TEST BIOTECH

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Dear Commissioner Kyriakides, dear Vice-President Timmermans,

We are writing out of concern that the EU Commission Staff Working Document on the status of new genomic techniques under Union law (SWD(2021) 92 final) sets undue political accents. Our detailed analysis shows that the term 'conventional GMO', in the sense of a 'transgenic organism', as used and defined by the EU Commission, is set to cause fundamental legal and scientific problems: it confuses and contradicts the categories of genetic engineering and conventional breeding that are essential for GMO Regulation in the EU. Furthermore, Testbiotech warns that the use of this term is likely to undermine the Court of Justice ruling in Case C-528/16.

As the attached backgrounder shows, experts with close affiliations to the biotech industry first coined the term 'conventional GMO' with a specific regulatory meaning, implying that there are no specific and inherent risks associated with the techniques of genetic engineering. That said, neither the EU scientific services, the European Food Safety Authority (EFSA), the Joint Research Center (JRC) nor the vast majority of experts participating in the consultation, used this terminology.

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European Commissioner Ms Stella Kyriakides Health & Food Safety Directorate-General

Vice-President of the EU Commission Mr Frans Timmermanns

B – 1049 Brussels Belgium

CC Experts of EU Member States

Re: Study on new genomic techniques

Nevertheless, the term 'conventional GMO' was integrated in the report - with exactly that meaning, i.e. 'transgenic', as proposed by industry.

The EU Commission Staff Working Document is meant to provide legal and scientific definitions to lay the groundwork for subsequent discussions and decision-making processes concerning the future of GMO regulation. Therefore, in light of the analysis we provide, we urge the EU Commission to carefully revise its report.

There are other strong indications that the influence exerted by industry and their affiliated experts led to a bias in the EU Commission report: the Staff Working Document falsely assumes that no generic risks arise from the processes of New GE. This assumption is in marked contrast to many relevant scientific publications and findings. Therefore, contrary to what is claimed by the Commission and industry, unintended genetic changes arising from the multistep processes of New GE applications and their inherent risks, must undergo mandatory risk assessment.

Therefore, we request the EU Commission, when reviewing its report, to ensure that the inherent risks associated with the processes of 'old' or 'new' GE are treated with due diligence.

With kind regards,

Dr Christoph Then, legal representative of Testbiotech Tel 0049 15154638040 e-mail: <u>christoph.then@testbiotech.org</u>

Annex: Testbiotech Backgrounder: <u>What is a conventional GMO?</u> Testbiotech Backgrounder: <u>Deregulation of New GE: Reasonable? Proportional?</u>