

Testbiotech | Frohschammerstraße 14 | 80807 Munich

To
Ursula von der Leyen, President of the EU Commission
Frans Timmermans, Executive Vice-President
Stella Kyriakides, Commissioner for Health and Food Safety
Phil Hogan, Commissioner for Trade
Virginijus Sinkevicius, Commissioner for Environment, Oceans and Fisheries
Marija Gabriel, Commissioner for Innovation, Research, Culture, Education and Youth
Janusz Wojciechowski, Commissioner for Agriculture

03/03/2020

Dear President, Vice-President and Commissioners

No speeding up of EU approval for GMOs

We are writing to you after becoming aware that the EU might be about to speed up the approval process for genetically engineered organisms imported into the EU as part of a mini trade agreement with the Trump Administration.

Testbiotech has followed the issue of GMO EU approvals for many years. We frequently file comments during the official EU Commission consulting process regarding upcoming new approvals and EFSA opinions. Our work has resulted in a number of publications in peer reviewed journals showing the current gaps in EU risk assessment (see some references below). Just recently we presented the findings of the international RAGES research project (Risk assessment of genetically engineered organisms in the EU and Switzerland) in Brussels (see below). The project was carried out completely independently of the interests of the biotech industry.

Our findings show that risk assessors and risk managers in the EU have failed to sufficiently deal with the risks to public health and the environment. The current approval process does not take all relevant risks into account, instead it mostly confines its focus to those risks that can be most easily assessed. Consequently, current standards of risk assessment are not sufficient to determine the safety of genetically engineered organisms. They fail to fulfill legal requirements to apply the *“highest possible standard”* to *“any risks which they present”* (Regulation (EC) No. 1829/2003).

**TEST
BIOTECH**

Testbiotech e. V.
Institute for Independent
Impact Assessment in
Biotechnology

Headquarter:
Frohschammerstraße 14
80807 Munich, Germany
Tel: +49 89 35 89 92 76

EU office:
Rue de la Pacification 67
1000 Brussels, Belgium
Tel: +32 23 15 33 08

info@testbiotech.org
www.testbiotech.org

Executive Director:
Dr. Christoph Then

Tax Number:
143/222/75510

Registered Office:
Munich

Registration Nr.:
Amtsgericht München
VR 202119

**EU Transparency
Register:**
ID number 151554816791-61

The EU Commission failed to deal with these problems satisfactorily during its last term in office, in fact, it mostly just defended current standards. This is surprising since neither the EU Commission nor EFSA or the biotech industry ever produced a detailed analysis refuting our scientific findings. EFSA simply defended its position by claiming that our work would not find anything new. However, this is missing the point. It is not surprising that EFSA is already aware of some deficiencies in the current practice. Experts from member states, the EU Parliament and scientists have for many years repeatedly tried to make EFSA and the EU Commission acknowledge these issues. We should all agree that risks, problems and deficiencies in risk assessment will not disappear just because they have been evident for some time. On the contrary, these problems need urgent solutions.

In view of this situation, we urge the EU 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. A rigid time frame of two years for the approval process is not appropriate if the complex risks of genetically engineered plants have to be assessed in detail.

Instead, the EU Commission should, as part of the Green Deal, actively organise a process to re-evaluate market approvals issued so far, assessing their overall and combinatorial impact on the food and feed chain as well as on the environment. At the same time, the findings of scientists working independently of the interests of the biotech industry should be given sufficient weight. In addition, the considerable number of resolutions adopted by the EU Parliament within the last few years should be taken into account. Many of these resolutions are critical of the current approval process for not being sufficiently based on rigorous scientific standards. They further admonish the lack of democratic legitimacy of the approval process.

One of the promises of the Green Deal is to increase transparency and consumer information, as well as to make EU agriculture and food systems more sustainable in an effort to protect the environment and the climate. However if the Commission pushes ahead with fast-tracking GMO approvals as part of the trade deal with the US, this would threaten the precautionary principle as a foundation of EU policy-making and contradict the Commission's overall goal of strengthening the protection of public health and the environment.

With kind regards



Dr. Christoph Then



Astrid Österreicher

Contacts:

Christoph Then, Director, + 49 151 54 63 80 40

Astrid Österreicher, EU policy advisor, + 32 23 15 33 08

Further information on RAGES:

Factsheet: Overview of RAGES findings

www.testbiotech.org/en/content/rages-factsheet-summary

The reports published by RAGES:

www.testbiotech.org/en/content/research-project-rages

A list of selected peer reviewed publications with relevance to GMO regulation and EU risk assessment, resulting from or being supported by the work of Testbiotech (chronological order)

Bauer-Pankus A, Miyazaki J, Kawall K, Then, C. (2020) Risk assessment of genetically engineered plants that can persist and propagate in the environment. *Environ Sci Eur* doi: 10.1186/s12302-020-00301-0. (Forthcoming).

Miyazaki J., Bauer-Pankus, A., Bøhn, T., Reichenbecher, W., & Then, C. (2019) Insufficient risk assessment of herbicide-tolerant genetically engineered soybeans intended for import into the EU. *Environmental Sciences Europe*, 31(1): 92, <https://link.springer.com/article/10.1186/s12302-019-0274-1>

Trtikova, M., Lohn, A., Binimelis, R., Chapela, I., Oehen, B., Zemp, N., Widmer, A., Hilbeck, A. (2017) Teosinte in Europe – Searching for the Origin of a Novel Weed. *Scientific Reports*, 7: 1560.

Then, C., & Bauer-Pankus, A. (2017). Possible health impacts of Bt toxins and residues from spraying with complementary herbicides in genetically engineered soybeans and risk assessment as performed by the European Food Safety Authority EFSA. *Environmental Sciences Europe*, 29, 1. doi: 10.1186/s12302-016-0099-0

Trtikova, M., Wikmark, O.G., Zemp, N., Widmer, A., Hilbeck, A. (2015) Transgene expression and Bt protein content in transgenic Bt maize (MON810) under optimal and stressful environmental conditions. *PloS one*, 10(4): e0123011.

Bauer-Pankus, A., Breckling, B., Hamberger, S., & Then, C. (2013). Cultivation-independent establishment of genetically engineered plants in natural populations: current evidence and implications for EU regulation. *Environmental Sciences Europe*, 25, 34. doi: 10.1186/2190-4715-25-34 .

Mesnager, R., Clair, E., Gress, S., Then, C., Székács, A., Séralini, G.-E. (2012) Cytotoxicity on human cells of Cry1Ab and Cry1Ac Bt insecticidal toxins alone or with a glyphosate-based herbicide. *Journal of Applied Toxicology*, 33(7): 695–699.

Székács, A., Weiss, G., Quist, D., Takács, E., Darvas, B., Meier, M., Swain, T., Hilbeck, A. (2011) Interlaboratory comparison of Cry1Ab toxin quantification in MON 810 maize by enzyme-immunoassay. *Food and Agricultural Immunology*, 23(2): 99-121. www.tandfonline.com/doi/abs/10.1080/09540105.2011.604773

Then, C., (2010), New pest in crop caused by large scale cultivation of Bt corn, in: Breckling, B. & Verhoeven, R. (2010) *Implications of GM-Crop Cultivation at Large Spatial Scales*, Theorie in der Ökologie, Frankfurt, Peter Lang.

Then, C. (2010). Risk assessment of toxins derived from *Bacillus thuringiensis*—synergism, efficacy, and selectivity. *Environmental science and pollution research*, 17(3), 791-797. doi:10.1007/s11356-009-0208-3.

Then, C., & Lorch, A. (2008). A simple question in a complex environment: How much Bt toxin do genetically engineered MON810 maize plants actually produce. In: *Implications of GM-crop cultivation at large spatial scales*. Breckling, B., Reuter, H. & Verhoeven, R. (eds.). Theorie in der Ökologie, 14, Frankfurt, Peter Lang.