

To:

Commissioner Stella Kyriakides
Executive Director Bernhard Url

cc:

DG SANTE, Deputy Director-General, Claire Bury
DG SANTE, Head of Unit Biotechnology, Irene Sacristán Sánchez
EFSA, Head of Nutrition & Food Innovation Unit, Ana Afonso

Brussels, 14th December 2022

Re: Legislative proposal for plants obtained by certain new genomic techniques (NGTs) and criteria for risk assessment

Dear Commissioner,
Dear Director,

Plants for the Future ETP (Plant ETP) and its members welcome the EU Commission's initiative to put forward a new legislative proposal for plants obtained by certain NGTs. These NGTs represent just a few of the many ground-breaking innovations brought to us by science and it is our hope that new legislation will soon enable their use in the EU. Conventional-like NGT plants must be regulated similarly to their conventionally bred counterparts, in order for them to contribute to the transition to more sustainable agri-food systems.

If conventional-like NGT plants fall within the scope of the GMO Directive, they will not be used by European breeders or farmers. As such, an "adapted risk assessment" for conventional-like NGT plants will have little effect, as the acreage for GMOs in the EU is too low to warrant investment (18 out of 27 Member States have either completely or partially opted-out of cultivating GMOs). The stigmatisation and administrative burden that accompany developing and growing GMOs will ensure little to no uptake in the EU. Additionally, the current lengthy timelines for import approvals of GMOs, would discourage investment and would currently neutralise any efficiency gains for breeding with certain NGTs.

In addition to the impact assessment, the EU Commission has requested that EFSA provides a statement on criteria for the risk assessment of plants obtained by certain NGTs. **We regret the**

narrow framing of the Terms of Reference (ToR), which restricted EFSA's work on developing criteria for risk assessment and seemingly kept the ToR within the scope of the GMO regulatory framework, rather than allowing consideration of whether a risk assessment would be needed for conventional-like NGT plants. Inasmuch as the background to this same ToR states that “EFSA considered that plants produced by targeted mutagenesis and cisgenesis, in some cases, do not pose new hazards compared to plants produced with classical mutagenesis or conventional breeding techniques”, it is difficult to reconcile the narrow framing of the ToR.

The criteria put forward by EFSA are, in our view, too restrictive and uncertain, particularly criterion 5, “a history of safe use”. In fact, if applied to conventionally bred varieties that are already on the market, many would fail to meet all the criteria. For example:

- Wild relatives of modern crops that are not consumed by animals or humans, are often used in plant breeding to broaden the genetic diversity of crops and introduce required characteristics, such as disease resistance, to commercial varieties¹. If the EFSA criteria were applied to varieties obtained in this way, they could not demonstrate a history of safe use (criterion 5), even if these varieties were developed using conventional breeding methods.
- Several crops that we commonly consume, such as rapeseed, common and durum wheats, oat and coffee, are the result of spontaneous intraspecific (within the same species) or interspecific (with another species) hybridisation, followed by chromosome doubling (i.e., allopolyploidy)². Breeders regularly make use of these processes to introduce genetic variation into such species and, once a characteristic of interest has been identified, move it into commercial varieties. Such varieties would not meet the criteria outlined by EFSA, even though they would have been entirely developed using conventional breeding methods.

The genetic changes that occur during conventional breeding are most often randomly induced and more extensive than with certain NGTs. Regardless of the breeding method used, breeders always perform a thorough screening, selection and characterisation of the new varieties. Therefore, criteria to determine whether conventional-like NGT plants could potentially pose new

¹ Dempewolf, H., Baute, G., Anderson, J., Kilian, B., Smith, C. and Guarino, L. (2017), Past and Future Use of Wild Relatives in Crop Breeding. *Crop Science*, 57: 1070-1082. <https://doi.org/10.2135/cropsci2016.10.0885>

² Jesske, T., Olberg, B., Schierholt, A. *et al.* Resynthesized lines from domesticated and wild *Brassica* taxa and their hybrids with *B. napus* L.: genetic diversity and hybrid yield. *Theor Appl Genet* **126**, 1053–1065 (2013). <https://doi.org/10.1007/s00122-012-2036-y>

hazards for which a risk assessment might be warranted, should be compatible with what is undertaken in conventional breeding and should not be more demanding.

We appreciated the opportunity to participate in the EFSA stakeholder event on NGTs on 12th December, but regret that the nature of the discussion was focussed on how, rather than whether, to conduct risk assessments of conventional-like NGT plants.

Once again, we welcome the EU Commission's initiative to propose a legislative framework for plants obtained by certain NGTs, and we hope that with this letter the Commission will adopt a broader view than has been apparent so far. An increasing number of countries around the world have established effective and robust regulatory approaches to determine whether a plant obtained by certain NGTs falls within the scope of the GMO directive or not. Although these approaches are based on individual regulatory backgrounds, they result in similar conclusions and enable a harmonised scope of regulatory oversight.

Several studies engaging consumers and citizens on the topic of NGTs have shown that the public supports their use, if they provide benefits for society (e.g., reduce world hunger), but the public expects policymakers to take leadership roles in fostering confidence in our agri-food systems^{3,4,5,6}.

We thank you for your time and would welcome any opportunity for further discussions.

Best wishes,

Plants For the Future ETP

³ Bioteknologirådet and GENEinnovate (2020) Norwegian consumers' attitudes toward gene editing in Norwegian agriculture and aquaculture <https://www.bioteknologiradet.no/filarkiv/2020/04/Report-consumer-attitudes-to-gene-editing-agri-and-aqua-FINAL.pdf>

⁴ SLU and Gentekniknämnden (2021) Svenskars inställning till genomredigering inom växtförädling https://www.genteknik.se/wp-content/uploads/2022/02/Svenskars-installning-till-genomredigering_2022.pdf

⁵ Bearth, A., Kaptan, G. & Kessler, S.H. Genome-edited versus genetically-modified tomatoes: an experiment on people's perceptions and acceptance of food biotechnology in the UK and Switzerland. *Agric Hum Values* 39, 1117–1131 (2022). <https://doi.org/10.1007/s10460-022-10311-8>

⁶ Spök A, Sprink T, Allan AC, Yamaguchi T and Dayé C (2022) Towards social acceptability of genome-edited plants in industrialised countries? Emerging evidence from Europe, United States, Canada, Australia, New Zealand, and Japan. *Front. Genome Ed.* 4:899331. <https://doi.org/10.3389/fgeed.2022.899331>
