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Ursula von der Leyen, President of the EU Commission
cc Frans Timmermans, Executive Vice-President
cc DG SANTE

-open letter-

Munich, 29 May 2020

Dear President von der Leyen

Re: Trade deal and safety of genetically engineered plants

We would like to thank you for asking DG SANTE to reply to our letter of 3 March 2020[1]. In their reply, DG SANTE informed us of bilateral talks being held with the US that aim *"to exchange information and foster cooperation in innovative biotechnology fields."*[2]

After receiving this reply, we would further like to request that you ask the responsible DG of the EU Commission to provide us with additional information regarding the content, schedule, participants and specific goals of these ongoing bilateral dialogues.

In addition, we would be interested in gaining a better understanding of how this dialogue relates to the discussion on the potential trade deals mentioned in our letter. We would also like to know if there is a specific framework or mandate for this ongoing dialogue.

In this context, we once more emphasise our concerns about current risk assessment standards for genetically engineered plants. As you may know, Testbiotech filed a request for an internal review regarding the renewal of authorisations granted in December 2019 (regarding genetically engineered, herbicide resistant soybeans A2704-12 and MON89788)[3]. The reply that we received from DG SANTE in April 2020[4] has raised new concerns about double standards regarding the safety of transgenic plants: New applications for import of transgenic plants require 90-day animal feeding studies, as well as data from field trials that are representative for the agricultural and environmental conditions under which the crops will be cultivated (Commission Implementing

1 https://www.testbiotech.org/content/letter-eu-commission-no-speeding-eu-approval-gmos-march-2020
2 https://www.testbiotech.org/content/letter-eu-commission-regarding-trade-deal-and-rages-april-2020
3 https://www.testbiotech.org/content/technical-background-request-internal-review-against-decision-A2704-12; https://www.testbiotech.org/content/technical-background-request-internal-review-against-decision-eu-commission-MON89788
4 https://www.testbiotech.org/content/letter-eu-commission-testbiotech-internal-review-soybeans-mon89788-and-a2704-12

Regulation 503/2013). However, no such requirements are demanded for the renewal of authorisations granted before Regulation 503/2013 came into force.

Therefore, as our cases show, genetically engineered plants are allowed for import for more than 10 years without a single whole food study being carried out, and without any updated data, e.g. on changes in herbicide applications and other changes in agricultural practice. In conclusion the safety standards are significantly lower for some transgenic plants compared to others. This cannot be justified.

Also Regulation 503/2013 appears to request the same standards for renewals as for new applications. Recital 21 of the Regulation reads: "*In order to ensure that test methods included in the application are adequate to demonstrate that the food or feed complies with the requirements for authorisation set out in Regulation (EC) No 1829/2003, they should be carried out in accordance with the present Regulation, or internationally agreed guidelines such as those described by the OECD, when available. To ensure that applications for renewal meet the same standards as regards tests methods, it is appropriate that these requirements also apply to application for renewal of authorisation of GM food and feed.*"

As the outcome of the RAGES research project shows, the gaps in risk assessment of renewals just add to a more general problem. The RAGES project provides evidence pointing to several other deficiencies in risk assessment. For example, stacked events (genetically engineered plants engineered with several gene constructs that, e.g. produce insecticidal toxins and are resistant to several herbicides) are approved for import and human and animal consumption without any whole food feeding studies being requested to assess cumulative risks, such as mixed toxicity. It is obvious that this current practice in risk assessment is not sufficient to demonstrate safety as requested by EU regulation 1829/2003.

We are also aware that the requirements for post-market monitoring are in no way sufficient to identify potential negative health impacts. While it seems to be likely that no acute health risks are linked to the consumption of products derived from the plants allowed for import, there are also no data that would allow conclusions to be drawn on their general safety and, for example, impact on chronic diseases.

We conclude, current risk assessment of GE plants is not consistent with the legal requirements that the safety of genetically engineered organisms has to be "adequately and sufficiently demonstrated" by applying the "highest possible standard" of "any risks which they present". It does not fulfill the legitimate expectations of the wider public who believe that food safety deserves the highest priority. Contrary to what is implied in the recent letter from DG SANTE as cited above, it is not EFSA, but the responsibility of the EU Commission to set adequate standards in risk assessment. If gaps in risk assessment are identified, the EU Commission cannot simply leave it to EFSA alone to correct these gaps or to set the right standards. Therefore, we ask the EU-Commission to:

- produce its own analysis of the RAGES findings and acknowledge political responsibility, independently of the expected EFSA report;
- take action to close the most obvious gaps in current risk assessment, such as double standards for renewals and missing data on cumulative risks and mixed toxicity;
- participate in an open dialogue with the EU Parliament and civil society about the EU Parliament resolutions requesting higher standards of risk assessment before granting approval;
- grant full transparency about ongoing negotiations and dialogues with the US government and CETA.

Finally, we would like to congratulate you on your new ‘Farm to Fork’ Strategy. However, we are also concerned about the language bias towards new genomic technologies in the strategy: while potential benefits are pointed out in the document, there is no mention of the risks (for overview, see, for example, Testbiotech, 2020[5]).

As the ‘Farm to Fork’ Strategy rightly underlines, Europe needs ‘to do much more to keep ourselves and the planet healthy’. For this reason, it is the responsibility of the Commission to regain public trust, ensure that safety is demonstrated and the precautionary principle is adhered to, before any GE plants are allowed for import into the EU. We would therefore like to kindly ask you to ensure that future communications and decision-making give more weight to the protection goals, and, in addition, that the Commission will avoid simply repeating the language of the stakeholders most interested in the application of the technology.

With kind regards

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5 Testbiotech (2020) Overview of genome editing applications using SDN-1 and SDN-2 in regard to EU regulatory issues, Testbiotech, www.testbiotech.org/node/2569