COMPLAINT ABOUT MALADMINISTRATION

1
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On behalf of Testbiotech e.V.,
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2
Against which European Union (EU) institution or body do you wish to complain?
European Commission, DG Research & DG Sanco

3
What is the decision or matter about which you complain? When did you become aware of it?

In October 2014, the results of a 90-day feeding study with genetically engineered maize MON810 were published in the journal Archives of Toxicology (Zeljenková et al., 2014). The study is part of the EU research project GRACE (GMO Risk Assessment and Communication of Evidence, www.grace-fp7.eu/).
Testbiotech has criticised the composition of the GRACE-Consortium (Bauer-Panskus & Then, 2013), as well as the process of publication and the presentation of the results in the journal Archives of Toxicology (Bauer-Panskus & Then, 2014, 2015). Many of the leading experts involved in GRACE have close affiliations to institutions such as ILSI (International Life Sciences Institute) and ISBR (International Society for Biosafety Research), which are funded to a large extent by industry. There are even experts involved with GRACE who are contracted to work for companies such as Monsanto.

Testbiotech has further:

- exposed flaws in the presentation of the results from feeding trials, especially in regard to total serum protein concentration and pancreas weight and the increase in blood glucose levels. Contrary to the claims made in the publication, the data from feeding trials do give some indication of health impacts in rats fed with genetically engineered maize.

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- shown there are major flaws in the declaration of interests. In particular, these concern affiliations with Monsanto, ILSI and ISBR.
- revealed close contacts between GRACE experts and the editorial board of the Archives of Toxicology. These findings give the impression that the journal was not chosen for publication because of scientific reasoning, but because of personal networks established within a dubious context. Testbiotech, therefore, questioned whether in this case the conditions for a rigorous and independent peer review had been met.
- found evidence that the journal Archives of Toxicology itself is closely connected to industry, for example, several editors have close ties to the tobacco industry.

The coordinator of the GRACE Consortiums and the Editor-in-Chief of the Archives of Toxicology have responded to the Testbiotech reports. In their responses, they neither contest the close affiliations between the editors of Archives of Toxicology and the corresponding author of the publication, nor do they make any comment on the close relationship of the journal with industry. They do, however, dispute other points relating to conflicts of interest, flaws in scientific standards and presentation of the results. However, Testbiotech showed in detail that the statements made by GRACE on conflicts of interest to rebut the Testbiotech analysis are not correct and/ or are strongly misleading (Bauer-Panskus & Then, 2015). We became aware of the problem that the EU Commission is not willing to take any initiative in this context by two letters from DG Sanco, one in December 2014 and another in January 2015 (attached). We also found out in January that the GRACE project itself declared the “end of the debate” without having solved the problem.

4

What do you consider that the EU institution or body has done wrong?

EU Directive 2001/18 requires risk research on GMOs to be conducted in an independent manner:
Member States and the Commission should ensure that systematic and independent research on the potential risks involved in the deliberate release or the placing on the market of GMOs is conducted. (Recital 21)

According to the EU Commission, the results of GRACE will have an impact on future methods and criteria of risk assessment for the market authorisation of genetically engineered plants http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:157:0001:0048:EN:PDF). In the light of the importance of this project highest standards regarding avoidance of conflict of interest, credibility and scientific scrutiny have to be applied. However, despite evidence for substantial flaws in the declaration of conflicts of interest, too close affiliations between leading GRACE experts and industry and deficiencies in scientific standards, the

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EU Commission did not take any action to establish independence and scientific credibility. Instead the Commission simply took the position that the involvement of industry in GRACE was intended.

Testbiotech believes that it is primarily the task of the EU-Commission to make sure that credibility and scientific standards are safeguarded within the GRACE project. The answer provided by the Commission so far is without substance and partially misleading. Further, Testbiotech is convinced that the problems within the GRACE project are symptomatic of more general problems in current EU processes for organising risk research independently of industry.

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5
What, in your view, should the institution or body do to put things right?

Testbiotech recommended the following actions:

- given the importance of this study, Testbiotech recommends the retraction of the paper. Re-publication should only be considered under a rigorous peer review process and in a journal with a scientific reputation not tarnished by questionable cooperation with industry; it should not be affected by any affiliations to the authors and, furthermore, have the highest standards regarding conflicts of interest. The Commission should encourage the journal and the GRACE experts to retract the publication;
- since the journal Archives of Toxicology has been put into the difficult position of having to defend its own reputation it cannot be considered as a neutral platform for further discussions on the publication. Therefore, the Commission should take action to make sure that a framework is established that allows an open scientific debate on the outcome of GRACE;
- the EU Commission should provide full transparency on the experts involved in the selection of the EU projects in the context of risk assessment;
- the EU Commission should discourage plans to publish further results from GRACE or G-TwYST (another EU risk research project) in the Archives of Toxicology;
- the EU Commission should subject the GRACE-project and the interconnected EU Project G-TwYST to thorough examination to avoid further conflicts of interest.
- The EU Commission should establish much higher standards to avoid conflicts of interest of experts involved in publicly-funded research projects and for experts working with the EU authorities.

6
Have you already contacted the EU institution or body concerned in order to obtain redress?
Yes. See attached communication with the EU Commission. We also contacted GRACE directly. See attachments.

7
If the complaint concerns work relationships with the EU institutions and bodies: have you used all the possibilities for internal administrative requests and complaints provided for in the Staff Regulations? If so, have the time limits for replies by the institutions already expired?
Yes. See attached communication with the EU Commission.

8
Has the object of your complaint already been settled by a court or is it pending before a court?
No

9
Please select one of the following two options after having read the information in the box below:
Please treat my complaint publicly

10
Do you agree that your complaint may be passed on to another institution or body (European or national), if the European Ombudsman decides that he is not entitled to deal with it?
Yes

Date and signature:

Munich, 9.3.2015, Christoph Then

Attachments:
Bauer-Panskus, A. & Then, C. (2013) (DIS-)GRACE: Risk assessment on the leash of biotech industry. Testbiotech background. www.testbiotech.org/en/node/785

Bauer-Panskus, A. & Then, C. (2014) Comments regarding the GRACE publication „Ninety-day oral toxicity studies on two genetically modified maize MON810 varieties in Wistar Han RCC rats (EU 7th Framework Programme project GRACE)", www.testbiotech.org/node/1107

Testbiotech (2014), Comments regarding the GRACE open letter to Testbiotech in response to its report and press release dated 7-11- 2014, Testbiotech Background 18-11-2014, www.testbiotech.org/en/node/1114

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Bauer-Panskus, A. & Then, C. (2015) GRACE - the EU risk research project sold out to industry, TESTBIOTECH Background 9 - 1 – 2015 , www.testbiotech.org/en/node/1129

Letters from Testbiotech to The EU Commission:
November 2014 and January 2015

Letters from DG Research:
December 2014 and January 2015

Zeljenková, D., et al., (2014) Ninety day oral toxicity studies on two genetically modified maize MON810 varieties in Wistar Han RCC rats (EU 7th Framework Programme project GRACE) Archives of Toxicology, DOI 10.1007/s00204-014-1374-8

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