



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.

AGENDA

Context

G-TwYST (Genetically modified plants Two Year Safety Testing), a 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.

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

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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

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DAY ONE 28 March 2018

12:00 Registration

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

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

SESSION III: SUBCHRONIC TOXICITY (90-DAY) STUDIES WITH GM MAIZE NK603

CHAIR: RALF WILHELM

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

16:05 90-day feeding feeding studies with GM maize NK603: Haematology and immunology
Jana Tulinska, Slovak Medical University, Bratislava

16:35 90-day feeding feeding study with 50% GM maize NK603: Summary including body weight, feed consumption, relative organ weight, clinical chemistry and histopathology data
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

08:30 Welcome back

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

CHAIR: HILKO VAN DER VOET

08:40 Haematology
Jana Tulinska, Slovak Medical University, Bratislava

09:05 Summary including body weight, feed consumption, clinical chemistry and histopathology data
Pablo Steinberg, University of Veterinary Medicine, Hannover

09:50 Session discussion

10:55 COFFEE BREAK

SESSION V: QUALITY ASPECTS AND CONTROVERSIES AROUND FACTS AND VALUES

CHAIR: PABLO STEINBERG

11:20 Guidance on the quality aspects of animal feeding studies
Dieter Schrenk, Technische Universität Kaiserslautern

11:40 Controversies around facts and values in animal feeding studies
Monica Racovita, Alpen-Adria-Universität Klagenfurt - Vienna – Graz

12:05 Session discussion

13:00 LUNCH BREAK

SESSION VI. GENERAL DRAFT CONCLUSIONS AND DRAFT RECOMMENDATIONS

CHAIR: ARMIN SPÖK & HUIB DE VRIEND

- 14:00 Discussion at two parallel tables
- Table A: Lessons on guidance for conducting animal feeding studies
 - 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

- 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