STELLA KYRIAKIDES
MEMBER OF THE EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY

Rue de la Loi, 200
B-1049 Brussels – Berl 10/380
stella.kyriakides@ec.europa.eu

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Dear Dr Then,

Thank you for your letter of 16 June 2021[1], accompanied by background papers and addressed to Executive Vice President Timmermans and myself, on the Commission's study on new genomic techniques (NGTs). The Executive Vice President has asked me to reply on his behalf.

In your letter, you ask the Commission to revise the text of the study due to legal and scientific problems that in your view would arise from the use of the term "conventional GMO", in the sense of a "transgenic organism".

As regards potential legal problems, I would like to emphasise that, as specified in the study, the definition of "conventional GMO" provided in its glossary is an operational definition, used only for the purpose of the study and it has no legal value. The term was used in the study because several stakeholders and Member States made comparisons between GMOs resulting from established genomic techniques and those resulting from NGTs, to underline differences or similarities. These concepts reflect what you call in your letter "old" and "new" GMOs, without any legal implication.

Concerning potential scientific problems, I do not believe the term is subject to misinterpretation. As recognised in your letter, the term has been clearly defined in the glossary as indicating "GMOs resulting from established genomic techniques. Conventional GMOs that have been authorised to date in the EU are transgenic". You also recognise that several Member States made reference to the term "conventional GMOs" in

[1] Our reference Ares(2021)3955534.

Dr Christophe Then
Legal representative
Testbiotech
Frohschammerstrasse 14
DE-München
E-mail: Christoph.then@testbiotech.org // astrid.oesterreicher@testbiotech.org

their input to the Commission's consultation. In addition, the study has made a clear distinction in the text between conventional breeding and conventional GMOs, so that the two terms cannot be confused.

As regards your concern for potential far-reaching implications, it is important to emphasise that transgenic GMOs are not in the scope of the announced Commission's initiative on plants produced by targeted mutagenesis and cisgenesis and the Commission has not planned any policy action on transgenic organisms.

In the light of all the considerations above, the Commission does not see the need to revise the study on new genomic techniques.

In your letter, you also claim that the Commission study, contradicting many relevant publications and findings, falsely assumes that there are no inherent risks in the processes of new genomic techniques. In one of your background documents, you stress that current standards of risk assessment need to be significantly raised in order to assess the often highly complex genetic changes introduced by these techniques.

Let me clarify that the Commission's study has not drawn any general conclusion on the risks associated to NGTs as an overall category. On the contrary, the study has shown that NGTs are a diverse group of techniques that can achieve very different results, from limited and well-characterised modifications that might also occur naturally, to more extensive and less-known alterations. The study has concluded that this variety of outcomes calls for case-by-case risk assessment and more flexibility in the legal framework. The study has also indicated that, in terms of specificity, there is general agreement among, inter alia, Member States, EFSA, the Joint Research Centre and the Group of Chief Scientific Advisors, that targeted mutagenesis represents a substantial improvement over random genetic modifications and that several approaches have been developed to improve method specificity. Finally, based on EFSA scientific opinions and a significant part of scientific bodies, the study finds that plants obtained by targeted mutagenesis and cisgenesis do not pose new risks compared to conventionally bred plants.

On other techniques than targeted mutagenesis and cisgenesis, the Commission's study has clearly recognised that there is the need for further understanding of their potential risks.

I would like to underline that the safety concerns you have raised in your letter and in the attached papers had been reported by some respondents in the study's consultation and have been clearly included in the study. At the same time, I trust you recognise that EFSA, in the context of its relevant scientific opinions and public consultation reports and taking into account the most recent scientific evidence on the matter, has addressed these safety aspects.

Finally, in your background document containing a critical assessment of possible changes in the GMO legislation, you raise concerns on possible changes in the legislation, in particular as regards potential impact on consumers, farmers, breeders and food producers, and you recommend the Commission to examine existing legislation to determine whether

it already includes enough flexibility to achieve its aims. I would like to reassure you that an impact assessment, including a public consultation, will be carried out to examine the impacts of different potential policy options. Among the different policy options, the impact assessment will include the current situation as baseline scenario. The impact assessment will also consider any new relevant information and studies that become available.

Let me conclude by emphasising that, with the announced policy initiative, the Commission is not proposing a deregulation or lowering of safety standards. On the contrary, the Commission is aiming at a proportionate regulatory oversight that combines high levels of safety with clear benefits to society and the environment, in line with the objectives of the Green Deal and Farm to Fork strategy that are at the centre of current EU priorities.

Yours sincerely,