EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food Safety, Sustainability, and Innovation
The Director (acting)

Brussels,
SANTE.E.3/AH/so (2023) 4108630

Dear Dr. Then,

Subject: Your letter of 31 March on criteria for risk assessment of NGT plants

I refer to your above-mentioned letter ([1]) accompanied by a background document, addressed to Commissioner Kyriakides who asked me to reply on her behalf.

In your letter and the background document, you provide your views on a discussion paper that the Commission services shared with the Member States. You consider that the paper suffers from major misconceptions, and that it overlooked the fact that NGT processes may cause unintended genetic changes different from those that can be expected from conventional breeding. You also consider that EFSA was never asked to investigate potential unintended effect linked to NGTs, and that for this reason the Commission cannot rely on EFSA's conclusions. You finally claim that unintended genetic changes might spread withing breeding population and accumulate, resulting in risks for future plants, animals and food security. You then conclude that, in your view, plants obtained by NGTs should undergo a risk assessment as required by Directive 2001/18/EC.

First of all, the document you mention is a discussion document solely intended for an exchange with Member States' experts in the framework of the impact assessment of the Commission initiative on a legislation for plants produced by certain new genomic techniques. It does not represent a final position of the Commission or its services.

As regards the concerns you have raised, I would like to refer to our previous exchange of correspondence ([2]), in which we have already provided replies to several issues on the basis of the relevant scientific opinions of EFSA and of other major scientific bodies.

([1]) Our reference Ares(2023) 2350027

([2]) Reply (our reference Ares(2021)7605229) to your letter of 16 November 2021 (our reference Ares(2021)7056896); reply (our reference Ares(2022)743929) to your letter of 22 December 2021(our reference Ares(2021)7938060) and reply (our reference Ares(2022)3616283) to your letter of 11 April 2022 (our reference Ares(2022)3162135).

Dr Christoph Then
Testbiotech
Frohschammerstraße 14
80807 München
Germany
E-mail: Christoph.then@testbiotech.org

In particular, regarding your claim that EFSA was not mandated to investigate potential unintended effects linked to NGTs, I would like to recall that the Commission mandated EFSA to assess potential new hazards and risks of NGTs, and that in the context of the GMO framework this included risks associated to unintended effects at molecular and phenotypical level that NGTs could pose in comparison with conventional breeding or established genomic techniques.

To reply to these mandates, EFSA has published, since 2012, several scientific opinions on plants produced by NGTs. All these opinions have indeed also addressed possible risks associated to unintended effects, taking into account the most recent scientific evidence.

We have read with interest your background document. In our view, it does not provide new evidence contradicting the considerations of this and our previous letters. In any event, we have shared it with EFSA as we normally do with any relevant report.

Yours sincerely,

Klaus Berend