# FORMAT FOR THE PRESENTATION OF THE RESULT OF DELIBERATE RELEASE INTO THE ENVIRONMENT OF GENETICALLY MODIFIED HIGHER PLANTS IN ACCORDANCE WITH ARTICLE 10 OF DIRECTIVE 2001/18/EC

#### 1. GENERAL INFORMATION

1.1 European notification number

B/ES/06/36

1.2 Member State of notification

Spain

1.3 Date of consent and consent number

18/04/2006

#### 2. REPORT STATUS

2.1 Please indicate whether, according to Article 3 of the present Decision, the

Post-release monitoring report

#### 3. CHARACTERISTICS OF THE RELEASE

3.1 Scientific name of the recipient organism

Zea mayz

 $3.2\ Transformation\ event(s)\ (acronym(s)\ or\ vectors1\ used\ (if\ transformation\ event\ identity\ not\ available)$ 

1507x59122xNK603 maize, result of crossing the following events: 1507 with 59122 and NK603

3.3 Unique identifier, if available

DAS-1507-1xDAS-59122-7 xMON-0603-6

3.4 Please provide the following information as well as the field(s) layout: In the case of small-scale field trials where several lines may be tested, the vectors used should be mentioned, which gives insight into the introduced traits and/or genetic

elements. In the case of large-scale trials, the number of events notified is limited to only one or a few events

Location	Area (m <sup>2</sup> )	Identity and Approx. Number of GMOs	<b>Duration of trials</b>
Calatorao (Zaragoza) Provincia:50 (Zaragoza) Municipio:068(Calatorao) Polígono 04; Parcela 076	5000 m <sup>2</sup>	TC1507xNK603xDAS-59122- 7:1088 seeds. NK603: 1088 seeds	Sowing: 16/Jun/06 Destruction: 30/Nov/06
Cogullada.(Zaragoza) Provincia:50 (Zaragoza) Municipio:900(Calatorao) Polígono 06; Parcela 059	5000 m <sup>2</sup>	TC1507xNK603xDAS-59122- 7:1088 seeds. NK603: 1088 seeds	Sowing: 04/Jul/06 Destruction: 19/12/06
Gurrea de Gallego (Huesca) Provincia:22 (Huesca) Municipio:167(Gurrea de Gallego) Polígono 03; Parcela 142	2500 m <sup>2</sup>	TC1507xNK603xDAS-59122- 7:1088 seeds. NK603: 1088 seeds	Sowing: 20/Jun/06 Destruction: 18/12/06
Gurrea de Gallego (Huesca) Provincia:22 (Huesca) Municipio:167(Gurrea de Gallego) Polígono 03; Parcela 155	1800 m <sup>2</sup>	TC1507xNK603xDAS-59122- 7:1088 seeds. NK603: 1088 seeds.	Sowing: 20/Jun/06 Destruction: 18/12/06

Trial design

# 4. ANY KIND OF PRODUCT THAT THE NOTIFIER INTENDS TO NOTIFY AT A LATER STAGE

m. 8 m	2 m.	8 m	2 m.	8 m	2 m.	8 m	2 m.
			<del></del>				<del></del>
Trt1		Trt1		Trt1		Trt1	
Trt1		Trt1		Trt1		Trt1	
Trt1		Trt1		Trt1		Trt1	
Trt1		Trt1		Trt1		Trt1	
Trt2		Trt2		Trt2		Trt2	
Trt2	i i	Trt2	<b>1</b>	Trt2	] [	Trt2	
Trt2	_	Trt2	]	Trt2	]	Trt2	
Trt2	_	Trt2		Trt2		Trt2	
Trt3		Trt3		Trt3		Trt3	
Trt3		Trt3		Trt3		Trt3	
Trt3		Trt3		Trt3		Trt3	
Trt3		Trt3		Trt3		Trt3	
Trt4		Trt4		Trt4		Trt4	
Trt4		Trt4		Trt4		Trt4	
Trt4		Trt4		Trt4		Trt4	
Trt4		Trt4		Trt4		Trt4	
Trt5		Trt5		Trt5		Trt5	
Trt5		Trt5		Trt5		Trt5	
Trt5		Trt5		Trt5		Trt5	
Trt5		Trt5		Trt5		Trt5	
Trt6		Trt6		Trt6		Trt6	
Trt6	_	Trt6	<b>↓</b>	Trt6	<b>.</b>	Trt6	
Trt6	_	Trt6		Trt6	_	Trt6	
Trt6		Trt6		Trt6	_	Trt6	
Trt7	_	Trt7		Trt7		Trt7	
Trt7		Trt7		Trt7		Trt7	
Trt7	_	Trt7		Trt7		Trt7	
 Trt7		Trt7		Trt7		Trt7	
					-		

4.1 Does the notifier intend to notify the released transformation event(s) as product(s) for placing on the market under Community legislation(s) at a later stage?

Yes

If yes, indicate the country (ies) of notification

Not defined as yet

## **5. TYPE(S) OF DELIBERATE RELEASE(S)**

5.1 Deliberate release(s) for research purposes

The trials were performed with research purposes

5.2 Deliberate release(s) for development purposes

Not applicable

5.3 Official testing

Not applicable

5.4 Herbicide authorization

Not applicable

5.5 Deliberate release(s) for demonstration purposes

Not applicable

- 5.6 Seeds multiplication
- 5.7 Deliberate release(s) for biosafety/risk assessment research Vertical gene transfer studies

Not applicable, though during the trials, general observations were taken on potential impact on the environment.

5.8 Other(s) type(s) of deliberate release(s)

Not applicable

# 6. METHOD(S), RESULT(S) OF THE RELEASE, MANAGEMENT AND MONITORING MEASURE(S) IN RESPECT OF ANY RISK TO HUMAN HEALTH OR THE ENVIRONMENT

# **6.1 Risk management measure(s)**

#### *6.1.1 Before the sowing/planting:*

Seeds were packed and clearly labelled to avoid confusion and possible mixture with conventional seed

Seed were stored and transported to the field on the same day when the trials will take place, in the original package. Before the planting, no processing of the seeds takes place

# 6.1.2 During the sowing/planting activities

The local authorities were informed that the trials were going to go ahead. Isolation distances of at least 200 m away from any commercial maize were respected

Seeds were planted with a standard sowing machine which allows an easy cleaning of the remaining seeds. At the end of the individual plot sowing, the remaining seeds in the machine (if any) were buried at the end of the plot

Personnel involved with the trials have been trained to prevent involuntary release/spillage

#### 6.1.3 During the period of release

Monitoring has taken place during the growing season; during the visits, in addition to the observations planned in the study, general observations have taken place to look for any unanticipated adverse effect such as weed tendencies, susceptibility to insect pests and diseases

The material used during the monitoring was cleaned before leaving the trial plots

#### 6.1.4 At the end of the release

The authorities were informed when the destruction of the trials will take place

All transgenic material was clearly identifiable and none of the seeds or plant parts was moved outside the trial site

Waste from harvest along with plants which were not used in the study were chopped and ploughed in the plot

All the machinery used in the trial was cleaned on the release site before leaving the plot

#### 6.1.5 Post-harvest measures

The release site will be visited several times, in particular when the weather conditions will favour germination

Avoid growing maize on this site on the following year

If needed, any undesired plant emerged would be mechanically destroyed or by using herbicides (other than glufosinate ammonium)

6.1.6 Other(s) measure(s) (describe)

Not applicable

6.1.7 Emergency plan(s)

All biosafety measures aimed at preventing escapes into the environment will be implemented. However, in the unlikely eventuality of an escape, an ELISA screening will be performed and all positive plants will be destroyed. The competent authorities will be immediately informed of any incident affecting the trials

Indicate:

(a) of the release proceeded s planned

Yes

No (describe for which reason)

(b) if measures according to the emergency plan(s) (Article 6(2)(a)(vi) and Annex III.B of Directive 2001/18/EC) had to be taken:

No

#### **6.2 Post-release monitoring measures**

Monitoring results confirm that 1507x59122xNK603 maize plants do no present a risk for the human, animal health and the environment

Specify

Monitoring measures within site

The trial sites will be visited in the following growing season to control the growth of volunteer plants

Monitoring measures of adjacent areas

Not applicable

# 6.3 Plan for observation(s)/methods(s) involved

General observations on plant health, susceptibility to diseases, on development of the plants will be carried out along with any other unusual and unanticipated characteristics

#### **6.4 Observed effect(s)**

1507x59122xNK603 maize plants didn't show any risk to human, animal health and the environment when compared with conventional maize. One of the sites has been cancelled/destroyed because of poor germination due to lack of water

6.4.1. All results of the deliberate release(s) in respect of any risk for human health or the environment shall be stated, without prejudice to whether the results indicate that any risk is increased, reduced or remains unchanged

6.4.2 Expected effect(s)

1507x59122xNK603 maize plants have developed normally, in a comparable way with the non GM near isogenic line differing only in the resistance against lepidopteran and coleopteran pest insects, were there is high infestation pressure

*6.4.3 Unexpected effect(s)* 

No unexpected effects posing risks to the environment were identified

6.4.4 Other information

Not relevant

# 7. CONCLUSION

The trials have been carried out in the predicted manner. No negative effects to human health or the environment have been observed. 1507x59122xNK603 maize plants have grown as expected