ANNEX

Specific issues in relation to the public consultation raised in the additional document annexed to ECVC’s letter¹ of 9 June 2022.

(1) “Incorrect legal context and definitions”

ECVC considers that there is no legal uncertainty in the current GMO legal framework, and that the Commission makes a mistake in consulting on legal uncertainties of Directive 2001/18/EC, since the Court of Justice of the European Union (CJEU) has already clarified the meaning of the mutagenesis exemption in Case C-528/16.

The Commission has made it clear in the study of 29 April 2021², and in the inception impact assessment on this policy initiative³, that products of targeted mutagenesis, as well as other products obtained by NGTs, are GMOs subject to the requirements of the EU legislation on GMOs. This is fully in line with the CJEU ruling.

However, while the ruling of the Court provided important clarifications, the study referred to various other instances of legal uncertainties as regards new techniques and their applications, with unclear or undefined terms and notions in Directive 2001/18/EC. In this context, the public consultation questionnaire allows respondents to agree or disagree with the Commission’s assessment in this regard.

As regards the comments concerning the case currently pending before the CJEU (Case C-688/21), we refer to the letter from Commissioner Kyriakides to ECVC dated 4 March 2022⁴.

2) “Unsubstantiated claims about the development, value and sustainability of NGTs”

ECVC further states that the consultation contains unsubstantiated claims about the potential contribution of NGT plants to the sustainability of food systems and the objectives of the European Green Deal and Farm to Fork and Biodiversity strategies. ECVC also considers that it is not a variety that should be sustainable, but a food system.

We agree that no variety, breeding technique, or farming system is the only solution to address the sustainability of the food system. However, we also believe, based on the outcome of the study of 29 April 2021 and the accompanying report of the Joint Research Centre⁵, that plant varieties with specific traits generated via NGTs could be an important tool, which can contribute to social (health), environmental and economic aspects of sustainability. These are the matters put forward in the public consultation, which allows to take a position on whether sustainability provisions are adequate in the context of this

¹ Our reference Ares(2022)4478242
⁴ Our reference Ares(2022)1627452
⁵ https://publications.jrc.ec.europa.eu/repository/handle/JRC123830
initiative and on the potential of different traits to contribute positively or negatively to sustainability.

3) “Intellectual property rights are nowhere to be found in this consultation”

ECVC expresses concerns on the absence of questions regarding intellectual property and patents in the questionnaire.

While this policy initiative does not include the regulation of intellectual property in its scope, a dialogue between relevant Commission services and stakeholders on matters relating to farmers’ concerns linked to intellectual property and the availability of non-GM seeds is ongoing in order to better understand concerns and exchange views in view of exploring possible solutions.

(4) “Misleading statements concerning the traceability of these techniques”

Concerning the current analytical detection methods, ECVC considers that there is no technical barrier to develop a method capable of differentiating certain NGT plant products, and that the Commission has refused to fund related research.

On these matters, the Commission bases itself on the opinions of the European Reference Laboratory for Genetically Modified Food and Feed (EURL) and the European Network of GMO laboratories (ENGL), which are the reference for the EU when it comes to analytical aspects of GMO enforcement. They consider that, when small changes in the genome are introduced, it is often not possible to confirm whether these changes occurred by natural mechanisms, by techniques not subject to the GMO legislation or by NGTs. General analytical screening strategies employed for conventional GMOs cannot be applied to unequivocally detect and identify all products of targeted mutagenesis.

The study of 29 April 2021 assessed the views of the Member States and stakeholders on the implementation challenges and explored alternative traceability strategies. The ongoing impact assessment will also look into these issues and any potential solutions, and in this context these matters are put forward in the public consultation. This does not prejudge the fact that advances in technological developments may eventually allow addressing the limitations described above.

The Commission supports research through the Horizon Europe programme. There were several calls in the 2021-2022 Work Programme that can support research in the area of NGT detection and traceability. For instance, a recent call included within its scope “developing knowledge, technologies and practices to improve, among other, detection of non-authorised substances”7; a further call included the need to update detection and traceability mechanisms to scientific developments and innovative technologies in breeding8. Under the next Work Programme 2023-2024, the Commission is considering topics related to transparency and safe innovation in the food system by traceability strategies and detection methods of products obtained through NGTs.

7 HORIZON-CL6-2021-FARM2FORK-01-07
8 HORIZON-CL6-2022-FARM2FORK-01-11