EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
The Director

Brussels
SANTE.DDG2.E.3/SH/gk (2020) 2522323

Dear Mr Then and Ms Österreicher,

Subject: Your letter on No speeding up of EU approval for GMOs

Thank you for your letter of 3 March 2020[1], addressed to President von der Leyen, Executive Vice-President Timmermans and several Commissioners, concerning the approval of genetically modified organisms in the EU. President von der Leyen has asked me to reply on her behalf.

In your letter, you raise concerns about speeding up of the approval process for genetically engineered organisms imported into the EU in the context of discussions with the US and ask the Commission not to agree to *"any trade deal that might hinder the EU in putting higher risk assessment standards in place for genetically engineered plants, or which might enable fast track approval procedures with potentially lower standards"*.

The EU adheres to high standards on human and animal health and for environment, which is reflected in its stringent food safety legislation. Trade deals do not change the standards related to food safety, nor on the content of the risk assessment or on the speed of the risk assessment. EU legislation on genetically modified food and feed, like all other food safety legislation, remains fully applicable in all trade deals.

On the other hand, the EU and the US are engaged in regular dialogues on biotechnology policies in both parties, with a view to exchange information and foster cooperation in innovative biotechnology fields.

You also raise concerns about the current approval process and the risk assessment of GMOs.

I would like to note that in the EU system the risk assessment is entrusted to EFSA. Each GMO application is assessed on a case-by-case basis by the GMO Panel experts, strictly following the EU legislation and the applicable EFSA guidance documents.

[1] Our reference Ares(2020)1360624

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You may have noticed that EFSA follows closely scientific developments and develops when appropriate new guidance documents, thus ensuring the maintenance of high standards on risk assessment. As you mention in your letter, Testbiotech frequently submits comments to the public consultations of EFSA opinions. I consider it very important that this possibility provided by the legislation is actively used and would like to encourage you to continue submitting scientific comments during the public consultation phase, where appropriate.

EFSA's opinions are the basis on which the risk managers, the Commission and the Member States, will take their decisions. The legislation on genetically modified food and feed requires draft authorisations to be submitted to the Committee within three months from the publication of favourable opinions by EFSA. The Commission endeavours to adhere to this legal deadline, when submitting a proposal for the regulatory Committee.

Concerning your comments on the quality of EFSA risk assessment, both the Commission and EFSA contributed to the RAGES process, but no consensus was reached between RAGES and EFSA. In her recent letter[2], Commissioner Kyriakides suggested that you discuss these scientific findings directly with EFSA. Nevertheless, I would like to inform you that the Commission has asked EFSA to further analyze the scientific elements included in the published RAGES reports, and the Commission will carefully study EFSA's reply once available.

Regarding the resolutions adopted by the EU Parliament, the Commission attends the debates taking place in the ENVI Committee and listens to the concerns expressed by MEPs. I would like to reassure you that the procedures set out in the GMO legislation are strictly implemented by the Commission and by EFSA.

Finally, I would like to note that the transparency and sustainability of risk assessment by EFSA will be further reinforced by the new rules adopted last year by the Council and the European Parliament[3]. I trust that this transparency will improve the acceptance by society on how the EU ensures that food and feed placed on the market is safe for human and animal health, and for the environment.

Yours sincerely,

Sabine Jülicher

[2] Our reference Ares(2020)809650.

[3] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (OJ L 231, 6.9.2019, p. 1–28).