To:

Commissioner Stella Kyriakides

Cc:

DG Sante, Deputy Director-General, Claire Bury

DG Sante, Director for Food Safety, Sustainability and Innovation, Klaus Berend

DG Sante, Head of Unit Biotechnology, Irene Sacristán Sánchez

Brussels, 26 June 2023

Re: Commission Proposal on plants obtained by certain New Genomic Techniques

Dear Commissioner,

Euroseeds and CropLife Europe (CLE) appreciate the Commission's ongoing work on the proposal on plants obtained by certain New Genomic Techniques (NGTs) to be published on 5th July 2023. We herewith provide comments on the draft proposal that has become publicly available[1].

We welcome the **differentiation between conventional-like NGT plants (Category 1) and transgenic plants** in terms of the requirements of the premarket approval system for transgenic GMOs. This is a **prerequisite for a proportionate and science-based framework adapted to different risk profiles of these plants**. At the same time, we would like to highlight the need for **clear definitions and scientific criteria (in the Annexes) providing legal certainty** for developers and efficient administrative processes instead of politicized decision procedures.

The **future framework should be based on science**. In this respect, the criteria to establish equivalence with conventional plants should not provide any limits on the number of modifications and allow crops with complex genomes (such as wheat) to benefit most from these new breeding techniques. Otherwise, the same trait in a diploid crop might be considered conventional-like while only because of a more complex ploidy it will be considered a Category 2 in polyploid crops. In addition, some more complex traits to make varieties e.g. more resilient to a changing climate may require editing multiple genes. A restriction of the number of modifications would restrict the potential for the application of NGTs.

We reiterate that a regulatory approach within the GMO framework for NGT plants that are not equivalent to conventional plants (Category 2) would limit the application of those NGTs only to certain crops and traits as well as to certain developers because of the burdensome and lengthy approval process and the respective labelling and co-existence measures that are disregarding the reality of EU's

[1] https://www.arc2020.eu/leak-draft-ngt-regulation-and-impact-assessment-revealed/

agriculture. To provide legal certainty and coherence and avoid enforcement issues when it comes to traceability, labelling and coexistence measures for Category 2 plants, any **NGT products for which no detection method can be developed should be considered as a Category 1 NGT plant.**

NGTs -like any other breeding methods- are not trait-specific and can be used to develop all kinds of plant characteristics. We consider **any technology specific regulation of certain traits as lacking a scientific basis and being discriminatory.**

A notification process to verify the regulatory status of NGT plants via national competent authorities is adequate and workable specifically for Small and Medium Enterprises (SMEs). Nevertheless, we need a **clear, fast and predictable system that is strictly driven by science.** A similar simple and science-based process should be in place also for food/feed products of NGTs. The procedure as foreseen in the draft again provides for political considerations in the decision-making process. This opens the door to leading to unpredictable outcomes that are not justified from a scientific standpoint. This approach would put the EU in clear misalignment with other jurisdictions like, e.g. Canada, Japan, Argentina and others and would constitute a major burden to developers including those wanting to test their products in the field at an early development stage.

The **prohibition for organic farmers to use conventional-like NGTs in their production is neither science-based nor politically justifiable.** It restricts organic breeders and farmers from using the best performing tools to provide the most suitable genetic basis for organic seeds and thus organic production. This would also lead to the creation of an additional category of products that on the one hand are conventional, but for organic breeders and farmers are considered prohibited GMOs. This could trigger confusion and with that legal uncertainty.

In regulating similar products similarly, **no differentiated labelling or traceability requirements should apply to conventional-like NGT products that are not required for conventional plants.** Euroseeds and CLE members are committed to full transparency by making information on the use of NGTs available in a public register. This allows for full freedom of choice for all farmers and value chains: those who wish to use NGT products as well as those who would rather exclude this technology from their production would be enabled to do so without creating unnecessary burden and costs across the entire agri-food chain.

We also hope that the full roll-out of the new regulatory system will be applicable as soon as possible with the timely adoption of the necessary implementing acts.

We thank the European Commission in advance for the consideration of the above suggestions, and we are looking forward to the publication of the final proposal on 5 July.

Kind regards,

Garlich von Essen,

Secretary General, Euroseeds

Olivier de Matos

Director General, CropLife Europe