GRACE
GMO Risk Assessment and Communication of Evidence

STAKEHOLDER CONSULTATION ON ANIMAL FEEDING STUDIES AND IN-VITRO STUDIES IN GMO RISK ASSESSMENT

3 – 4 DECEMBER 2012
Diplomatic Academy, Favoritenstrasse 15a, Vienna

DRAFT AGENDA

Objective

In the course of the recently started European Commission funded research project GRACE (GMO Risk Assessment and Communication of Evidence) 90-day animal feeding trials, animal studies with an extended time frame as well as analytical, *in-vitro* and *in-silico* studies will be conducted on GM maize and GM potato in order to evaluate comparatively their use in GMO risk assessment. The overall aim of the consultation is to discuss planning-stage issues relevant to these studies. The focus will be on the draft plans for the design, conduct and analysis of the 90-day animal feeding trials. Possible options and constraints for animal studies with extended time frame and the choice and designs of the *in-vitro* approaches will also be discussed. The comments received will be considered for advancing or finalising the plans for these studies.

Scope

The consultation will focus on issues related to methodology, design and analysis. More general questions such as the value of these studies for GMO risk assessment or possible triggers to conduct such studies will be discussed in another stakeholder consultation on the results and draft interpretation of the studies conducted in the GRACE project.

Anticipated Output

A report capturing the inputs, the substantive discussion, and the comments/issues will be prepared in draft by the GRACE team and sent to all participants to ensure that they accurately and fairly reflect the outputs. Final proceedings will then be prepared based on comments received.

Context

One aim of GRACE is to evaluate different designs and two different types of animal feeding trials as well as analytical, *in-vitro* and *in-silico* methods in order to determine how suitable they are and what useful scientific information they provide for health risk assessments of GM food and feed. GRACE is thereby expected to inform EU policy making on GMO risk assessment requirements. A second aim of GRACE is to provide comprehensive reviews of the evidence available on health, environmental and socio-economic risks and benefits of GM plants. This aim will be pursued by using a systematic, transparent and inclusive approach based on the concept of systematic reviews. Transparency, external expert, and stakeholder review are key features of GRACE. For more information, please visit our website at www.grace-fp7.eu which will be online very soon.

Participation

This consultation is open to all stakeholders in GMO risk assessment as well as professional risk assessors, risk managers, and members of the academia. Attendance is free of charge but registration is required. Given the limited room capacity participants are kindly requested to express their interest to participate by 9 Nov 2012 the latest. Travel information will be circulated separately.

DAY ONE 3 DECEMBER 2012

12:00 **Registration**
Coffee, juices, sandwiches available

13:00: GETTING STARTED

13:00 **Welcome**
Armin Spök, IFZ-Inter-University Research Centre for Technology, Work and Culture, Graz, Austria

Introduction to GRACE by the Coordinator
Joachim Schiemann, Julius Kühn Institut, Quedlinburg, Germany

Stakeholder and User Involvement in GRACE

Introduction to the Workshop
Armin Spök

13:45 90-DAY FEEDING STUDIES – TEST MATERIAL

CHAIR: ARMIN SPÖK

13:45 **GM Maize**
Maria Pla, Centre de Recerca Agrigenòmica Consorci, Barcelona, Spain

14:15 **GM Potato**
Ralf Wilhelm, Julius Kühn Institut, Quedlinburg, Germany

14:45 **Analysis of Plant Material, Storage, and Diet Preparations**
Gijs Kleter, RIKILT-Institute of Food Safety, Wageningen University, The Netherlands

15:15 **Discussion**

15:45 **Coffee Break**

16:10: 90-DAY FEEDING STUDIES – DESIGN AND ANALYSIS
CHAIR: GREET SMETS

16:10 **Test and Histopathological Laboratories**
Dagmar Zeljenkova, Slovenska Zdravotnicka Univerzita v Bratislave, Bratislava, Slovak Republic

16:40 **Statistical Rationale**
Michael Festing, Consultant, UK

17:10 **Study Design**
Dagmar Zeljenkova

17:40 **Immunologic and Metabolomic Analysis on Animals**
Jean-Michel Wal, Institut National de la Recherche Agronomique, Paris, France

18:10 **Discussion**

19:00 **Adjourn for Day 1**

19:30 **Opportunity for Joint Dinner**

DAY TWO 4 DECEMBER 2012

8:30 **Getting Started**
Armin Spök

8:45 GENERAL CONSIDERATIONS ON TOXICITY STUDIES WITH GM CROPS
CHAIR: ARMIN SPÖK

8:45 **General Thoughts about Extended Toxicity Studies**
Mark Martens, MMTA, Belgium

9:15 **Constraints and Challenges of Extended Studies in GRACE**
Gijs Kleter
RIKILT-Institute of Food Safety, Wageningen University, The Netherlands

9:45 **Discussion**

10:15 **Coffee Break**

10:45 ANALYTICAL, IN-VITRO AND IN-SILICO STUDIES
CHAIR: SANDRA KARNER

10:45 **In-Vitro Studies**
Ralf Einspanier, Freie Universität, Berlin, Germany

11:15 **Omics Studies on Plant Material**
Esther Kok, RIKILT-Institute of Food Safety, Wageningen University, The Netherlands

11:45 **Discussion**

12:15 GENERAL DISCUSSION
CHAIR: ARMIN SPÖK

12:15 **General Discussion**

13:30 **Closure Remarks**

13:45 **End of Consultation**

Snacks and Refreshments

Contact GRACE Stakeholder Consultation

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Contact GRACE general issues

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