ASSESSING FEEDING STUDIES AND ALTERNATIVE APPROACHES FOR GMO RISK ASSESSMENT

Stakeholder Consultation on the results of the GRACE feeding studies as well as of the in-vitro, in-silico, and analytical studies and on general conclusions and recommendations

7-8 October 2015

Modul Conference Center
Peter-Jordan-Straße 78, 1190 Vienna

DRAFT AGENDA

Context

In the course of the European Commission funded research project GRACE (GMO Risk Assessment and Communication of Evidence) 90-day and 1-year whole food/feed animal feeding studies with as well as analytical, in-vitro and in-silico studies (here: referred to as "alternative approaches) are conducted on GM maize in order to evaluate comparatively their use in GMO risk assessment. Planning-stage issues relevant to these studies were discussed in the workshop of December 2012 and in the written consultation of December 2013. The comments received at the occasion of those consultations were addressed when finalising the study plans. Comments and GRACE-team responses are available at http://www.grace-fp7.eu/content/reports-study-plans-consultation-documents.

This stakeholder workshop will provide an opportunity to review the results obtained and to discuss their interpretation.

To prepare for the consultation, documentation will be provided in advance of the meeting to registered parties. Written comments, also from interested parties not able to attend, are welcome.

Objective

The aim of this workshop is to discuss the results and draft conclusions of the 1-year chronic toxicity study and alternative approaches to feeding studies. The overall conclusions and recommendations for using feeding studies (90-day and 1-year whole-food/feed studies) and alternative approaches in GMO risk assessment will be discussed as well. The results of the 90-day subchronic toxicity study with GM maize were already discussed in a stakeholder consultation in May 2014.

This workshop is funded by the European Commission 7th Framework Programme in the context of the large collaborative project GRACE (Grant Agreement No 311957).

Consultation Procedure and Anticipated Output

Feed-back can be provided in the workshop and/or in writing to GRACE-consultation@aau.at (Deadline for comments in writing: 19 October 2015). The feed-back received in the course of the stakeholder consultation will be summarised in a stakeholder report which will be published at the GRACE website.

Attendance

This consultation is open to all stakeholders interested in health risk assessment of GMOs. This includes but is not limited to GMO risk assessors, risk managers as well as representatives of all relevant sectors (industry, professional organisations, civil society organisations and academia). Participation is free of charge but registration is required to GRACE-consultations@aau.at by 4 Sept 2015 the latest. Early registration is encouraged, as places are limited. Travel information is provided in a separate document.

Contacts

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DAY ONE 7 OCTOBER 2015

12.00 **Registration**

13:00 WELCOME AND INTRODUCTION

13:00 **Welcome**

Patrick Rüdelsheim, Perseus, Ghent

Update on the GRACE project by the Coordinator

Joachim Schiemann, Institute for Biosafety in Plant Biotechnology, Julius Kühn Institut, Quedlinburg

Stakeholder Involvement, Transparency Requirements, and Accessibility of Data
Introduction to the Workshop

Armin Spök, IFZ-Inter-University Research Centre for Technology, Work and Culture, Graz

Ralf Wilhelm, Institute for Biosafety in Plant Biotechnology, Julius Kühn Institut, Quedlinburg

14.00 CHRONIC TOXICITY (1 YEAR) STUDY WITH GM MAIZE

CHAIR:

14.00 **General design and analysis**

Pablo Steinberg, University of Veterinary Medicine, Hannover

14.30 **Maize cultivation**

María Plá, Center for Research in Agricultural Genomics (CRAG), Barcelona

15.00 **Analysis of plant material and diets**

Gijs Kleter, RIKILT-Institute of Food Safety, Wageningen University and Research Centre, Wageningen

15.30 Coffee Break

16.00 **Test facility, periodic observations and necropsy**

Dagmar Zeljenková, Department of Toxicology, Slovak Medical University, Bratislava

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DAY ONE 7 OCTOBER 2015 (CONT.)

CHRONIC TOXICITY (1 YEAR) STUDY WITH GM MAIZE (CONT.)
CHAIR: N.N.

16.30 **Haematology and biochemistry**

Jana Tulinska, Department of Toxicology, Slovak Medical University, Bratislava

17.00 **Histopathology**

Pablo Steinberg, University of Veterinary Medicine, Hannover

17.30 **Session Discussion**

18:30 **Adjourn for Day 1**

DAY TWO 8 OCTOBER 2015

8.30 90-DAY LONGITUDINAL METABOLOMICS STUDY – RESULTS
CHAIR: N.N.

8:30 **Welcome back**

8:40 **General design, diets, conduct, and analysis**

Ralf Wilhelm, Institute for Biosafety in Plant Biotechnology, Julius Kühn Institut, Quedlinburg

9.05 **Results of the immunological studies**

Karine Adel-Patient, Unité INRA d'Immuno-Allergie Alimentaire, Gif-sur-Yvette

Jana Tulinska, Department of Toxicology, Slovak Medical University, Bratislava

9:45 **Session discussion**

10:30 Coffee break

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DAY TWO 8 OCTOBER 2015 (CONT.)

11:00 OMICS AND IN-VITRO STUDIES ON ANIMAL TISSUE AND CELLS
CHAIR: N.N.

11:00 **Omics studies on plant material**

Esther Kok, RIKILT-Institute of Food Safety, Wageningen University and Research Centre, Wageningen

11:30 ***In vitro* studies**

Ralf Einspanier, Freie Universität, Berlin

12:00 **Session Discussion**

13:00 Lunch Break

14:00 GENERAL DRAFT CONCLUSIONS AND DRAFT RECOMMENDATIONS
CHAIR: N.N.

14:00 **On toxicity studies in GMO risk assessment**

N.N.

14:30 **On alternative studies in GMO risk assessment**

N.N

15:00 **On the role of alternative studies vs. toxicity studies**

N.N

15:30 **Coffee Break**

15:30 GENERAL DISCUSSION
CHAIR: N.N.

15:30 **Breakout groups or World Cafe**

17:00 **Plenary Discussions**

18:00 **Closing Remarks**

ca. 18.15 End of Workshop

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