



G-TWYST

GM PLANTS TWO YEAR SAFETY TESTING

# Animal feeding studies - Study design -



## Study design (I)

- Male and female Wistar Rcc Han rats will be purchased from Harlan and will only be a few days apart in age.
- Rats will be acclimatised to the animal housing conditions 4-6 days prior to the start of the feeding trials.
- A detailed examination of all animals will be carried out on study day 1, prior to the start of the treatment.

## Study design (II)

- The design of the feeding trials is a randomised complete block design.
- The route of administration will be the oral route.
- Sentinels will be fed the standard rat diet Teklad Global Diet<sup>®</sup>.
- The different diets will be coded and labelled by the supply company; feed containers and scoops will be colour-coded.

## Study design (III)

- Animal house staff will be “blind” with respect to the identity of the diets.
- The dose groups will be unblinded for the histopathological evaluation of the tissues after necropsy and the weighing of organs.

## 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>

## 90-day feeding trial with GM maize NK603 (alternative proposal)

Group	Content in the diet (%)			No. of animals	
	Isogenic non-GM	NK603	NK603 + Roundup	Males	Females
1	50	0	0	16	16
2	39	11	0	16	16
3	17	33	0	16	16
4	0	50	0	16	16
5	39	0	11	16	16
6	17	0	33	16	16
7	0	0	50	16	16
<b>Sentinels</b>				<b>6</b>	<b>6</b>
<b>Total</b>				<b>118</b>	<b>118</b>



## Combined chronic toxicity/carcinogenicity feeding trial with GM maize NK603 (alternative proposal)

Group	Content in the diet			No. of animals			
	Isogenic non-GM	NK603	NK603 + Roundup	Chronic toxicity		Carcinogenicity	
1	50	0	0	10	10	50	50
2	39	11	0	10	10	50	50
3	17	33	0	10	10	50	50
4	0	50	0	10	10	50	50
5	39	0	11	10	10	50	50
6	17	0	33	10	10	50	50
7	0	0	50	10	10	50	50
Sentinels						10	10
<b>Total</b>				<b>70</b>	<b>70</b>	<b>360</b>	<b>360</b>