EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR RESEARCH & INNOVATION

The Director-General

Brussels, 17 DEC. 2014
rtd.ddg3.f.2(2014)4534324

Dr Christoph Then
Executive Director
Testbiotech
Institute for Independent
Impact Assessment in
Biotechnology
Frohschammerstrasse 14
DE - 80807 München

Subject: **Suspected manipulation in the outcome of the EU research project GRACE**

Dear Dr Then,

I would like to thank you for your letters of 7 November 2014 and 18 November 2014, which were initially addressed to Mr Vytenis Andriukaitis, European Commissioner for Health and Food Safety. In your letters you criticise the scientific content and conclusions of an article on 90-day rats feeding trial[1] recently published by the EU-funded GRACE (GMO Risk Assessment and Communication of Evidence) project consortium. You also question the scientific independence and transparency of the study and more in general of the GRACE consortium and allude to possible conflict of interests of some of the project partners.

The European Commission has a long and successful experience in designing and managing the Research and Innovation Framework Programmes in full respect of sound science and the ability of researchers to derive independent, unbiased conclusions. In the field of GMOs research, since 1982, the European Commission has invested over €300 million to co-fund more than 130 projects, related to potential environmental and health impacts as well as developing risk assessment and management methodologies in support of EU policy development[2].

Specifically, the GRACE project was funded under the European Commission 7th Framework programme, topic: KBBE.2012.3.5-04, "*Verification of GMO risk assessment elements and review and communication of evidence collected on the biosafety of GMO*".

---

1 Zeljenková et al. Ninety- day oral toxicity studies on two genetically modified maize MON810 varieties in Wistar Han RCC rats (EU 7th Framework Programme project GRACE); Arch Toxicol. 2014, 88: 2289-314;

2 A decade of EU-funded GMO research (2001-2010): http://ec.europa.eu/research/biosociety/library/brochures_reports_en.htm

EC-sponsored research on Safety of Genetically Modified Organisms (1985-2000), http://ec.europa.eu/research/quality-of-life/gmo/

The selection process was based on international peer reviewing standards by independent and highly qualified experts. The applicable evaluation and selection criteria focused on: scientific and technological excellence and relevance to the objectives of the specific programme; the potential impact through the development, dissemination and use of project results; the quality and efficiency of the implementation and management.

According to the provisions set forth in the FP7 submission[3], evaluation, selection and award procedures, the Commission has published on a yearly basis on the Internet[4] the overall list of experts used within each specific programme, without reference to specific calls or proposals for which they were asked to assist.

The GRACE project has two key objectives:

a) implement systematic and inclusive reviews of existing evidence of potential health, environmental, and socio-economic impacts (risks and benefits) of GM plants (GMPs) or food and feed derived from GMPs;

b) elaborate further guidance relevant to the design, conduct, interpretation, and scientific value of both animal feeding trials and in-vitro studies to be used in the context of GM food/feed safety.

The need for linking up with existing activities (e.g. International Society for Biosafety Research) was explicitly mentioned in the call text and interaction and networking with a wide range of stakeholders, including local, regional and national authorities, science organisations, but also industry, were specific requirements of the topic.

In line with the specific requirements of the call text, the GRACE consortium has engaged in a wide stakeholders consultation for the design and execution of the study but also analysis and interpretation of the results. These have been made publicly available and discussed before publication. To further stir the scientific discussion and appraisal of the results, a dedicated platform is hosted by the Archives of Toxicology, where the GRACE results have been published.

To conclude, I would like to reiterate that research under the EU Framework Programmes is funded openly, published widely and, therefore, open to public debate. We attach great value to the latter, as driving force for scientific advancement.

Robert-Jan Smits

[3] Decision 2011/161/EU of 28/2/2011

[4] http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html#fp7