## Annex

## Request for a scientific opinion on genetically modified plants developed through new genomic techniques

### Background

On 8 November 2019, the Council of the EU has approved Council Decision (EU) 2019/1904 requesting the European Commission to submit a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of new genomic techniques (NGTs) under Union law, and a proposal, if appropriate in view of the outcomes of the study.

The Council's Decision, based on Article 241 of the Treaty on the Functioning of the European Union, requests the Commission to submit:

- a study, by 30 April 2021, regarding the status of new genomic techniques under Union law and in light of the Court of Justice's judgment;
- if appropriate, in view of the outcomes of the study, a proposal (accompanied by an impact assessment) or otherwise to inform the Council on other measures required as a follow-up to the study.

As regards the requested study, the Commission needs an analysis of the status of new genomic techniques that includes safety considerations. In this respect, the Commission intends to include in the study relevant existing scientific opinions addressing the safety assessment of plants developed through NGTs.

EFSA published in 2012 a scientific opinion addressing the safety assessment of plants developed using Zinc Finger Nuclease 3 and other Site-Directed Nucleases with similar function (SDN 3)[1]. In 2012 EFSA also published a scientific opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis[2]. Work by EFSA is currently ongoing on a scientific opinion on plants developed using type 1 and type 2 Site-Directed Nucleases and oligonucleotide directed mutagenesis.

### Terms of reference

Considering the relevant expertise in EFSA and the above-mentioned work of EFSA on NGTs, the European Commission asks EFSA, in accordance with Article 29 of Regulation (EC) No 178/2002, to provide an overview on the risk assessment of plants developed through NGTs, based on its own previous and current work and on work carried out at national level.

For the purpose of the overview, the following definition for new genomic techniques applies: techniques that are capable to alter the genetic material of an organism and that have emerged or have been developed since 2001.

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[1] EFSA Scientific opinion addressing the safety assessment of plants developed using Zinc Finger Nuclease 3 and other Site-Directed Nucleases with similar function. EFSA Journal 2012;10(10):2943.

[2] EFSA Scientific opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis. EFSA Journal 2012;10(2):2561.

For this overview, EFSA is not requested to develop new opinions on plants developed through specific NGTs. Rather, EFSA is asked to take into account its previous scientific opinions, its ongoing work on the topic as well as opinions published by competent authorities and national institutions since 2012[3], where available.

[3] This timeline is proposed to align with the first EFSA scientific opinions on NGTs dating from 2012.