



## ASSESSING SHORT- AND LONG-TERM RAT FEEDING STUDIES WITH THE GENETICALLY MODIFIED MAIZE NK603

Stakeholder consultation on the results of the G-TwYST animal feeding studies  
and on general conclusions and recommendations

28-29 MARCH 2018

Hotel Seminarie Elzenveld  
Lange Gasthuisstraat 25, 2000 Antwerpen, Belgium.

### PRELIMINARY AGENDA

#### Context

G-TwYST (Genetically modified plants Two Year Safety Testing), an European Commission funded research project, conducted two 90-day feeding trials and a combined chronic toxicity/carcinogenicity feeding study with the GM maize NK603. The studies were to constitute a base on which to develop guidance on the conduct and analysis of such studies and to comparatively evaluate their value for GMO risk assessment. Planning-stage issues relevant to these feeding studies were discussed in a workshop in December 2014 and in a written consultation in January 2015. The comments received in the frame of these consultations were addressed when finalising the study plans. Comments and G-TwYST-team responses are available at [the G-TwYST website](#).

#### Objective

The aim of this workshop is to discuss the results of the 90-day study with an inclusion rate of up to 50% GM maize NK603 in the diets, the combined chronic toxicity/carcinogenicity study, and the overall draft conclusions.

The results of the 90-day subchronic toxicity study with diets containing 11% and 33% GM maize NK603 has undergone a written stakeholder consultation in February 2018 and is not within the scope of the workshop.

#### Registration

To prepare for the consultation, documentation will be provided in advance of the stakeholder meeting to registered parties. Registration is open until March 14, 2018. An [electronic registration form](#) is available at the G-TwYST website.

Written comments, also from interested parties not able to attend, are very welcome. Written comments should be submitted to [info@g-twyst.eu](mailto:info@g-twyst.eu) before 9 April 2018, 0:00 hrs.

#### NDA

Since the documentation will contain unpublished information that will be used for publication in a peer reviewed journal at a later stage, we also require all participants to sign a Non Disclosure Agreement (NDA). [The NDA can be downloaded from the G-TwYST website](#). Please fill in your name, affiliation, address and signature and send it to [info@g-twyst.eu](mailto:info@g-twyst.eu).

## Stakeholder consultation on the results of the G-TwYST animal feeding studies and on general conclusions and recommendations



GMP Two Year Safety Testing” (G-TwYST) is a Collaborative Project of the European Union’s Seventh Framework Programme for research, technological development and demonstration.

Grant agreement no 632165

Project duration: 21 April 2014 – 20 April 2018

Project website: [www.g-twyst.eu](http://www.g-twyst.eu)

# Stakeholder consultation on the results of the G-TwYST animal feeding studies and on general conclusions and recommendations

DAY ONE 28 March 2018

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12:00 Registration

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## SESSION I: WELCOME AND INTRODUCTION

13:00 Welcome and introduction to the workshop (objectives, time line, programme)  
Huib de Vriend, LIS Consult, Driebergen

13:15 Stakeholder involvement and transparency, accessibility of data  
Armin Spök, Alpen-Adria-Universität Klagenfurt and Graz University of Technology  
Ralf Wilhelm, Julius Kühn Institut, Quedlinburg

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## SESSION II: GENERAL DESIGN, FEED PRODUCTION AND ANALYSIS

CHAIR: HUIB DE VRIEND

13:45 General design and analysis  
Pablo Steinberg, University of Veterinary Medicine, Hannover

14:00 Feed production  
Ralf Wilhelm, Julius Kühn Institut, Quedlinburg

14:15 Analysis of plant material and diets  
Gijs Kleter, Wageningen University and Research Centre  
Ralf Wilhelm, Julius Kühn Institut, Quedlinburg

14:35 Statistical analyses  
Hilko Van Der Voet, Biometris Wageningen University & Research

14:55 Test facility, periodic observations and necropsy  
Dagmar Zeljenková, Slovak Medical University, Bratislava

15:15 COFFEE BREAK

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## SESSION III: SUBCHRONIC TOXICITY (90-DAYS) STUDY WITH 50% GM MAIZE NK603

CHAIR: RALF WILHELM

15:45 Summary of the 90-day feeding study with 11% and 33% GM maize NK603  
Pablo Steinberg, University of Veterinary Medicine, Hannover

16:05 Haematology, clinical chemistry and immunology  
Jana Tulinska, Slovak Medical University, Bratislava

16:35 Histopathology  
Pablo Steinberg, University of Veterinary Medicine, Hannover

17:05 GMO 90+ results  
Bernard Salles, Toxalim, Toulouse

17:35 Session Discussion

ca.18:30 Adjourn for Day 1

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DAY TWO 29 March 2018

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08:30 Welcome back

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## **SESSION IV: COMBINED CHRONIC TOXICITY/CARCINOGENICITY STUDY WITH GM MAIZE NK603**

**CHAIR: HILKO VAN DER VOET**

08:40 Haematology and clinical chemistry  
Jana Tulinska, Slovak Medical University, Bratislava

09:10 Histopathology  
Pablo Steinberg, University of Veterinary Medicine, Hannover

09:40 Session discussion

10:45 COFFEE BREAK

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## **SESSION V: QUALITY ASPECTS AND CONTROVERSIES AROUND FACTS AND VALUES**

**CHAIR: PABLO STEINBERG**

11:15 Guidance on the quality aspects of animal feeding studies  
To be confirmed

11:35 Controversies around facts and values in animal feeding studies  
Monica Racovita, Alpen-Adria-Universität Klagenfurt - Vienna – Graz

12:00 Session discussion

13:00 LUNCH BREAK

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## **SESSION VI. GENERAL DRAFT CONCLUSIONS AND DRAFT RECOMMENDATIONS**

**CHAIR: ARMIN SPÖK & HUIB DE VRIEND**

- 14:00 Discussion at two tables
- Table A: Risk assessment
    - Design, conduct, and methods for analysis of whole-food animal feeding trials
    - Interpretation of results and scientific value
  - Table B: Risk governance, lessons to be learned from previous cases of scientific controversies

15:30 COFFEE BREAK

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- 16:00 Plenary reporting of discussion tables
- Design, conduct, and methods for analysis of whole-food animal feeding trials
  - Interpretation of results and scientific value
  - Lessons to be learned from previous cases of scientific controversies

17:00 Closing remarks

ca. 17:15 End of Workshop