



Open letter:

European Commission's biased road to deregulation of new GMOs

Targeted survey is fatally flawed and cannot be used for impact assessment of "new genomic techniques" legislation

Brussels, October 4th 2022

Commissioner Stella Kyriakides
 EU Commission
 Rue de la Loi / Wetstraat 200
 1049 Brussels
 CC Cabinet Timmermans
 CC IA unit in Gen Sec

Dear Commissioner Kyriakides,

We are writing to express our serious concerns about how DG SANTE is organising the impact assessment on new GMOs - new genomic techniques (NGTs) - and in particular, the consultations that will feed into the assessment. The outcome of this assessment could have

far reaching impacts on consumer choice, food safety, organic and conventional farming and the environment.

We are especially concerned about how the targeted survey on NGTs, in which most of us have been invited to participate, was designed and carried out by the Technopolis Group Amsterdam.

The EU Commission's public consultation¹, which closed on 22 July 2022, was already characterised by strong bias regarding the tone, content, and questions and response options, which together appeared to be formulated to weaken the existing GMO regulation.² We were also concerned about the absence of policy options in the public consultation material and subsequent lack of transparency on this topic.

The targeted survey seems to be even more biased in favour of far-reaching deregulation of GMOs in agriculture and food. The survey is alarmingly one-sided and several elements make it inadequate for a serious evaluation of the regulation of NGTs. The questions and answer options, the presented scenarios and accompanying texts again reveal the seemingly already fixed aim of deregulation of NGTs. It even appears that some defining conclusions were integrated into the survey's design.

Under these circumstances, answering the targeted survey was impossible for many stakeholders. Some did fill out the targeted consultation (or planned to do so) but later had to withdraw or re-submit.

Below we outline some of our criticisms of the targeted consultation (these are fully elaborated in the Annex to this letter). These criticisms lead us to the conclusion that it does not meet the required EU Commission standards for a targeted consultation and therefore cannot be used as a basis for the impact assessment or any new legal framework for NGTs:

- The targeted consultation was based on opinions and speculation, with no robust data
- The questions and answer options were unclear
- Framing of questions was biased
- Claims and assumptions of benefits for NGT plants are unverifiable
- Participant selection was characterised by lack of transparency
- Consultants have a conflict of interest
- The Commission failed to disclose policy options, meaning that the results of the public consultation cannot be meaningfully analysed
- The Commission and the consultation failed to recognise that any sustainability assessment of new GMOs must be transparent and performed separately from the risk assessment.

Conclusion and demands

To summarise, the targeted consultation suffers from the following serious shortcomings:

- Full transparency should have been – but was not – provided about the selected stakeholders from the outset, including the sectors they come from, the criteria that led to their selection, and how their inputs will be weighted in the outcome of the survey and the Commission's impact assessment.

- The policy scenarios for new GMOs should have been made public, but were not, so the public consultation must be repeated. A broad and objective consultation of experts and stakeholders is needed, based on facts and studies, workshops and exchanges. A technology assessment must be carried out of the risks and potential benefits of specific new GM plants, and also of the systemic impact that the introduction of the new technology would have on health, the environment, and food production processes.
- Sustainability must be assessed separately from the genetic modification regulation and the assessment must be based on evidence and clear objectives and be reviewed by independent authorities. The whole agricultural/production system must be taken into account – not just the isolated intended trait of the new GMO.

We conclude that the targeted survey is fundamentally flawed and cannot provide a sound basis to feed into decisions about safety regulations for GMOs, nor can it justifiably be used as a basis for the assessment of a legal framework.

We call on the Commission to repeat those parts of the impact assessment on new genomic techniques that fall short of the required standards.

More broadly, we reiterate our demand to follow the ECJ decision that products of new GMOs (NGT) are GMOs and must be regulated as such. The precautionary principle must be respected. Deregulation would put at risk the environment, food safety, consumers' and farmers' right to choose, as well as the organic, conventional, and non-GMO sectors.

We urge you, our governments and European decision makers to take a strong stand against any attempts to exclude new GMOs from the existing EU GMO legislation and to uphold mandatory safety checks, transparency, and labelling for all GMOs to guarantee the safety of our food, as well as to protect nature, the environment, and our freedom of choice. We trust you will ensure safety for consumers and sustainability objectives by upholding existing standards and law designed specifically to achieve this.

We look forward to your reply.

Kind regards,

Europe/International

Biodynamic Federation Demeter International

Compassion in World Farming EU, Europe

Corporate Europe Observatory, Europe

ENGA - European Non-GMO Industry Association, Europe

Euro Coop, Europe

European Coordination Via Campesina (ECVC), Europe

European Network of Scientists for Social and Environmental Responsibility (ENSSER), Europe

Friends of the Earth Europe

Greenpeace

IFOAM Organics Europe

IG Saatgut – Initiative for GE-free seeds and breeding, Europe

National

AGROLINK Association for sustainable environmental solutions, Bulgaria
Amigos de la Tierra, Spain
Arbeitsgemeinschaft bäuerliche Landwirtschaft (AbL) e.V., Germany
ARCHE NOAH, Austria
ARGE Gentechnik-frei, Austria
Beyond GM/A Bigger Conversation, UK/EU
Bio Austria
Bund Ökologische Lebensmittelwirtschaft e.V. (BÖLW), Germany
Demeterforbundet i Danmark, Demeter Denmark
Forenigen for Biodynamisk Jordbrug, Danmark, Biodynamic Association, Denmark
Frie Bønder Levende Land, La Via Campesina Denmark
Friends of the Earth Cyprus
GLOBAL 2000 - Friends of the Earth Austria
GMWatch, UK
Landsforeningen Praktisk Økologi, Association for Practical Ecology Denmark
Magyar Természetvédők Szövetsége, Friends of the Earth Hungary
Nature & Progrès, Belgium
NOAH - Friends of the Earth Denmark
Občianska iniciatíva Slovensko bez GMO – Citizens' initiative Slovakia without GMOs, Slovakia
Objectif Zéro OGM, France
ÖBV-Via Campesina Austria
OGM dangers, France
POLLINIS, France
Save Our Seeds, Germany
Sciences Citoyennes, France
Testbiotech, Institute for Independent Impact Assessment of Biotechnology, Germany
Urgenci International Network, France
Verbraucherzentrale Bundesverband e.V., Germany
Zelena akcija – Friends of the Earth Croatia

Annex: Detailed criticisms of the targeted consultation

The targeted consultation suffered from the following serious shortcomings:

- The targeted consultation was based on opinions and speculation, with no robust data: The targeted survey presents different deregulation scenarios and asks stakeholders to give opinions, make assumptions and estimates, and speculate about the impacts of NGTs for the years 2030–2035. An example of a speculative question is: “Do you expect that the more widespread availability of plant varieties developed using CG/TM [cisgenesis/targeted mutagenesis] techniques will be *typically* positively or negatively associated with the following impacts for the environment?” It is not possible to give meaningful answers to such questions in the absence of data. Indeed, it is not clear which NGT products, with which traits, will actually be commercialised. Much information on what is said to be in the pipeline falls under business confidentiality. Therefore this type of question allows GMO developers to treat hypothetical benefits of NGTs as facts. A better approach would be to conduct a broad consultation among independent experts and representatives of organisations active in sustainable farming and the environment. The consultation should identify gaps in data and knowledge, which must be filled before the regulatory framework is changed.
- The questions and answer options were unclear: The questions leave room for interpretation. This led some NGO stakeholders to unintentionally submit diametrically opposed answers, even while they meant to answer in the same way. For example, some answered a question about the association of increased use of NGTs with “total pesticide use” in opposite ways, while both meant to answer that increased use of NGTs would lead to increased use of pesticides. We therefore requested clarifications from Technopolis, which they provided at the end of July/beginning of August. They also enabled those who had already submitted their answers to correct their submission – but only until 8 August. This means that an unknown number of submissions may not be completed in the way intended. If these submissions are taken into account nonetheless, the outcome of the targeted consultation will be misguided. In addition, the concept of “risk profile” for NGTs is used, even though no scientific data are available on which to assess their risk profile and Technopolis offers no definition for the term in this context. Accordingly, no conclusions can be drawn.
- Framing of questions was biased: The framing of some of the questions was biased, such as the term “proportionate risk assessment” in scenario A1, which assumes that the current GMO regulations are not proportionate.
- Claims and assumptions of benefits for NGT plants are unverifiable: It is not acceptable for the consultation text to assume that NGTs can contribute to “sustainability”, since that assumption is only or largely based on developers’ and industry’s unverifiable claims unsupported by independent evidence, especially as such NGT plants do not yet exist beyond the research stage.³
- Participant selection was characterised by lack of transparency: The targeted survey was not transparent regarding stakeholders and their influence on the impact

assessment. Despite several requests for a breakdown of invitees to the consultation by category, Technopolis did not provide that information, so it is not possible to assess the balance of different stakeholder groups. However, this information was published in the consultation on new genomic techniques in 2020, when the list of invited participants was revealed to be heavily biased towards industry actors. Perhaps this is the case also with the Technopolis survey. In addition, regarding both consultations, there is no transparency on how the EU Commission intends to weigh the inputs in the impact assessment.

- Consultants have a conflict of interest: Wageningen University & Research (WUR) is part of the group of consultancies carrying out the consultation. However, WUR researchers have themselves lobbied in favour of the deregulation of new GMOs on various occasions, including when speaking at Brussels events and in meetings with the Commission and with hand-picked national officials through the European Plant Science Organisation (EPSO).⁴ This is a clear case of conflict of interest, which adds to our doubts regarding this consultation. When we pointed this out to DG SANTE, it responded that the WUR staff involved would not have any role in analysing and summarising the stakeholder input. However, in our view, any company or consultancy that has lobbied on a certain topic should not then be hired to work on that topic by the EU institutions, whatever their particular task, as it could lead to a biased outcome. We were also told that an “independent expert” would review the assessment, but unless their identity and interests are disclosed, we cannot ensure that they are genuinely independent.
- The Commission failed to disclose policy options, meaning that the results of the public consultation cannot be meaningfully analysed: It is incomprehensible that the EU Commission has disclosed the policy scenarios only to an undisclosed group of stakeholders via the targeted consultation and not to the general public. The Commission should be transparent and openly communicate that it is pursuing the deregulation of many GM crops, even if its plans are unpopular. Every EU citizen would be affected by a lowering of food safety and transparency standards. Due to this omission, the responses of the participants of the public consultation, which ended on 22 July, cannot be meaningfully analysed or used for the impact assessment, as the participants and the public were not aware of the scenarios. The scenarios must be made public and the public consultation repeated.
- Coexistence was not properly addressed: The targeted survey lists so-called “coexistence impact indicators” and asks to what extent they will change up to 25% or more than 25% under different deregulation scenarios. However, it is likely that there would be a 50% or 100% decrease or increase in the respective indicator if breeders, farmers, feed and food processors, traders, and retailers lose their right to know about the presence of NGTs in their value chains. This would lead to massive financial setbacks or even the total loss of a business. Generally speaking, the targeted survey does not address the topic of coexistence seriously. To protect conventional and organic production systems against GMO contamination (especially given the EU’s intention to boost the organic sector), there must be legally binding rules that encompass the whole food chain (including breeding) and assign clear legal responsibilities, including compensation, in case of contamination and the need

to take anti-contamination measures (the “polluter pays” principle). This is currently not the case. The Commission must solve this problem before discussing deregulation of NGTs.

- The Commission and the consultation failed to recognise that any sustainability assessment of new GMOs must be transparent and performed separately from the risk assessment: We oppose the introduction of a sustainability assessment into genomic techniques regulation. These are two completely different areas of regulation that need to be examined and evaluated separately. Risk assessment has to be carried out first; sustainability analysis can only be a second step if new GMOs have previously been classified as safe for humans, animals, and the environment. A sustainability analysis of new GMO plants according to scientific, well-defined, verifiable, and binding criteria must include a "proof of claim" with regard to economic, social and environmental impacts, combined with a "proof of benefit". Mixing risk assessment and sustainability runs the risk of pitting safety aspects against sustainability claims. In the worst case, manufacturers of new GMOs could greatly exaggerate their product's potential contribution to sustainability in order to lower the requirements for a risk assessment; or a positive sustainability assessment would be weighted more heavily than a negative risk assessment. In addition, assessment of a single intended feature of a plant is not adequate to evaluate sustainability; any sustainability assessment must take into account the whole agricultural and/or production system. In terms of legalities, we expect the EU legal framework for sustainable food systems to be established first. This must then be reflected in individual legislative proposals, but must also be coherent and assess all dimensions of sustainability on the basis of robust evidence. For example, the cultivation system (monocultures, chemical-input-dependent) and business model (controlled by patents) for current and new GMOs are the opposite of a sustainable food system. These aspects must be taken into account.

1 See https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en

2 See <https://www.global2000.at/presse/global-2000-deckt-auf-nachhaltigkeits-etikett-statt-gentechnik-kennzeichnung>;
<https://www.eurovia.org/wp-content/uploads/2022/06/Open-Letter-ECVC-refuses-to-respond-to-NGT-consultation-EN.pdf>

3 See <https://gmwatch.org/files/Response-to-EU-Commission-on-gene-editing-deregulation-plans.pdf>

4 See <https://corporateeurope.org/en/food-and-agriculture/2016/02/biotech-lobby-push-new-gmos-escape-regulation> ; <https://corporateeurope.org/en/2021/03/derailing-eu-rules-new-gmos>