

Parma, 06 JUL 2018
Ref. BU/DD/lm (2018) – out-19592385

Testbiotech
Frohschammerstraße 14
DE-80807 München
Deutschland
christoph.then@testbiotech.org

Subject/Re: Reply to your letter of 7 May 2018

Ref.: open letter

Dear Mr Then,

Thank you for your letter of 7 May 2018 in which you raise concerns regarding an EFSA staff member's involvement in a scientific conference organised by the International Society for Biosafety Research (ISBR) and the same staff member's publication of an article on gene flow from genetically modified maize to teosinte. You also highlight recently published scientific evidence related to the import of herbicide-resistant oilseed rape kernels.

Concerning the publication by Devos et al. (2018), EFSA wishes to clarify that this publication summarises and builds on discussions at the ISBR Conference (ISBGM014, 2017) where Mr. Devos presented EFSA's Technical Report on teosinte that was published in 2016 (EFSA, 2016)¹. EFSA is of the view that the publishing of a peer-reviewed scientific paper by an EFSA staff member in co-authorship with industry affiliated scientists is not a conflict of interest incompatible with the obligations staff members have regarding independence under the EU Staff Regulations. This is because authorship is transparently declared and it undergoes peer-review by the publishing journal as well as scrutiny and potential rejection by the scientific community at large. In other words, it does not lead to a situation where the staff member directly or indirectly has any personal interest such as to impair his or her independence.

Notwithstanding this, I acknowledge that societal expectations of how independent science should be produced evolve over time and have changed since EFSA was established in 2002. As EFSA's objective is to improve consumer confidence in the EU food safety system, we have to pay particular attention to the balance between the scientific gain of such publications in disseminating EFSA's views and the concern they may raise among the public. I acknowledge that a case such as the one you refer to, while not a conflict of interest, may give rise to the perception of inappropriate proximity to industry and as such prejudice the legitimate interests of EFSA and the EU food safety system. I will therefore ensure that in the future EFSA staff members will no longer co-author scientific publications with industry affiliated scientists.

¹ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2016.EN-1094>

In your letter you state: "Currently, there are neither EFSA guidelines nor methods for making detailed assessments of the risks associated with genetically engineered plants emerging from unintended crossings and next generation effects". I wish to clarify that these aspects are considered in the GMO Panel guidance on the environmental risk assessment of transgenic plants². I invite you to consult Section 3.1 of this guidance document which outlines a staged approach on how the persistence and invasiveness of transgenic plants as well as of their cross-compatible wild/weedy relatives that may have acquired the transgene(s) through vertical gene flow can be assessed. Whether information is required for all stages or only for specific stages is defined on a case-by-case basis, depending on the intended trait(s), the plant species, the intended use(s), the receiving environments, and the conclusions drawn from lower stages.

On the specific case of gene flow from transgenic maize to teosinte, I would like to draw your attention to an EFSA Technical Report (EFSA, 2016) that EFSA produced upon request of the European Commission. In this report, the introgressive hybridization potential between the transgenic maize (events MON810, Bt11, 1507 and GA21) and its teosinte relatives and the potential adverse effects associated with such transgene flow were considered. For the assessment, EFSA made the conservative assumption that gene flow would occur and that the hybrid progeny would stably express the traits conferred by the transgene(s).

With regards to the publication by Fang et al. (2018), the authors report on increased fitness of Arabidopsis plants overexpressing EPSPS genes conferring tolerance to glyphosate. This increase in fitness is observed in the absence of glyphosate treatment. Thus, the authors conclude that it is the surplus of EPSPS that may affect plant growth and confer the increase in fitness. Whether these findings can be generalised to a broader range of species (including wild/weedy relatives of transgenic plants), transgenic EPSPS-expressing events and environmental conditions requires further research.

At any rate, fitness-related traits are assessed for each transgenic event. According to the requirements of the Commission Implementing Regulation (EU) No 503/2013 and relevant EFSA GMO Panel guidance documents (EFSA GMO Panel, 2010³, 2015⁴), applicants are required to perform field trials for the agronomic/phenotypic and compositional characterisation of transgenic plants, which include fitness-related traits covering growth habit and vegetative vigour, phenology and reproductive behaviour, and susceptibility to pests, diseases and abiotic stress. If the transgenic plant contains a trait for herbicide tolerance, agronomic/phenotypic data must be generated with and without the intended herbicide. Consequently, fitness-related traits of transgenic herbicide-tolerant plants treated with or untreated with the intended herbicides are typically assessed as part of the mandatory agronomic/phenotypic field trials.

In the case of oilseed rape MON88302 (application EFSA-GMO-BE-2011-101), the agronomic/phenotypic characterisation was performed with and without application of the intended herbicide glyphosate. It revealed no biologically relevant differences between oilseed rape MON88302 and its conventional counterpart, except for days-to-first flowering that was delayed for oilseed rape MON88302 in both conditions. The EFSA GMO Panel concluded that the likely effect of the observed difference in days-to-first flowering on survival, establishment and fitness is negligible and will thus not lead to any relevant increase in persistence or invasiveness of oilseed rape

² <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2010.1879>

³ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2011.2150>

⁴ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2015.4128>

MON88302 (EFSA GMO Panel, 2014⁵). Based on these results, there was no indication of increased fitness of oilseed rape MON83302 as compared to its conventional counterpart.

The European Food Safety Authority (EFSA) is grateful for the scrutiny that Testbiotech and other non-governmental organisations apply to its work. In line with its commitment to stakeholder engagement, the Authority firmly believes that open discussion with stakeholders provides a strong basis for the continual improvement of its processes. For this reason, I would like to thank you again for having brought your concerns to my attention.

Yours sincerely,



Bernhard Url

cc: Jaana Husu-Kallio, Guilhem de Seze

⁵ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2014.3701>

