

Testbiotech e. V. | Frohschammerstraße 14 | 80807 München

European Commission

European Commissioner for Health and Food Safety
Mr Vytenis Andriukaitis
Health & Consumers Directorate-General
B – 1049 Brussels
Belgium

8 December 2014

Dear Mr Andriukaitis

We are writing to you to inform you that we have received letters from both Professor Schiemann (GRACE) and Professor Hengstler (Archives of Toxicology). It is suggested that we send our analysis in a letter to the journal Archives of Toxicology (see attachment).

We would first of all like to re-state the reasons why we are asking for withdrawal of the publication:

- The conclusion of the study is not based on a sufficiently thorough assessment of the data that was obtained. In particular, it is unacceptable to dismiss the decrease in the total serum protein concentration and pancreas weight and the increase in blood glucose levels as toxicologically irrelevant. In terms of determining a dose with no toxic effects (no-observed-effect level) the study must be considered invalid.
- In addition to our concerns regarding the scientific contents of the publication, we see very serious problems with regard to conflicts of interest and the credibility of editors at the Archives of Toxicology in relation to the publication of results from the GRACE project.

In his letter Professor Hengstler suggests that we send our comments to the Archives of Toxicology. However, based on our analysis, we do not believe that the Archives of Toxicology is the appropriate journal for the publication of the data, and therefore see no reason to send our comments. We know that this kind of commenting is a common

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Impact Assessment in
Biotechnology

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procedure, but we are not convinced that it would be appropriate in this case.

Our concern about the scientific standards of the Zeljenkova et al. (2014) publication appears to have put Professor Schiemann and Professor Hengstler in a difficult position, which they feel the need to defend. We, on the other hand, believe that it is the duty of the EU Commission to ensure that highest standards are met in this important project.

The integrity of the publication process appears to be seriously impaired and we would urge the sponsor of the study, i.e. the European Commission, to seek ways to resolve this problem. Due to the two-fold nature of the problem, scientific deficiencies and lack of procedural integrity of the Zeljenkova et al. (2014) paper, we urge you

- to encourage the authors and/or the editors to retract this paper from its original publication
- to propose a re-submission of the paper (or a corrected version) to a journal of high editorial integrity, no conflict of interest and with a rigorous peer review process
- to strictly ensure the avoidance of similar problems when it comes to publishing the results of the ongoing one-year toxicity study with MON810-modified maize
- to strictly ensure the avoidance of similar problems within the ongoing G-TwYST project that seems to suffer from similar problems as GRACE.

With best regards



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attached:

letter from Professor Schiemann and Prof. Hengstler as well as answers from Testbiotech

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