mutagenesis; and on issues of sustainability, traceability and provision of information.[\[27\]](#)

Whether the information on the Commission's dedicated website was complete

48. The Ombudsman welcomes the fact that the summary reports of the meetings of the Joint Working Group are always published in full, and also that some reports from bilateral meetings with the Member State authorities have been disclosed upon request.

49. Proactively publishing all reports from bilateral meetings could enhance public trust in the Commission's policy-making role. However, the Ombudsman accepts the Commission's argument that this could require significant administrative effort and resources. Nonetheless, the Ombudsman encourages the Commission to consider proactive publication, where possible.

Whether the public consultation was transparent and inclusive

50. In reply to the Ombudsman, the Commission provided a detailed reply as regards the transparency of consultation activities carried out by the Commission's contractor. This reply appears reasonable.

51. According to the information provided by the Commission, groups representing a variety of views on genetic modification were consulted in the course of the impact assessment, covering civil society, public authorities and agricultural and industry groups. Based on the information reviewed in the course of the inquiry, there is no indication that any organisations were precluded from providing their views to the Commission.

Conclusion

Based on the inquiry, the Ombudsman closes this case with the following conclusion:

There was no maladministration in how the Commission carried out the impact assessment concerning new genomic techniques.

The complainant and the Commission will be informed of this decision.

Suggestion for improvement

52. The Ombudsman makes the following suggestion for improvement:

When responding to (scientific) concerns raised about policy choices, the Commission should seek to address those concerns substantively, rather than restating its position. The Commission should explain

publicly how any such concerns have been taken into account.

Sources:

[1] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms, OJ L 106/1, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32001L0018>; Regulation 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, OJ L 268/1, <https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32003R1829> [2] Creation of mutation(s) in an organism without insertion of foreign genetic material. See the glossary of scientific terms, pp. iv-vii, in the Commission Staff Working Document concerning new genomic techniques: https://food.ec.europa.eu/system/files/2023-07/gmo_biotech_ngt_ia_report.pdf [3] See Article 3(1) and Annex I B of the Directive 2001/18/EC [4] Judgment of 25 July 2018, Case C-528/16, *Confédération paysanne and Others*, <https://curia.europa.eu/juris/liste.jsf?language=en&td=ALL&num=C-528/16> [5] This included ‘random mutagenesis’, an umbrella term used to describe conventional breeding techniques based on mutagenesis, which have been used since the 1950s. Such techniques involve irradiation or treatment with chemicals in order to produce random mutations in a genome, and typically involve screening a large number of mutants to select one with desirable properties. See the glossary of scientific terms, pp. iv-vii, in the Commission Staff Working Document concerning new genomic techniques: https://food.ec.europa.eu/system/files/2023-07/gmo_biotech_ngt_ia_report.pdf [6] <https://eur-lex.europa.eu/eli/dec/2019/1904/oj> [7] https://food.ec.europa.eu/system/files/2021-04/gmo_mod-bio_ngt_eu-study.pdf [8] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en [9] In particular, EFSA Panel on Genetically Modified Organisms, ‘Applicability of the EFSA Opinion on SDNs type 3 for the safety assessment of plants developed using SDNs type 1 and 2 and oligonucleotide-directed mutagenesis’, *EFSA Journal* 2020;18(11):6299, <https://doi.org/10.2903/j.efsa.2020.6299> and EFSA Panel on Genetically Modified Organisms, ‘Updated scientific opinion on plants developed through cisgenesis and intragenesis’, *EFSA Journal* 2022;20(10):7621, <https://doi.org/10.2903/j.efsa.2022.7621> [10] Joint Research Centre, ‘New Genomic Techniques: State-of-the-Art Review’, <https://data.europa.eu/doi/10.2760/710056> [11] https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology_en [12] https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/better-regulation_en [13] The Commission’s representatives mentioned inception impact assessments on the revision of the ‘REACH Regulation’, available at https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12959-Chemicals-legislation-revision-of-REACH-Regulation-to-help-achieve-a-toxic-free-environment_en, and tobacco taxation, available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12645-Tobacco-taxation-excise-duties-for-manufactured-tobacco-products-updated-rules_en. [14] https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology_en [15] Under Regulation 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145/43, <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32001R1049> [16] https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/better-regulation_en [17] In particular, the proposal introduces a ‘verification procedure’ for plants obtained by targeted

mutagenesis or cisgenesis that could also occur naturally or be produced by conventional breeding. Such plants would be treated similarly to conventional plants and would not require authorisation, risk assessment, traceability and labelling as GMOs; a transparency register would be established for these plants. See Option 4 on pp. 9-10, https://food.ec.europa.eu/system/files/2023-09/gmo_biotech_ngt_proposal_2023-411_en.pdf [18] Article 31(1) of Regulation 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31/1, <https://eur-lex.europa.eu/eli/reg/2002/178/oj> [19] An umbrella term used to describe newer techniques of mutagenesis that induce mutations in selected target locations of the genome without insertion of foreign genetic material. See the glossary of scientific terms, pp. iv-vii, in the Commission Staff Working Document concerning new genomic techniques: https://food.ec.europa.eu/system/files/2023-07/gmo_biotech_ngt_ia_report.pdf [20] Insertion of genetic material (for example, a gene) into a recipient organism from a donor that is sexually compatible (crossable). The exogenous genetic material is introduced without modifications/rearrangements. See the glossary of scientific terms, pp. iv-vii, in the Commission Staff Working Document concerning new genomic techniques: https://food.ec.europa.eu/system/files/2023-07/gmo_biotech_ngt_ia_report.pdf [21] EFSA, 'Updated scientific opinion on plants developed through cisgenesis and intragenesis' (abstract), <https://doi.org/10.2903/j.efsa.2022.7621> [22] <https://www.efsa.europa.eu/sites/default/files/2023-05/extended-faqs-on-ngts-ts.pdf> [23] Such as the speed of genetic modification on hazards, the significance of the 'history of safe use' and possible substitutive criteria, potential risks associated with the possibility of simultaneous modification of multiple genomic locations, and whether new genomic techniques allow modifications in genomic locations which are not accessible through conventional breeding. [24] Annex 7: Applications of NGTs in plants and case studies on potential impacts to Commission Staff Working Document Impact Assessment Report Accompanying the document 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 (SWD/2023/412 final), available at <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52023SC0412> [25] See <https://www.eu-sage.eu/index.php/genome-search> and Food and Agriculture Organisation of the United Nations (FAO), 'Gene editing and agrifood systems', <https://doi.org/10.4060/cc3579en> [26] European Commission, 'Better Regulation Toolbox: July 2017', p. 103ff (shared with the Ombudsman during this inquiry). [27] See 'Public Consultation Factual Summary Report', https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques/public-consultation_en

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