

**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/11/05

**1.2 Member State of notification**

Spain.

**1.3 Date of consent and consent number**

Region of Andalucía: Resolution of 4<sup>th</sup> April, 2011 by the Andalusian Committee on Genetically Modified Organisms.

Region of Aragón: Resolution of 11<sup>th</sup> March, 2011 by the Regional Interdepartmental Commission on Genetically Modified Organisms.

Region of Castilla y León: Order of 23<sup>rd</sup> March, 2011 by the Regional Council of Environment.

**2. REPORT STATUS**

**2.1 Please indicate whether, according to Article 3 of the present decision, the current report is:**

FINAL report.

**3. CHARACTERISTICS OF THE RELEASE**

**3.1 Scientific name of the recipient organism**

*Zea mays*

**3.2 Transformation event(s) [acronym(s)] or vector(s) used (if transformation event identity is not available)**

NK603

**3.3 Unique identifier, if available**

MON-ØØ6Ø3-6

### **3.4 Please, provide the following information, as well as the field(s) layout**

<b>Geographical location (s)</b> (administrative region and, where appropriate, grid reference)	<b>Size of the release site(s)</b> (m <sup>2</sup> )	<b>Identity and approximate number of GM higher plants per event actually released</b> (number of seeds/plants per m <sup>2</sup> )	<b>Duration of the release</b>
<b>Fuente Palmera (Córdoba)</b>	<b>1.008 m<sup>2</sup></b>	<b>NK603 hybrids</b> <b>7-9 plants/m<sup>2</sup></b>	<b>Sowing: 10/05/2011</b> <b>Destruction: 22/09/2011</b>
<b>Grañén (Huesca)</b>	<b>86,4 m<sup>2</sup></b>	<b>NK603 hybrids</b> <b>8 plants/m<sup>2</sup></b>	<b>Sowing: 28/04/2011</b> <b>Destruction: 02/08/2011</b>
<b>Coreses (Zamora)</b>	<b>1.293 m<sup>2</sup></b>	<b>NK603 hybrids</b> <b>7-9 plants/m<sup>2</sup></b>	<b>Sowing: 10/05/2011</b> <b>Destruction: 27/10/2011</b>

Notes: trials initially foreseen in El Cuervo (Sevilla), Zuera (Zaragoza), Tauste (Zaragoza), Ejea de los Caballeros (Zaragoza), Corbillos de los Oteros (León), Valdevimbre (León), Arabayona de Mógica (Salamanca), Pelabravo (Salamanca), Cotanes (Zamora) and Molacillos (Zamora) were not planted because they did not meet the necessary isolation from fields of conventional maize, or any other guarantees for the successful execution of trials. The submission in the Region of Castilla-La Mancha did not receive a response from the Competent Authority.

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

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

NK603 maize was approved for import, feed use and processing in the EU under Directive 2001/18/EC (Commission Decision 2004/643/EC). The food and food ingredients derived from NK603 were approved under Regulation (EC) No. 258/97 (Commission Decision 2005/448/EC). The application for cultivation of NK603 maize was submitted according to Dir 2001/18/CE (C/ES/03/01) and later under Regulation (EC) No. 1829/2003 (EFSA-GMO-NL-2005-22), and EFSA adopted a favourable scientific opinion on 29 May 2009.

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

### **5.1 Deliberate release(s) for research purposes**

Not applicable.

### **5.2 Deliberate release(s) for development purposes**

Development and optimization of weed management programs. Trials have been communicated to the correspondent plant protection authorities and were carried out by Monsanto's technical staff, who are officially accredited by EOR 7/96.

### **5.3 Official testing**

Not applicable.

### **5.4 Herbicide authorisation**

Not applicable.

**5.5 Deliberate release(s) for demonstration purposes**

Demonstrative trials for large-scale evaluation of varieties and weed management programs.

**5.6 Seeds multiplication**

Not applicable.

**5.7 Deliberate release(s) for biosafety/risk assessment research**

Not applicable.

**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:**

- A minimum isolation of 200 m from other commercial maize fields was confirmed.
- Seeds of NK603 hybrids were packed in sealed bags and clearly labelled by qualified staff in our installations located in our research centre in Peyrehorade (France), authorized to carry out confined operations with genetically modified (GM) organisms (N° 4593, April 6<sup>th</sup> 2006, Commission de Genie Genetique, France).
- Seed transport to the field was made the same day of the sowing, in the pre-prepared bags, labelled and closed in the laboratory, and classified according to the trial layout. In those trials where it was necessary to sow different varieties, in order to avoid confusions or seed mixing, the bags were opened sequentially.

**6.1.2 During the sowing/planting activities**

- Seeds were transported in closed bags and their manipulation was made by qualified staff, warned about preventive measures to avoid any dissemination.
- Sowing was made with clean sowing machinery, avoiding spills onto the soil.
- To avoid involuntary dispersion, once the sowing was finalized the remaining seeds were buried within the trial site.
- Before removing the machinery out of the field, it was checked that all the sowing cones had been cleaned.
- Competent Authorities were informed of the sowing dates in advance, and the plantings were conducted under supervision of officials.
- A minimum of four lines of conventional maize were planted surrounding the trials in the sites of Andalucía and Aragon, and a minimum of eight lines in the site of Castilla y León, as pollen barrier.

### **6.1.3 During the period of release**

- Trials have been monitored during the growing season, including visits by some experts and competent authorities. During the visits, besides the observations described in the studies, it has not been observed that the crop tends to turn into weed, or with higher susceptibility to pests and diseases than the conventional maize.
- During the performed visits there was no observation of a different effect than the conventional corn on crop development, bees or other insects presence, birds or mammals occurrence. Therefore, it is suggested that the effect of the release on “non target” organisms”, on arthropofauna, or on the biodiversity in general has been similar to those caused by conventional corn.
- Pollen shed dates were notified in advance to the competent authorities.
- No incidences have been observed related to safety for human health and environment.

### **6.1.4 At the end of the release**

- Authorities have been informed in advance on the harvesting dates, which have been conducted under their supervision.
- In Grañén site, once the efficacy data from the different tested programs were collected the maize plants were destroyed. This activity facilitated the plant destruction and avoided seeds production. The destruction was performed by chopping the maize plants and subsequent tillage by rotovator equipment, which buried the plant residues
- In other sites, trials were harvested with a combine-harvester of cereals. The harvested grain was buried in an approximately 1,5-2,5 meter-deep pitch and covered by a soil layer of at least 0,5 m-depth.
- The grains were transported to the pitches in the combine itself. If the ditch was far from the original site, the grains were transported in a trailer, being very careful to avoid any spillage and under supervision of Monsanto’s technical staff.
- The trials crop residues were destroyed by tillage, chopped with an offset disc harrow and then, buried or ploughed up with moldboard.
- The combine and means of transport were cleaned before leaving the field.

### **6.1.5 Post harvest measures**

The release site will be monitored during the year following the trials, and up to the maize flowering period, in order to destroy any eventual maize volunteers. The commercial crop planted in this field during the following season will be different from maize. This destruction and the restrictions for cultivation next year will no longer be necessary when the NK603 event is authorized for cultivation in the European Union.

### **6.1.6 Other(s) measure(s) (Describe)**

Not applicable.

### **6.1.7 Emergency plan(s)**

All the biosafety measures planned to avoid accidental releases have been followed.

Please indicate:

**a) if the release proceeded as planned**

The release proceeded as planned.

**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]**

They were not necessary.

**6.2 Post-release monitoring measures**

The monitoring results confirmed that NK603 maize plants are as safe as any conventional variety for human and animal health, or the environment.

*According to the cases mentioned, please indicate the monitoring measures adopted*

**Please specify:**

**Monitoring measures within site**

Trial plots will be visited during the following growing season to destroy the volunteer maize plants, if any.

**Monitoring measures of adjacent areas**

Surrounding areas to the trials will be visited during the following growing season to destroy the germinated volunteer plants, if any.

**6.3 Plan for observation(s)/method(s) involved**

General observations on plant health, disease sensitivity and plant development; furthermore, unexpected and unusual characteristic has been recorded.

**6.4 Observed effect(s)**

Unexpected effects were not observed

**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.**

NK603 maize plants presented no risks to human or animal health, or the environment, different from those of conventional maize.

**6.4.2 Expected effect(s)**

NK603 maize plants developed normally and presented crop cycle and performance similar to their isogenic conventional counterparts.

In these trials, the tolerance to glyphosate herbicide of NK603 maize plants has been confirmed.

**6.4.3 Unexpected effect(s)**

Unexpected effects were not observed

#### **6.4.4 Other information**

Not applicable

### **7. CONCLUSION**

The deliberate release was carried out according to the notification proposal and in agreement with the conditions of consent in the Resolution of 4th April, 2011 by the Andalusian Committee on Genetically Modified Organisms, Resolution of 11<sup>th</sup> March, 2011 by the Aragón Interdepartmental Commission on Genetically Modified Organisms and Order of 23rd March, 2010 by the Castilla y León Council of Environment, guaranteeing safety to human and animal health and the environment.

All the measures were taken to avoid the pollen and grain spread of the genetically modified plants outside the trial field.

Trials have been executed as predicted. Behaviour of NK603 maize has been similar to conventional maize and no negative effect on the human or animal health, or on the environment has been detected during the trials execution. It is particularly important that a postemergence weed control in NK603 maize offers an alternative more compatible for the biodiversity, using herbicide formulations classified without risk pictograms and with low environmental impact.