

G-TWYST

GM PLANTS TWO YEAR SAFETY TESTING

# Introduction to G-TwYST



## Basic information regarding the call

- Call **KBBE-2013-FEEDTRIALS**: *Two-year carcinogenicity rat feeding study with maize NK603*
- Type of funding scheme: *Collaborative Project* (small or medium-scale focused research project)
- Budget: 2,999,890 €
- Duration: 4 years, starting date: 21<sup>st</sup> April 2014

# Issues related to two-year feeding trials that need to be addressed in a stepwise approach:

1. Execution of at least one rat feeding trial(s) with GM maize NK 603 (and additional GMOs where scientifically justified) applying the EFSA protocol. Participating institutions should strictly comply with all applicable international standards and norms concerning feeding trials in close collaboration with EFSA.

Issues related to two-year feeding trials that need to be addressed in a stepwise approach:

2. Analysing, reporting and providing recommendations, in particular as to the scientific justification and added value of such long-term feeding trials with regard to GMO risk assessment.

<b>Participant no.</b>	<b>Participant organisation name</b>		<b>Country</b>
<b>1 (Coordinator)</b>	<b>Tiermedizinische Hochschule Hannover (TiHo)</b>	<b>Uni</b>	<b>Germany</b>
<b>2</b>	<b>Centre de Recerca Agrigenòmica Consorci CSIC-IRTA-UAB (CRAG)</b>	<b>Res</b>	<b>Spain</b>
<b>3</b>	<b>Stichting Dienst Landbouwkundig Onderzoek (DLO)</b>	<b>Uni</b>	<b>The Netherlands</b>
<b>4</b>	<b>Julius Kühn-Institut (JKI)</b>	<b>Gov</b>	<b>Germany</b>
<b>5</b>	<b>LIS Consult (LIS)</b>	<b>SME</b>	<b>The Netherlands</b>
<b>6</b>	<b>Roger Alison Ltd. (RA)</b>	<b>SME</b>	<b>United Kingdom</b>
<b>7</b>	<b>Slovenska Zdravotnicka Univerzita v Bratislave (SZU)</b>	<b>Uni</b>	<b>Slovakia</b>
<b>8</b>	<b>Universitaet Klagenfurt (UNI-KLU)</b>	<b>Uni</b>	<b>Austria</b>

## Objectives of the G-TwYST project (I)

- to elaborate a scientifically sound approach to evaluate the potential toxicity of genetically modified plants in whole feed based on the results of extended feeding studies with the GM maize NK603 and MON810 performed according to current OECD Test Guidelines and EFSA recommendations
- to define criteria to evaluate the scientific quality of long-term feeding studies

## Objectives of the G-TwYST project (III)

- to define when long-term animal feeding trials are scientifically justified and which is their added value in the frame of the GMO risk assessment process
- to analyse the role/influence of broader societal issues including ethical aspects (normative dimensions) in/on the ongoing debate associated with animal feeding studies in GM food/feed risk assessment

## Objectives of the G-TwYST project (III)

- to make accessible the detailed scientific information including raw data via the project website, the open access database, open access journal papers and stakeholder consultations
- to communicate the results of the project and their significance for the GMO risk assessment process to risk assessors, risk managers, a broad range of stakeholders and the general public



## 90-day feeding trial with GM maize NK603 (original planning)

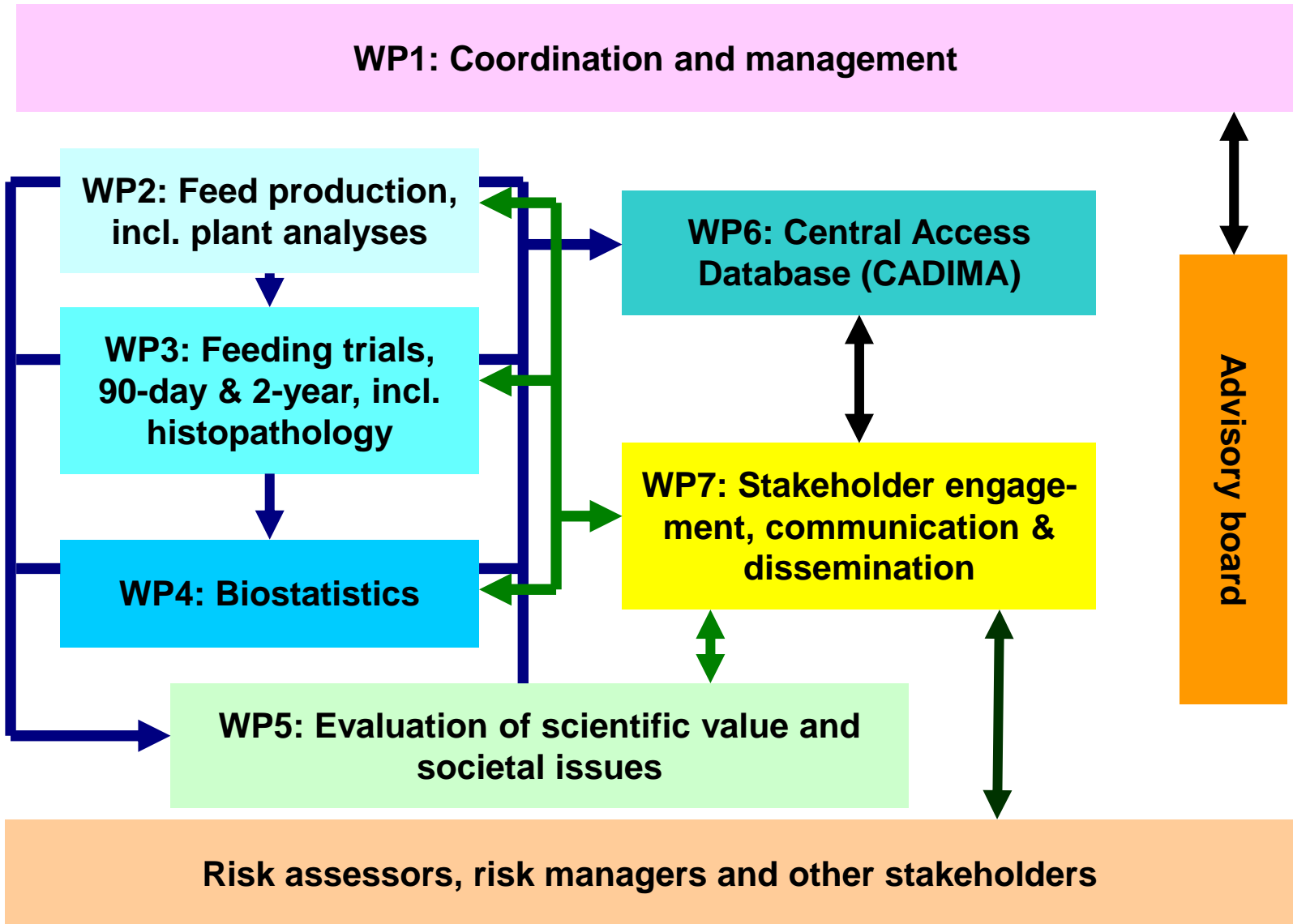
Group	Content in the diet (%)			No. of animals	
	Isogenic non-GM	NK603	NK603 + Roundup	Males	Females
1	33	0	0	16	16
2	22	11	0	16	16
3	0	33	0	16	16
4	22	0	11	16	16
5	0	0	33	16	16
Sentinels				6	6
Total				86	86

## Combined chronic toxicity/carcinogenicity feeding trial with GM maize NK603 (original planning)

Group	Content in the diet (%)			No. of animals			
				Chronic toxicity		Carcinogenicity	
	Isogenic non-GM	NK603	NK603 + Roundup	Males	Females	Males	Females
1	33	0	0	20	20	50	50
2	22	11	0	20	20	50	50
3	0	33	0	20	20	50	50
4	22	0	11	20	20	50	50
5	0	0	33	20	20	50	50
Sentinels						10	10
<b>Total</b>				<b>100</b>	<b>100</b>	<b>260</b>	<b>260</b>

## 2-Year carcinogenicity feeding trial with GM maize MON810 (original planning)

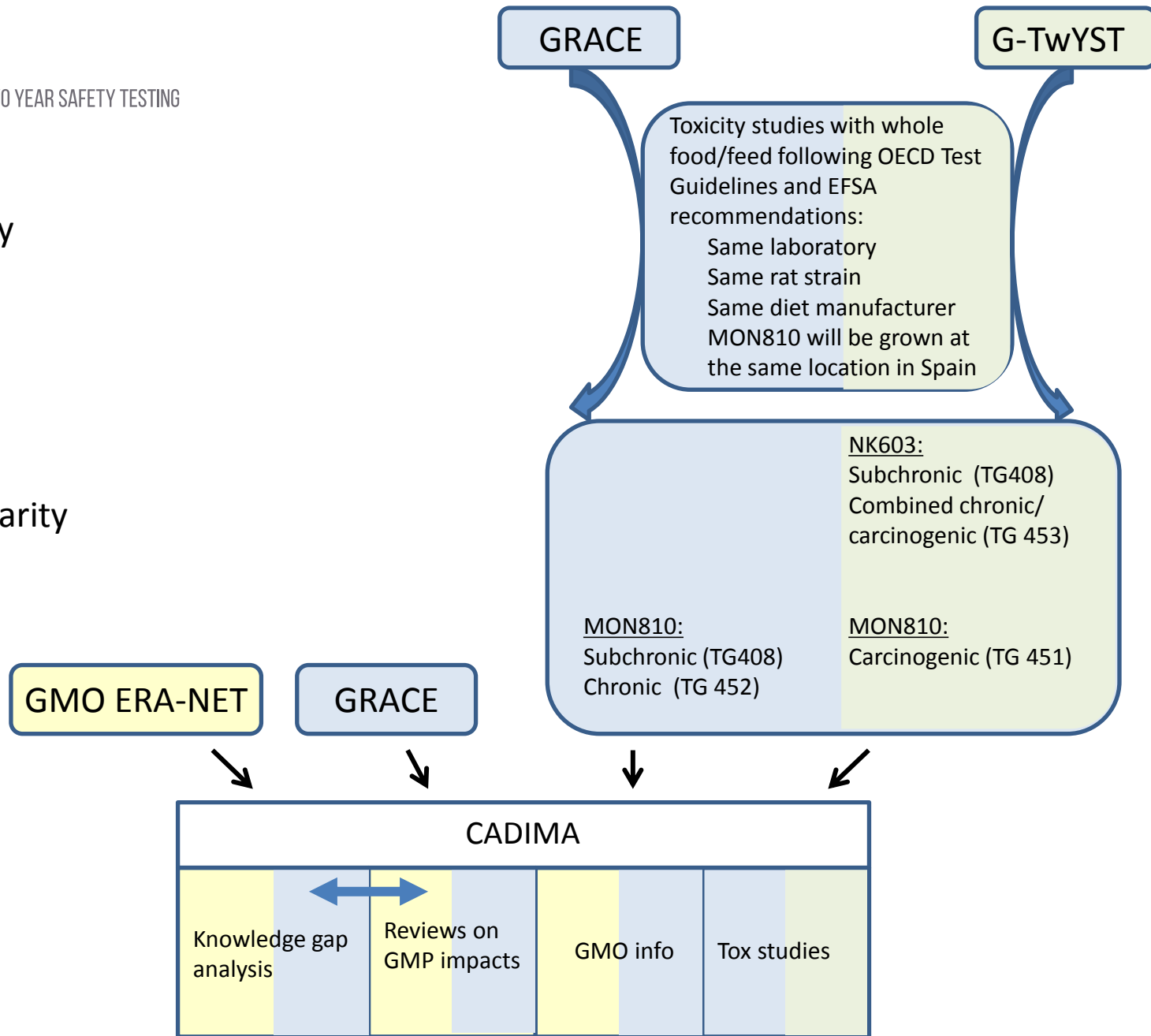
Group	Content in the diet (%)		No. of animals	
	Isogenic non-GM	MON810	Males	Females
1	33	0	50	50
2	0	33	50	50
Sentinels			6	6
<b>Total</b>			<b>106</b>	<b>106</b>



Comparability

Complementarity

Synergy



# Budget distribution per work package in the G-TwYST project

