Input consultation - Transparency and participation in EU decision making related to the environment

Thanks for the opportunity to participate in the consultation on Transparency and participation in EU decision making related to the environment. On behalf of Friends of the Earth Europe we want to share the following input:

7. Please raise any further issues you have observed in the transparency of decision making relating to the environment.

In July 2018, legal certainty was given when the CJEU ruled (C 528/2016) that newer generations of genetically modified organism (GMOs) are also defined as GMOs under Directive (EU) 2001/18 and therefore EU rules for GMOs shall be applied to them as well. The Court was explicit that *"excluding organisms obtained by new mutagenesis techniques from the scope of the GMO Directive would compromise the objective pursued by that directive, which is to avoid adverse effects on human health and the environment, and would fail to respect the precautionary principle which that directive seeks to implement."* The EU Directive 2001/18 is one important environmental legislation highlighting the protection of environment in its objective and set rules how to deal with the release of GMO into the environment. Thus ongoing decision making with setting a new legal framework for new GMO is highly relevant from an environmental perspective.

In reaction to the ruling, the Health Branch of the EU Commission, DG Sante, was running a series of consultation on so called new genomic techniques in 2020, 2021 and 2022. The EU Commission workplan 2023 announces a new legislation for new genomic techniques, meaning to exclude from the EU wide GMO definitions and weakening transparency and environmental risk assessment for them. DG Sante was downplaying impacts on the environment from 2020 onwards.

DG Sante presents new genomic techniques as safe as conventional plants and suggests to lower or eliminate environmental risk assessment for new genomic techniques as such. This approach relies on claims made by agribusiness associations and disregards current research and scientific evidence[1] as well as evidence presented by various stakeholders in the 2020 consultation run by DG Sante.

---

[1] Agapito-Tenfen SZ, Okoli AS, Bernstein MJ, Wikmark O-G, Myhr AI. Revisiting risk governance of GM plants: The need to consider new and emerging gene-editing techniques. Front Plant Sci. 2018;9. doi:10.3389/fpls.2018.01874

Eckerstorfer MF, Dolezel M, Heissenberger A, et al. An EU perspective on biosafety considerations for plants developed by genome editing and other new genetic modification techniques (nGMs). Front Bioeng Biotechnol. 2019;7. doi:10.3389/fbioe.2019.00031

Norris AL, Lee SS, Greenlees KJ, Tadesse DA, Miller MF, Lombardi HA. Template plasmid integration in germline genome-edited cattle. Nat Biotechnol. 2020;38(2):163-164. doi:10.1038/s41587-019-0394-6

Kawall K, Cotter J, Then C. Broadening the GMO risk assessment in the EU for genome editing technologies in agriculture. Environmental Sciences Europe. 2020;32(1):106. doi:10.1186/s12302-020-00361-2

Federal Agency for Nature Conservation, October 2021, New developments and regulatory issues in plant genetic engineering. https://www.bfn.de/sites/default/files/2021-10/Viewpoint-plant-genetic-engeneering_1.pdf

Eckerstorfer, M.F.; Grabowski, M.; Lener, M.; Engelhard, M.; Simon, S.; Dolezel, M.; Heissenberger, A.; Lüthi, C. Biosafety of Genome Editing Applications in Plant Breeding: Considerations for a Focused Case-Specific Risk Assessment in the EU. *BioTech* 2021, *10*, 10. https://doi.org/10.3390/biotech10030010

Hüdig, M.; Laibach, N.; Hein, A.-C. Genome Editing in Crop Plant Research—Alignment of Expectations and Current Developments. *Plants* 2022, *11*, 212. https://doi.org/10.3390/plants11020212

There is no scientific basis for deregulating whole classes of new genomic techniques and their products." The new genomic techniques are not fully understood yet in their effects. Thus the idea to release them to the environment, without any sound scientific understanding of plants that have never been genetically modified before and without knowledge of their dissemination in nature, poses a great threat to biodiversity and nature.

In the Inception Impact Assessment (autumn 2021) and in the public consultation to prepare the Impact Assessment (29 April 2022 - 22 July 2022), DG Sante focused on the promised positive contributions of new genomic techniques to sustainability. DG Sante failed to assess the impact on climate change and biodiversity and entire ecosystems of new genomic techniques.

Various problems with transparency were observed by Friends of the Earth Europe. The exchange with Members States on the topic of new genomic techniques was kept secret, neither meeting dates nor minutes were published until some MEPs requested access to them and are still incomplete.

In 2020, DG Sante set up a closed consultation only for invited stakeholders, with just 14% of stakeholders representing civil society groups – while 74% came from the industry.[2] DG Sante failed to publish which criteria were selected to invite stakeholders to the 2020 consultation. DG Sante stated that mainly stakeholders from the advisory group on the food chain were invited, but they actually represent less than 41 % of the stakeholders invited.

From 24 September to 22 October 2021, stakeholders and governments could give feedback to the Inception Impact Assessment on New Genomic Techniques. DG Sante failed to publish any summary of the feedback received over this period, as requested by the Better Regulation Guidelines.

DG Sante failed to publish policy options for the EU Commission public consultation held from 29 April 2022 - 22 July 2022. This means (governments and) stakeholders could only guess the intention of the EU Commission for their responses.

9. Under the EU Aarhus Regulation, EU institutions are required to provide early and effective opportunities for the public to participate during the preparation, modification or review of plans or programmes relating to the environment and to take the outcome of the public participation into account. [6] Are you aware of issues in this regard, such as instances where EU institutions did not adequately adhere to this obligation? If so, please provide relevant examples.

Civil society organisations took part in the five consultations on new genomic techniques from early 2020 until autumn 2022, send various letters to the lead Commissioner Kyriakides, collected more than 420,000 signatures to keep the new genomic techniques regulated under environmental law and transparent for consumers and farmers and ensure risk assessment before they can be released to the environment. But not a single view, argument, concerns was taken up by the EU Commission instead all concerns were downplayed in responses to the letters. The conclusions of the 2021 study[3] only refer to views and perspectives on promised benefits of deregulating new genomic techniques. The study's conclusions for instance emphasize that new genomic technique have the potential to achieve the aims of the European Green Deal whilst they downplay safety risks and negative impacts on the environment.

11. Please raise any further issues you have observed in the way the EU institutions facilitate public participation in decision making relating to the environment.

[2] https://friendsoftheearth.eu/wp-content/uploads/2021/03/Green-light-for-GMOs.pdf

[3] https://food.ec.europa.eu/system/files/2021-04/gmo_mod-bio_ngt_eu-study.pdf

More than 80 stakeholders presented their in-depth critique of the study in joint letters to Cabinet members of Kyriakides, Wojciechowski, Timmermans and Sinkevičius on 3 September 2021.[4] These concerns were left largely unanswered in the answer from the EU Commission.

In autumn 2021, DG Sante published the Inception Impact Assessment about new genomic techniques. More than 69.000 citizens took part in the so-called four-week feedback mechanism. The clear majority of respondent called to keep new GMOs fully regulated. Their contributions were largely disregarded in the public consultation for the Impact Assessment of 2022.

In summer 2022, the consultancy Technopolis was charged by DG SANTE to run an additional oral and written exchange with targeted stakeholders to collect more views for the Impact Assessment on New Genomic Techniques. DG SG Sante failed to publish which stakeholders were invited to this targeted consultation.

The approach, undertook for the actual Impact Assessment was criticised as biased as well as lacking of clear methodology, evidence-based working assumptions and pre-assuming results by very different stakeholders. These include European Coordination Via Campesina[5], European Non-GMO Industry association [6], Green MEPs[7] as well as Austrian environment organisation Global 2000 (28 July 2022), Corporate Europe Observatory (28 July 2022), or ARGE Gentechnikfrei (29 July 2022). The responses from DG Sante did not touch upon the main concerns raised.

[4] https://corporateeurope.org/en/media/4767

[5] https://www.eurovia.org/publications/open-letter-ecvc-refuses-to-respond-to-the-european-commissions-biased-consultation-on-new-genomic-techniques/

[6] https://www.enga.org/fileadmin/user_upload/pdf/Targeted_survey_letter_to_EC.pdf

[7] https://www.greens-efa.eu/en/article/letter/public-consultation-on-new-genome-techniques