Reply of the European Commission on a request for information from the European Ombudsman
- Complaint by M[redacted] ref. 346/2023/MIK

I. BACKGROUND/SUMMARY OF THE FACTS/HISTORY

On 25 July 2018, the European Court of Justice (CJEU) delivered a ruling (Case C-528/16)[1] on certain new genomic techniques (NGTs) known as "new mutagenesis techniques". The CJEU had been requested by the French Conseil d'Etat to give a preliminary ruling on whether organisms produced by means of new mutagenesis techniques are exempted from the GMO-legislation. Directive 2001/18/EC[2] on the deliberate release of GMOs into the environment contains an exemption applicable to mutagenesis. The CJEU concluded that only organisms obtained by means of techniques or methods of mutagenesis, which had conventionally been used in a number of applications and had a long safety record at the time of adoption of Directive 2001/18/EC, are exempted. Therefore, the GMO legislation applies to organisms obtained by new mutagenesis techniques, which have appeared or have been mostly developed since Directive 2001/18/EC was adopted.

On 8 November 2019, the Council requested the Commission to carry out "a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law". The term "new genomic techniques" (NGTs) is used to refer to techniques capable to change the genetic material of an organism that have emerged or have been developed since 2001, when the existing GMO legislation was adopted. The study was presented by the Commission on 29 April 2021[3] (hereinafter referred to as "Commission NGT study"). The Council also asked the Commission to submit a proposal (accompanied by an impact assessment), if appropriate in view of the outcomes of the study, or otherwise to inform the Council on other measures required as a follow-up to the study. The scope of the study included the use of NGTs in plants, animals and micro-organisms for agri-food, industrial and pharmaceutical applications.

Based on the results of the study, the Commission announced[4] it would initiate a policy action on plants obtained by certain NGTs (targeted mutagenesis and cisgenesis). The first step of this policy action was the publication of an inception impact assessment[5] on 24 September 2021, which was subject to a 4-week feedback period. The inception impact assessment outlined the initiative's context and aim, problems and objectives to address them, policy elements to be considered for the development of policy options, also discussing expected impacts and presenting the evidence base.

The impact assessment on legislation for plants obtained by certain NGTs examined options

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[1] Case C 528/16 Confédération paysanne and Others https://curia.europa.eu/juris/liste.jsf?language=en&num=C-528/16
[2] 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 and repealing Council Directive 90/220/EEC; https://eur-lex.europa.eu/eli/dir/2001/18/2021-03-27
[3] https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology/ec-study-new-genomic-techniques_en
[4] Letter of 29 April 2021 to the Portuguese Presidency of the Council, https://food.ec.europa.eu/system/files/2021-04/gmo_mod-bio_ngt_letter.pdf
[5] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en

as regards risk assessment and requirements to place on the market, sustainability, traceability and information. It has been conducted in line with the Commission's Better Regulation guidelines and toolbox[6]. To support the impact assessment, evidence and views have been gathered through a public consultation[7], which was launched on 29 April 2022 and remained open for a period of 12 weeks until 22 July 2022. In the public consultation, the possible options for each of the policy elements were outlined and these reflected the full range of stakeholders' views submitted in the context of the Commission NGT study and as feedback to the inception impact assessment. The options also took into account scientific opinions of the European Food Safety Authority (EFSA) and other scientific bodies and relevant scientific literature. Over 2000 replies were received, both in favour and against the policy initiative and expressing a wide range of positions on the most suitable policy options. In addition, the external contractor supporting the Commission in the preparation of the impact assessment has gathered and analysed evidence from a targeted survey, two focus groups, a large number of structured interviews and through case studies and extensive literature review. The Joint Research Centre (JRC) has carried out three case studies on specific NGT products to examine the potential economic, social and environmental impacts. In the context of the impact assessment, EFSA developed a statement on criteria for risk assessment[8] and an update of its 2012 opinion on cisgenesis[9].

A legislative proposal[10] was adopted on 5 July 2023, accompanied by the impact assessment[11]. The report of the external contractor[12] as well as the JRC case studies[13] supporting the impact assessment were also published on the same day. The proposal aims at combining high levels of safety with clear added value to society by allowing to transform into reality the potential of NGT plants to deliver on sustainability, resilience, food security and adaptation to climate change.

II. THE COMPLAINT TO THE EUROPEAN OMBUDSMAN

The European Ombudsman has received on 17 February 2023 a complaint from Friends of the Earth Europe (FoEE) and Corporate Europe Observatory (CEO) regarding the Commission's impact assessment on NGTs. The complainants raised concerns about the way the stakeholder consultations were organised and their selected representatives, the transparency of the impact assessment process, and whether it took into account the risks to the natural environment as expressed in the expert opinion from the German Federal Agency

[6] https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/better-regulation/better-regulation-guidelines-and-toolbox_en#
[7] https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology_en
[8] EFSA Panel on Genetically Modified Organisms, 2022. Statement on criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis. EFSA Journal 2022;20(10):7618, 12 pp. https://doi.org/10.2903/j.efsa.2022.7618
[9] EFSA Panel on Genetically Modified Organisms, 2022. Updated scientific opinion on plants developed through cisgenesis and intragenesis. EFSA Journal 2022;20(10):7621, 33 pp., https://doi.org/10.2903/j.efsa.2022.7621
[10] https://food.ec.europa.eu/system/files/2023-07/gmo_biotech_ngt_proposal.pdf
[11] https://food.ec.europa.eu/system/files/2023-07/gmo_biotech_ngt_ia_report.pdf
[12] Final Report: https://op.europa.eu/en/publication-detail/-/publication/44b784a1-1ae3-11ee-806b-01aa75ed71a1/language-en
Annexes: https://op.europa.eu/en/publication-detail/-/publication/f00cd313-1ae1-11ee-806b-01aa75ed71a1/language-en
[13] https://publications.jrc.ec.europa.eu/repository/handle/JRC131721
https://publications.jrc.ec.europa.eu/repository/handle/JRC131711

for Nature Conservation (BfN). The complainants considered that the impact assessment process does not adhere to the Better Regulation guidelines and toolbox.

The complainants argue that – while FoEE and CEO have been closely involved in this process since the beginning of 2020, participating in consultations in 2020, 2021, and 2022, and communicating their questions and concerns throughout this period – the Commission did not respond appropriately to specific critiques, failed to comply with evidence-based decision-making rules and better regulation requirements, and did not develop and publish policy options. The complainants recommend that the impact assessment process on NGTs undertaken by DG SANTE, on-going at the time of the submission of the complaint, should be rejected, and a new assessment should be conducted in alignment with the Better Regulation tools and incorporating feedback from citizens and stakeholders. They believe that the questions in the assessment should be evidence-based and avoid potential future developments while DG SANTE should communicate better its consultation strategy to relevant stakeholders and follow basic transparency rules for consultations. The complainants advise additional research to be conducted in order to understand better the economic and environmental impacts of NGTs, including negative impacts on the conventional and organic food sector. Moreover, they suggest EFSA's further assessment of the potential unforeseen impacts of NGT on human and animal health and biodiversity.

III. EUROPEAN OMBUDSMAN'S INQUIRY

The European Ombudsman opened an inquiry in response to this complaint. The European Ombudsman requested the Commission to send responses to the questions listed below to the complainants and provide a copy to the Ombudsman:

1. How did the Commission ensure that the study and the ongoing impact assessment process included a comprehensive analysis of existing research on NGTs, distinguishing stakeholder opinions from empirical scientific research?
2. How did the Commission ensure that the study and the ongoing impact assessment take into account all relevant factors, including those raised in the expert opinion from the German Federal Agency for Nature Conservation (BfN) to which the complainant refers?
3. How did the Commission ensure that the impact assessment also includes an assessment of the risks to the natural environment of products obtained through NGTs?
4. Did the Commission assess the reliability of declarations, especially those coming from the private sector, regarding products in development that rely on NGTs? If so, how?
5. The inception impact assessment lists, in its section B "Objectives and Policy options", objectives of the initiative and "[d]ifferent policy elements" that "will be considered in the subsequent development of the policy options". Could the Commission please clarify whether it was required, under the Better Regulation Guidelines, to publish the envisaged policy options prior to the public consultations?
6. Does the dedicated Commission website[14] contain complete and up-to-date information about all the meetings and exchanges between the Commission, the

[14] https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology_en

Member States and the stakeholders?

7. How has the Commission ensured the transparency of consultation activities carried out by the contractor mentioned by the complainant?

IV. THE REPLY OF THE EUROPEAN COMMISSION

1. How did the Commission ensure that the study and the ongoing impact assessment process included a comprehensive analysis of existing research on NGTs, distinguishing stakeholder opinions from empirical scientific research?

In its (now published) impact assessment on NGTs the Commission has relied strongly on EU-level scientific advisory bodies and scientific organisations, which are directly tasked with advising EU institutions or are representative of the scientific and academic community. The Commission has requested opinions based on specific mandates where necessary. The work of these bodies is underpinned by comprehensive literature reviews. The views emerging from this work underpin the impact assessment. The main analyses of existing research on NGTs used by the Commission are the following:

- The Commission's Scientific Advice Mechanism High-Level Group (SAM HLG) issued in 2017 an explanatory note on new techniques in agricultural biotechnology applied to plants, animals and microorganisms[15]. The SAM HLG also issued a statement[16] in 2018 on a "Scientific perspective on the regulatory status of products derived from gene editing and the implications for the GMO Directive".
- The European Academies' Science Advisory Council (EASAC), formed by the national science academies of the EU Member States, Norway, Switzerland and the United Kingdom, issued a report in 2017 on scientific opportunities, public interests and policy options in the EU on genome editing[17].
- The European Union Reference Laboratory for GM food and feed (EURL GMFF) and the European Network of GMO Laboratories (ENGL) issued in 2019 a report on the detection of food and feed plant products obtained by new mutagenesis techniques[18]. An updated report by the EURL-ENGL was published in June 2023[19].
- The Commission Joint Research Centre (JRC) published a report in 2021 on the latest scientific developments[20] relating to NGTs.

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[15] European Commission, Directorate-General for Research and Innovation, *New techniques in agricultural biotechnology*, Publications Office, 2017, https://data.europa.eu/doi/10.2777/574498

[16] European Commission, Directorate-General for Research and Innovation, Group of Chief Scientific Advisors, *A scientific perspective on the regulatory status of products derived from gene editing and the implications for the GMO Directive : statement by the Group of Chief Scientific Advisors*, Publications Office, 2019, https://data.europa.eu/doi/10.2777/407732

[17] EASAC (2017) Genome editing: scientific opportunities, public interests and policy options in the European Union https://easac.eu/fileadmin/PDF_s/reports_statements/Genome_Editing/EASAC_Report_31_on_Genome_Editing.pdf

[18] European Network of GMO Laboratories (ENGL), Detection of food and feed plant products obtained by new mutagenesis techniques, 26 March 2019 (JRC116289). https://gmo-crl.jrc.ec.europa.eu/doc/JRC116289-GE-reportENGL.pdf

[19] European Network of GMO Laboratories, Detection of food and feed plant products obtained by targeted mutagenesis and cisgenesis, Publications Office of the European Union, Luxembourg, 2023, doi:10.2760/007925, JRC133689 https://gmo-crl.jrc.ec.europa.eu/doc/JRC133689_kjna31521enn.pdf

[20] New Genomic Techniques: State-of-the-Art Review https://data.europa.eu/doi/10.2760/710056

- EFSA published scientific opinions on NGTs applied to plants, in particular on site directed nucleases (SDN) type 1 and 2 and oligonucleotide-directed (ODM) mutagenesis[21], and on cisgenesis and intragenesis (with a recent opinion updating a previous one from 2012)[22]. EFSA also published scientific opinions on plants obtained through synthetic biology, where certain applications make use of SDN technologies[23].
- The European Group on Ethics in Science and New Technologies (EGE) published in 2021 an opinion on the ethics of genome editing, which focuses on applications in the human, animal and plant domains[24].

This scientific evidence base was supplemented by further analysis, carried out by the external contractor and by SANTE and JRC staff, of more recent reports and peer-reviewed publications, which included research on economic impacts (also on the organic sector) and on consumer behaviour. All these sources are referenced in the impact assessment (section 1.1, Annexes 5 and 6; they underpin the analysis of safety impacts and environmental, social and health impacts in section 6) and in the annexes to the final report of the external contractor.

The whole body of evidence considered includes the views of scientific organisations and agencies, such as the BfN[25], the European Network of scientists for social and environmental responsibility (ENSSER)[26] and TestBiotech[27], who disagree with the opinions expressed by the above-listed bodies, in particular with regard to environmental and health risks, unintended genetic changes and the sustainability potential of NGTs. While EFSA has already evaluated the scientific literature provided by these organisations in the public consultations on EFSA's draft opinions on NGTs and considered that it does not provide new evidence challenging the validity of the assessment and conclusions of EFSA scientific opinions, these views are reflected in the impact assessment (section 1.1, Annex 6) in order to transparently present the diversity of views on the safety of NGTs.

In addition to the scientific evidence analysed and considered, stakeholder views expressed in the various consultation activities and the evidence supporting them, including those from the academic and research sector, have fed into the different consultation activities. In the impact assessment, stakeholder views are always clearly reflected as such, and the research/academic

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[21] 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

[22] EFSA Panel on Genetically Modified Organisms, 2012. Scientific opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis. EFSA Journal 2012;10(2):2561.
EFSA Panel on Genetically Modified Organisms, 2022. Updated scientific opinion on plants developed through cisgenesis and intragenesis. *EFSA Journal* 2022;20(10):7621, 33 pp. https://doi.org/10.2903/j.efsa.2022.7621.

[23] EFSA Panel on Genetically Modified Organisms, 2022. Scientific Opinion on the evaluation of existing guidelines for their adequacy for the food and feed risk assessment of genetically modified plants obtained through synthetic biology. EFSA Journal 2022;20 (7):7410, 25 pp. https://doi.org/10.2903/j.efsa.2022.7410
EFSA Panel on Genetically Modified Organisms, 2021. Scientific Opinion on the evaluation of existing guidelines for their adequacy for the molecular characterisation and environmental risk assessment of genetically modified plants obtained through synthetic biology. EFSA Journal 2021;19(2):6301, 21 pp. https://doi.org/10.2903/j.efsa.2021.6301

[24] https://ec.europa.eu/info/files/ethics-genome-editing_en

[25] https://www.bfn.de/en/publications/position-paper/new-developments-and-regulatory-issues-plant-genetic-engineering

[26] https://ensser.org/publications/2021-publications/enssers-response-to-the-inception-impact-assessment-iaa-on-new-genomic-techniques/

[27] https://www.testbiotech.org/en; https://www.vzbv.de/sites/default/files/2022-11/vzbv-report_final_final.pdf

community are treated as a stakeholder group directly affected by the initiative (see e.g. sections 2, 6 and 7, Annex 2).

2. How did the Commission ensure that the study and the ongoing impact assessment take into account all relevant factors, including those raised in the expert opinion from the German Federal Agency for Nature Conservation (BfN) to which the complainant refers?

In 2020, Member States and stakeholders were extensively consulted in preparation of the Commission's study on the status of NGTs under EU law and in light of the CJEU in Case C-528/16[28] in order to identify all relevant issues with regard to the regulation of NGTs. The Commission organised specific meetings where the Member States and stakeholders could contribute to the preparation of the consultation questionnaires[29]. The agreed questionnaires were then used for gathering input. The study was thus intended to respond to the issues raised during its preparation to provide a basis to answer the second part of the Council request ("to submit a proposal, if appropriate in view of the outcomes of the study, or otherwise to inform the Council on other measures required as a follow-up to the study").

In the light of the findings in the study, the Commission subsequently initiated the policy initiative, with the publication of the inception impact assessment. The feedback to the inception impact assessment, as well as a public, high level event organised by the Commission with stakeholders and representatives of the Council and the European Parliament on 21 November 2021[30], allowed to start the impact assessment based on a detailed overview of relevant issues. During the impact assessment, open questions in the public consultation, in depth-interviews with stakeholders and focus groups served to further deepen the identification and detailed understanding of the relevant issues, which are fully analysed in the impact assessment.

In these consultation processes, views and opinions were received from stakeholders and Members States, and all have been considered in the preparation of the impact assessment, including those from the BfN. Regarding the contributions received from BfN, the Commission's 2021 study refers to a 2019 national survey conducted by BfN, which was provided by Germany during the targeted consultation in 2020. Also, EFSA's overview of opinions on the risk assessment of NGT plants[31] (which was one of the technical contributions to the Commission NGT study) took into consideration a 2019 BfN public hearing on genetic engineering. Contributions from CEO, submitted during the public consultation on the inception impact assessment, included a study carried out by BFN in 2021[32] and fed into the preparation of the policy options.

BfN's expert opinion of 27 February 2023 on the 2021 Commission study was communicated by email to the Regulatory Scrutiny Board and DG SANTE by the German Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection on 3 March 2023[33]. Most issues raised in the document had already been identified by other stakeholders and Member States and were considered in the context of the impact assessment, in particular impacts on GM-free agriculture.

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[28] https://food.ec.europa.eu/system/files/2021-04/gmo_mod-bio_ngt_eu-study.pdf
[29] https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology_en
[30] https://commission.europa.eu/events/new-genomic-techniques-way-forward-safe-and-sustainable-innovation-agri-food-sector-2021-11-29_en
[31] https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2021.6314
[32] https://www.bfn.de/fileadmin/BfN/presse/2021/Dokumente/2021_10_15_Positionspapier_EN.pdf
[33] Our reference: Ares(2023)1795581

More generally, BfN is not the only national competent authority in the area of GMOs that has contributed to the impact assessment process. The impact assessment (and the factual summary of the public consultation) identify the contributions received from national competent authorities to the inception impact assessment, the public consultations and the targeted survey (to which all Member States were invited) and the interviews carried out (see section 6 and Annex 2). Further additional detail is provided in the annexes to the report of the external contractor.

Moreover, to further engage and involve national authorities in the process, the Commission set up, already at the time of the preparation of the Commission NGT study, a Joint Working Group on NGTs made up of experts from the three regulatory committees active in the field of GMOs. During the preparation of the impact assessment, the Group met three times[34] to discuss different issues, in particular linked to safety and risk assessment aspects.

3. How did the Commission ensure that the impact assessment also includes an assessment of the risks to the natural environment of products obtained through NGTs?

Since the entry into force of Directive 2001/18/EC on GMOs, the Commission has requested many scientific opinions from EFSA on the risk assessment and safety of GM plants. Several of these opinions specifically addressed the safety of plants obtained through the use of various NGTs for human, animal health and the environment.

More specifically, potential risks from plants obtained through cisgenesis and intragenesis were addressed in an EFSA opinion of 2012[35] and in a recent update of 2022 (requested in the context of the initiative on NGT plants in order to be able to rely in the most recent scientific assessment)[36], in which more than 650 recent publications were screened for relevant scientific information. Additionally, a patent search following criteria listed in a specific protocol was performed to obtain relevant information. All this information is publicly available in two detailed annexes published by EFSA together with the scientific opinions[37]. EFSA published further opinions on SDN-1, SDN-2 and ODM[38] as well as SDN-3[39] approaches considering the, at that time, most recent scientific literature in 2020 and 2012, respectively.

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[34] https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology_en

[35] European Food Safety Authority (EFSA), EFSA Panel on Genetically Modified Organisms, 2012. Scientific opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis. EFSA Journal 10(2):2561; https://doi.org/10.2903/j.efsa.2012.2561

[36] European Food Safety Authority (EFSA), EFSA Panel on Genetically Modified Organisms, 2022. Updated scientific opinion on plants developed through cisgenesis and intragenesis. EFSA Journal 20(10):7621; https://doi.org/10.2903/j.efsa.2022.7621.

[37] https://efsa.onlinelibrary.wiley.com/action/downloadSupplement?doi=10.2903%2Fj.efsa.2022.7621&file=efs27621-sup-0001-Annex_A.pdf
https://efsa.onlinelibrary.wiley.com/action/downloadSupplement?doi=10.2903%2Fj.efsa.2022.7621&file=efs27621-sup-0002-Annex_B.pdf

[38] European Food Safety Authority (EFSA), EFSA Panel on Genetically Modified Organisms, 2020. Applicability of the EFSA Opinion on site-directed nucleases type 3 for the safety assessment of plants developed using site-directed nucleases type 1and 2 and oligonucleotide-directed mutagenesis. EFSA Journal 2020;18(11):6299, 14 pp. https://doi.org/10.2903/j.efsa.2020.6299

[39] European Food Safety Authority (EFSA), EFSA Panel on Genetically Modified Organisms, 2012. Scientific opinion addressing the safety assessment of plants developed using Zinc Finger Nuclease 3 and other Site-Directed Nucleases with similar function. EFSA Journal 2012;10(10):2943. https://doi.org/10.2903/j.efsa.2012.2943

After the drafting stage, all these scientific opinions were opened to public consultation, where interested parties could provide comments, scientific evidence and additional considerations. Following these consultations, EFSA analysed all comments[40] and supplied additional information and revised and complemented the draft opinions where appropriate.

The scientific opinions from EFSA, as well as studies conducted by the JRC[41], the Commission's Scientific Advice Mechanism High-Level Group[42] and major international regulatory bodies have been considered in the impact assessment in relation to environmental and other safety aspects (see sections 1.1, Annexes 5 and 6). This includes opinions raised by certain scientific organisations and agencies and disagreeing with EFSA's opinions, which have also been shared with EFSA to ensure that any possible new evidence is taken into account. To discuss issues raised by stakeholders in response to its opinions, EFSA organised a stakeholder event in December 2022[43]. As part of that continuous engagement, EFSA also updated its communication material[44] on NGTs in May 2023 to respond to questions and comments from stakeholders and the public.

The inception impact assessment describes possible environmental impacts from the use of plants obtained by targeted mutagenesis and cisgenesis. It explicitly recognises that concerns exist about potential negative impacts of plants obtained by NGT on the environment and on biodiversity (e.g. due to potential displacement of traditional varieties and loss of agricultural diversity, concerns for increased use of pesticides) and indicates that these possible impacts will also be assessed. Accordingly, in the impact assessment process, stakeholders have been consulted to collect expert opinions and data in order to map potential effects and impacts of the different components of the policy scenarios, including in relation to assessment of risks for human, animal health and the environment[45].

This was also addressed in the targeted consultation survey[46], intended to collect concrete data on potential impacts (questions relate, for instance, to whether an increased availability and adoption of plant varieties developed using NGTs could be positively or negatively associated with various environmental, as well as health, consumer and social, impacts).

All the above underpins the analysis of environmental impacts of each policy option in sections 6 and 7 of the impact assessment. These sections were reinforced after the initial negative opinion of the Regulatory Scrutiny Board, as described in Annex 1 to the impact assessment.

In summary, the Commission followed an approach to collect comprehensive information from a broad spectrum and reliable sources of information with the objective that the impact

[40] E.g. https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/sp.efsa.2020.EN-1972
[41] Schneider, K., Barreiro-Hurle, J., Kessel, G., et al., 2023. Economic and environmental impacts of disease resistant crops developed with cisgenesis. EUR 31355, Publication office of the European Union, Luxembourg. Sánchez, B., Barro, F., Smulders, M. J. M. et al. 2023. Socioeconomic impact of low-gluten, celiac-safe wheat developed through gene editing, EUR 31380 EN, Publications Office of the European Union, Luxembourg.
[42] European Commission, 2017. New techniques in agricultural biotechnology. Publications Office of the European Union, doi:10.2777/17902; https://data.europa.eu/doi/10.2777/574498
[43] See also https://www.efsa.europa.eu/en/events/stakeholder-event-safety-plants-derived-new-genomic-techniques-looking-future-risk
[44] https://www.efsa.europa.eu/en/news/faq-criteria-risk-assessment-plants-produced-targeted-mutagenesis-cisgenesis-and-intragenesis
[45] E.g. An open question in the public consultation (Question 4) allowed participants to express their views on the potential economic, social, environmental or other impacts of NGTs
[46] https://food.ec.europa.eu/system/files/2022-09/sc_modif-genet_targeted-survey-questionnaire.pdf

assessment considers all relevant aspects and has a robust scientific basis in relation to the environmental safety of NGT plants.

4. **Did the Commission assess the reliability of declarations, especially those coming from the private sector, regarding products in development that rely on NGTs? If so, how?**

The Commission has carried out its own research to map the development pipeline of NGTs with respect to crop species, traits and stage of the R&D process.

In order to assess how NGTs have evolved and to obtain an understanding of the current scientific state of the art, the JRC analysed the latest scientific developments[47] and market applications relating to NGTs[48]. The latter study did not rely on promises made by developers but was based on an extensive validation process. The JRC collected data from information available online and from a survey of public and private technology developers. These data were subsequently integrated and validated by experts from government agencies in charge of biotechnology regulation, private sector technology developers and public sector technology developers[49]. In the impact assessment (see sections 1.1 and 1.4. and Annex 7), these data have been complemented with information from the EU-Sage database (which maps peer-reviewed literature on NGT applications)[50], recent work by FAO[51] and publicly available information from regulatory bodies in non-EU countries[52].

Furthermore, in order to arrive at a more detailed and complete picture of the potential impacts of NGT plants, the JRC conducted three case studies in the context of the impact assessment (see Annex 7), to examine the potential effects, whether positive or negative, of NGTs on the social, environmental, and economic dimensions of sustainability using the best available scientific evidence. These case studies focused on commercially significant crop plants that were developed using targeted mutagenesis or cisgenesis techniques. These plants are currently in different stages of development within the EU or other regions and possess traits that have the potential to contribute to sustainability goals. The case studies were published along with the impact assessment[53].

The Commission has gathered information to obtain a broad understanding of the NGTs market landscape and the products in development. This data includes information provided by private sector entities, to a large extent publicly available, but including some confidential information, about their NGT-based products and review of scientific literature. The Commission takes all possible steps to assess and to ensure the accuracy and reliability of the gathered information. This includes cross-referencing claims with other available data sources, engaging in dialogue with relevant stakeholders, and seeking additional evidence to substantiate declarations made.

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[47] European Commission, Joint Research Centre, Broothaerts, W., Jacchia, S., Angers, A.et al., New genomic techniques – State-of-the-art review, Publications Office, 2021, https://data.europa.eu/doi/10.2760/710056

[48] European Commission, Joint Research Centre, Parisi, C., Rodríguez-Cerezo, E., Current and future market applications of new genomic techniques – , Publications Office, 2021, https://data.europa.eu/doi/10.2760/02472

[49] See section 2.2 in Parisi & Rodriguez-Cerezo (2021)

[50] https://www.eu-sage.eu/genome-search

[51] Food and Agriculture Organisation of the United Nations (FAO), 2022. Gene editing and agrifood systems. Rome. ISBN 978-92-5-137417-7, https://doi.org/10.4060/cc3579en

[52] E.g. https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulatory-processes/confirmations/responses/cr-table

[53] https://publications.jrc.ec.europa.eu/repository/handle/JRC131721
https://publications.jrc.ec.europa.eu/repository/handle/JRC131711

Some examples (based on publicly available information) of NGT products already on the market include a tomato with high content of γ-aminobutyric acid (GABA) (Sicilian Rouge) (Japan), increased growth Tiger puffer fish ("torafugu") (Japan) and red sea bream (Pagrus major) fish (Japan). Other products have been cleared by regulatory authorities and could reach the market already in 2023- 2024: a drought tolerant soybean with higher nutritional value (Brazil, Argentina, US, Colombia), gene edited rice and maize lines resistant to bacteria and pests (Colombia), high amylopectin starch potato (Canada), high oleic acid soybean (Canada), golden rice enriched in carotenoids (Philippines), reduced acrylamide potato (US and Canada), herbicide tolerant yellow mustard (Canada), high amylose starch wheat (Canada) and insect resistant cowpea (Ghana). The Commission considers these examples, along with other available information, as part of the assessment process to gauge the reliability of declarations regarding NGT products in development. By analysing both existing market products and those approaching regulatory authorisation, the Commission has aimed to ascertain the credibility and potential impact of NGTs on various dimensions, including social, environmental, and economic aspects of sustainability.

5. **The inception impact assessment lists, in its section B "Objectives and Policy options", objectives of the initiative and "[d]ifferent policy elements" that "will be considered in the subsequent development of the policy options". Could the Commission please clarify whether it was required, under the Better Regulation Guidelines, to publish the envisaged policy options prior to the public consultations?**

The Better Regulation toolbox was last revised on 3 November 2021[54]. While the revised Better Regulation Toolbox now clearly indicates (Tool #51[55]) that alternative policy options should be outlined in the "call for evidence" document (previously called inception impact assessment), it should be noted that the inception impact assessment[56] for the NGT initiative was published while the new toolbox was still being discussed (on 24 September 2021).

Therefore, while the inception impact assessment outlines policy elements to be considered in the subsequent development of the policy options, the Commission was not required to publish envisaged policy options prior to the consultations.

In any event, the inception impact assessment, published on the "Have your Say" portal on 24 September 2021, already provided an overview of the context, problem definition, objectives, policy elements, preliminary assessment of impacts as well as the approach for the data collection. Given the importance of public and stakeholder consultation in this area, where various divergent views exist, it was decided to use the consultation process on that document (as well as the high-level event of 21 November 2021) to inform the definition of the range of policy options. Such a decision on the degree of detail was in line with the Better Regulation rules applicable at the time[57].

After that, there has been ample opportunity for interested parties to comment on the policy options in the steps following the publication of the inception impact assessment, at a sufficiently early stage for those comments to be considered in the impact assessment. The

[54] https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/better-regulation/better-regulation-guidelines-and-toolbox_en
[55] https://commission.europa.eu/system/files/2022-06/br_toolbox_-_nov_2021_-_chapter_7.pdf
[56] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en
[57] Better Regulation Toolbox – July 2017

Commission has already specifically addressed this issue in the e-mail sent on 20 July 2022[58] to FoEE, which also refers to previous correspondence from DG SANTE in response to expressed concerns and in the Commission's response[59] to the complaint from FoEE submitted to the Secretariat-General on 2 November 2022[60].

As explained at these occasions, the public consultation conducted during the impact assessment[61], which was open for contributions from 29 April to 22 July 2022, specified the different policy options that were being considered in the impact assessment for each of the key policy elements (risk assessment, sustainability, and provision of information). These reflected the full range of opinions and proposed policy approaches received as feedback to the inception impact assessment. For instance, it was possible to express the view (as done by CEO and FoEE) that existing provisions of the GMO legislation are adequate for plants obtained by targeted mutagenesis or cisgenesis, that risk assessment requirements of the current GMO legislation should be maintained, or that transparency should be achieved via physical label. Moreover, since a number of stakeholders and citizens supported in the feedback to the inception impact assessment the continued application of the existing GMO legislation to all NGTs, this baseline was considered as a viable policy option in the impact assessment and the economic, social and environmental impacts of this option were fully analysed.

These potential policy solutions were presented in the public consultation in a format that was intended to be understandable by non-experts and the general public. This approach is in line with the Better Regulation guidelines and common practices of the Commission. The factual summary of the public consultation[62] shows that the consultation allowed to gather feedback on the adequacy or not of the existing framework and on a wide range of policy options as regards risk assessment, sustainability, traceability and provision of information, as well as to collect views on issues such as co-existence among different types of agriculture, including organic, or on measures to facilitate access to technologies/plant genetic resources. It also shows that the Commission was able to collect views from the whole range of stakeholders and interested parties in this area.

In turn, the targeted consultation survey and interviews also included the various policy options to be analysed in the impact assessment. In that case, pursuant to the input received in the consultations, further level of technical and procedural detail was provided and the different elements (as regards risk assessment, sustainability, traceability and provision of information) presented in the public consultation were packaged in several distinct options, in order to receive concrete data on their impacts and costs from expert stakeholders.

The results of these consultations and the way in which they have been taken into account, are reported in the impact assessment (see section 5 and Annex 2) and in the annexes to the external contractor's report. Moreover, in view of the strong stakeholder interest in this initiative, the actual text of the targeted survey[63] and a breakdown of stakeholder groups

[58] Our reference Ares(2022)5267820
[59] Our reference Ares(2022)8943806
[60] Our reference Ares(2022)7649127
[61] Available under « Public consultation » at https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en
[62] Available under « Public consultation » at https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en
[63] https://food.ec.europa.eu/system/files/2022-09/sc_modif-genet_targeted-survey-questionnaire.pdf

involved[64] was already published in the Commission website in September 2022 for transparency (although not required by the Better Regulation rules). This allowed interested parties as well as citizens that had not participated in the survey to contribute their views through letters and position papers, which were also incorporated to the impact assessment materials.

6. **Does the dedicated Commission website contain complete and up-to-date information about all the meetings and exchanges between the Commission, the Member States and the stakeholders?**

The Commission has set up a dedicated website about "New techniques in biotechnology"[65] to inform the public on the background and objectives of the policy initiative on new genomic techniques. The website includes ongoing developments, including information on the consultation activities, summary reports from meetings with Member States experts (Joint Working Group referred to above) and with stakeholders in the Advisory Group, an information session to third countries, technical reports and scientific mandates to EFSA and previous EU initiatives on new biotechnology techniques. The website also includes a "frequently asked questions" section to provide information and replies to recurring queries on NGTs. The Commission updates the website regularly (most recently after adoption of the legal proposal on 5 July 2023), ensuring that it reflects the most up-to-date information available.

The website was not intended to disseminate information on bilateral meetings with Members States or stakeholders. However, information on the outcome (meeting reports) of such meetings is regularly disclosed on the basis of requests to access to documents in accordance with Regulation (EC) No 1049/2001. CEO has availed itself of this opportunity on several occasions[66] in the course of the preparation of the Commission NGT study and of the impact assessment.

7. **How has the Commission ensured the transparency of consultation activities carried out by the contractor mentioned by the complainant?**

The Commission has been consistently committed to a transparent consultation process and to transparently reporting on the results of the consultation activities and on how contributions are used in the policy-making process.

Regarding the consultation strategy for the impact assessment, in line with the Better Regulation guidance, an outline of how the Commission intended to consult stakeholders featured already in the inception impact assessment, with a view to inform all stakeholders and to invite them to provide feedback. The consultation strategy has also been published on the Commission's website[67], as well as the factual summary of the public consultation, mentioned above. Furthermore, DG SANTE presented at the meeting of the Advisory Group - Food Chain and Animal and Plant Health on 6 May 2022 an update on the initiative, including the overview of the inception impact assessment feedback and public consultation questionnaire (the summary of the meeting including a link to the presentation on NGTs is

[64] https://food.ec.europa.eu/system/files/2022-10/sc_modif-genet_info-targeted-survey.pdf
[65] https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology_en
[66] GestDem 2021/1201, GestDem 2021/8072, GestDem No 2022/3966, EASE No 2023/1112, EASE 2023/2158, EASE 2023/3072
[67] https://food.ec.europa.eu/system/files/2022-09/sc_modif-genet_consultation-strategy-ngts.pdf

publicly available[68]). Further updates were given in the Advisory Group on Sustainability of Food Systems 19 October 2022[69] and 12 May 2023[70].

The commitment of the Commission to ensure transparency applies also in all consultation activities carried out by the external contractor. The Terms of Reference (ToR) of the specific contract required that all consultation activities run by the contractor should be planned and carried out in accordance with the Better Regulation Guidelines. The ToR required the contractor to seek input from a broad range of key stakeholders concerned with agriculture, food and feed, plants, bioeconomy and biotechnology and with the application of targeted mutagenesis and cisgenesis in plants, including their food and feed products. In their offers, the tenderers had to provide details of how they would plan and conduct consultation activities, how they would identify appropriate stakeholders and to present clear selection criteria to justify which groups would be invited to respond to the targeted survey and interviews. The evaluation of the offers took these elements of the ToR into account and the selected contractor fulfilled all conditions in their offer.

In September 2022, the Commission published on its website a detailed overview of the consultation activities[71], including those conducted by the external contractor. The information published included, as mentioned above, the text of the targeted survey, the breakdown of the stakeholders invited to respond to the survey and a breakdown of the stakeholders that replied. It shows representation of the main stakeholder groups including economic operators (breeders, farmers -including organic and GM-free-, traders, retail, etc), academic/research organisations, public authorities, and civil society organisations.

The input from citizens, businesses and civil society to the different consultation activities is presented in the synopsis report that accompanies the impact assessment document, along with explanations on how this information has been taken into account (Annex 2 of the impact assessment). Moreover, a very detailed overview of the contractor's work on consultation activities is published in the Annexes to the contractor's report. This includes: a more detailed synopsis report of all consultation activities, participating groups, how data was taken into account and results (Annex 1); methodological aspects about the design of the consultations (Annex 2); detailed analysis of the targeted survey replies (Annex 3); detailed analysis of public consultation replies (Annex 4); description (participants, agenda, results) of focus groups (Annex 6).

These materials show that measures have been put in place to ensure broad and representative participation and transparency throughout the process, and that all stakeholders groups (regardless of their position) have been able to contribute their evidence and views. All consultation activities carried out by the external contractor were compliant with the principles of transparent and participatory engagement of Better Regulation. The contractor, under supervision of the Commission, ensured that all relevant target groups were reached and invited. The contractor ensured that consultation documents were translated into as many languages as feasible, that the documents were clear and understandable (with clarifications provided where necessary), and that sufficient time was allowed for replying in order to increase participation. The contractor was required to follow ethical and research integrity

[68] https://food.ec.europa.eu/system/files/2022-06/adv-grp_plenary_20220506_sum.pdf
[69] https://food.ec.europa.eu/system/files/2023-01/adv-grp_plenary_20221019_sum.pdf
[70] https://food.ec.europa.eu/system/files/2023-07/adv-grp_plenary_20230512_sum.pdf
[71] https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology/questions-and-answers-ngt-ia-consultations_en

policies, which include maintaining a high level of transparency towards the Commission in its activities.

V. CONCLUSION

The Commission fully complied with Better Regulation requirements in the process of preparing the impact assessment on the NGT initiative. The Commission put in place a comprehensive structure to thoroughly scrutinise the quality of the impact assessments and the proper application of the Better Regulation guidelines. Any significant issue due to incorrect application of these guidelines is captured by this scrutiny process.

An interservice group, composed of all relevant Commission services, prepares and discusses all key elements of the impact assessment and the policy initiative. The interservice group steers the impact assessment process and contributes to the preparation of the call for evidence, agrees on the stakeholder consultation strategy and documents, and helps to enhance the quality of the impact assessment report. All impact assessments are scrutinised by the Regulatory Scrutiny Board (RSB). The RSB considers the quality of evidence, analysis and the logic of intervention. Moreover, the RSB ensures that the views of stakeholders, including dissenting views, are properly addressed and taken into account in the analysis.

The impact assessment reflects -as required by the Better Regulation guidance- the composition and involvement of the interservice group, the consultation of the RSB and the way in which the comments of the RSB were addressed (Annex 1).

The RSB issued a first negative opinion on 17 March 2023. After submission of a revised version of the impact assessment, the RSB concluded with a positive opinion on 26 May 2023[72] with the following reservations: (1) the report did not describe in sufficient detail the notification procedure and criteria to verify whether a product could also occur naturally or be produced by conventional breeding; (2) the report was not sufficiently clear on the preferred option concerning the use in organic production of NGT plants/products fulfilling the notification criteria; (3) the report did not present a comprehensive overview of benefits and costs. These comments were addressed in the final version.

The RSB opinion of 26 May 2023 did not contain reservations linked to the concerns raised by FoEE and CEO about the way the stakeholder consultations were organised, the transparency of the impact assessment process, and whether it took into account risks to the natural environment[73].

To conclude, the Commission NGT study and the impact assessment process both included a comprehensive analysis of existing research on NGTs, distinguishing stakeholder opinions from empirical scientific research, taking into account all relevant issues including the assessment of risks to the natural environment. The Commission conducted its own research regarding products in development that rely on NGTs and their potential impacts, and did not base its impact assessment on private sector declarations. The inception impact assessment was fully compliant with the requirements of the Better Regulation Guidelines applicable at

[72] SEC(2023) 411, https://food.ec.europa.eu/system/files/2023-07/gmo_biotech_ngt_swd_2023-411_ia.pdf
[73] In its initial negative opinion of 17 March 2023, the RSB found that the draft impact assessment did not sufficiently assess the impact on the environment. Annex 1 of the impact assessment explains how this comment – no longer raised in the final opinion- was addressed.

the time of its publication. The dedicated Commission website contains comprehensive and up-to-date information about the initiative. The Commission has ensured transparency of consultation activities carried out by the contractor; both the impact assessment and the contractor's report inform extensively about the consultation activities and how they have been taken into account.

For the Commission
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