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 Mr Gall,

I would like to thank you and the signatories of the open letter of 30 March 2021[1], addressed to Executive Vice President Timmermans, for your interest in the regulation of products of new genomic techniques (NGTs). The Executive Vice President has asked me to reply on his behalf.

In your letter, you are concerned that the Commission might consider a separate regulatory regime for organisms deriving from NGTs. As you are aware, the Council of the European Union[2] requested the Commission to submit a proposal (accompanied by an impact assessment), if appropriate in view of the outcome of the Commission's study on NGTs under Union law, or otherwise to inform the Council on other measures required as a follow-up to the study.

The Commission has just issued the requested study, which has been submitted to the Council and published on the Commission's website[3]. One of the key findings of the study is that these techniques have the potential to contribute to sustainable agri-food systems in line with the objectives of the European Green Deal and Farm to Fork Strategy. In the pharmaceutical sector, these techniques would allow faster, more affordable development of medicinal products and would have the potential to tackle currently unmet medical

[1] Our reference Ares(2021)2199599
[2] Decision (EU) 2019/1904
[3] https://ec.europa.eu/food/plant/gmo/modern_biotech/new-genomic-techniques_en

Mr Eric Gall
Deputy Director
IFOAM Organics Europe
124 rue du commerce
1000 Brussels

needs. At the same time, the study identified a number of concerns among respondents to the consultation, related to possible safety and environmental impacts, to the coexistence with organic and GM-free agriculture, as well as to labelling and consumers' right to information.

The study identified implementation challenges and legal uncertainties as regards the application of the GMO legislation to new techniques. The study has concluded that there are strong indications that the current GMO legal framework is not fit for purpose for some NGTs products, and that it needs adaptation to scientific and technological progress.

As regards safety, the European Food Safety Authority (EFSA) has concluded that plant products with similar risk profiles can be obtained with conventional breeding techniques and certain NGTs, namely targeted mutagenesis and cisgenesis.

Based on the available information and the outcome of the study, the Commission has concluded that there is sufficient evidence and scientific basis to initiate an impact assessment aiming at a targeted policy action on plants derived from targeted mutagenesis and cisgenesis.

The envisaged impact assessment will look into the design of a proposal that combines high levels of safety with clear added value to society and the environment, taking also into account the concerns identified in the study.

The Commission will engage in a wide-ranging communication effort to share and discuss the outcome of the study and the envisaged policy initiative, as it is important for the Commission to gather views on the proposed follow-up. I would like to encourage you and the co-signatories of your letter to contribute to an open, inclusive and transparent debate that takes into account the key issues at stake, from the protection of health and the environment to the opportunities for societal benefits from innovation.

In the meantime, I would like to confirm that the Commission and the Member States continue to cooperate to ensure the proper implementation of the EU legislation.

In your letter, you also ask the Commission to take action in response to the public consultation on the GMO regulatory framework recently carried out in England. I would like to reassure you that the Commission is closely monitoring the respect on the side of the UK of obligations undertaken in the framework of the EU-UK Trade and Cooperation Agreement in relation to the non-regression of environmental standards. In that respect, any regulatory changes introduced by the UK will be assessed on a case-by-case basis in the light of those provisions. Furthermore, I wish to note that only products complying with EU's GMO rules may enter EU's internal market from third countries, including the UK.

Finally, you request the Commission to support the European Parliament's call for a global moratorium on the release of gene drives in view of the Conference of the Parties to the

Convention on Biological Diversity (COP15) and the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP10).

I would first like to emphasise that any release of gene drive modified organisms into the environment is strictly regulated in the EU. Any possible application has to undergo a thorough assessment of all identified risks in accordance with Directive 2001/18/EC.

Let me reassure you that the Commission, together with the Member States, is thoroughly preparing the forthcoming negotiations at these conferences and will give due consideration to the different views on the potential applications of gene drive modified organisms as well as to the related uncertainties and risks.

I would also like to recall that, following a request by the Commission, EFSA has been working on genetically modified insects engineered with gene drives to assess the adequacy of existing risk assessment guidance[4]. The Commission is currently discussing with EFSA how to follow-up on this work.

I thank you again for your interest and look forward to further exchanges on these important topics.

Yours sincerely,

D. Kyprakides

[4] EFSA GMO Panel, 2020. Scientific Opinion on the adequacy and sufficiency evaluation of existing EFSA guidelines for the molecular characterisation, environmental risk assessment and post-market environmental monitoring of genetically modified insects containing engineered gene drives. EFSA Journal 2020;18(11):6297, 90 pp. https://doi.org/10.2903/j.efsa.2020.6297