

**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/09/04

***1.2 Member State of notification***

Spain.

***1.3 Date of consent and consent number***

Region of Aragón: Resolution of March 13<sup>th</sup>, 2009 by the Regional Interdepartmental Commission on Genetically Modified Organisms.

Region of Castilla-La Mancha: Resolution of March 25<sup>th</sup>, 2009, by the Regional Biosafety Commission.

Region of Castilla y León: Order of April 21<sup>st</sup>, 2009 by the Regional Council of Environment.

Region of Cataluña: Resolution of March 6<sup>th</sup>, 2009 by the Regional Directorate-General of Agriculture and Farming.

Region of Navarra: Resolution 1240/2009, of June 1<sup>st</sup>, 2009, by the Regional Directorate-General of Environment & Water.

***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>Grañén (Huesca)</b>	<b>720 m<sup>2</sup></b>	<b>NK603 hybrids</b> <b>7-9 plants/m<sup>2</sup></b>	<b>Sowing: 05/27/2009</b> <b>Destruction: 11/3/2009</b>
<b>Calera y Chozas (Toledo)</b>	<b>3.016 m<sup>2</sup></b>	<b>NK603 hybrids</b> <b>7-9 plants/m<sup>2</sup></b>	<b>Sowing: 5/4/09</b> <b>Destruction: 10/28/09</b>
<b>Daimiel (Ciudad Real)</b>	<b>4.440 m<sup>2</sup></b>	<b>NK603 hybrids</b> <b>7-9 plants/m<sup>2</sup></b>	<b>Sowing: 4/30/09</b> <b>Destruction: 10/29/09</b>
<b>Dueñas (Palencia)</b>	<b>3.948 m<sup>2</sup></b>	<b>NK603 hybrids</b> <b>7-9 plants/m<sup>2</sup></b>	<b>Sowing: 05/13/2009</b> <b>Destruction: 11/03/2009</b>
<b>Molacillos (Zamora)</b>	<b>4.770 m<sup>2</sup></b>	<b>NK603 hybrids</b> <b>7-9 plants/m<sup>2</sup></b>	<b>Sowing: 05/12/2009</b> <b>Destruction: 10/20/2009</b>
<b>Alcarrás (Lleida)</b>	<b>5.625 m<sup>2</sup></b>	<b>NK603 hybrids</b> <b>7-9 plants/m<sup>2</sup></b>	<b>Sowing: 05/21/2009</b> <b>Destruction: 11/4/2009</b>
<b>Milagro (Navarra)</b>	<b>1.568 m<sup>2</sup></b>	<b>NK603 inbred lines</b> <b>5 plants/m<sup>2</sup></b>	<b>Sowing: 05/19/09</b> <b>Destruction: 11/13/09</b>

Notes: According with the communication of 07/28/2009, trials initially foreseen in Bujaraloz (Zaragoza), Ejea de los Caballeros (Zaragoza), Zuera (Zaragoza), Yunquera de Henares (Guadalajara), La Puebla de Montalbán (Toledo), Santovenia de Pisuerga (Valladolid), Peñarandilla (Salamanca), Albesa (Lleida) and Gimenezells (Lleida), were not carried out because they did not meet the necessary isolation from fields of conventional maize, or any other conditions for the successful execution of trails.

**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 by the European Commission (Commission Decision 2005/448/EC). The application for cultivation of NK603 maize was submitted 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**

Evaluation of agronomic performance of the genetically modified inbred lines and comparison with the conventional parental lines (not genetically modified), from which they derive.

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

Evaluation of agronomic performance of genetically modified maize (including yield, germination capacity, plant vigour and plant height) and its comparative development with lines not genetically modified.

Development and optimization of weeds management programs.

### **5.3 Official testing**

Not applicable.

### **5.4 Herbicide authorisation**

Efficacy and selectivity trials with glyphosate formulations, to get the necessary data for their registration by Spanish Authorities.

Application programs were communicated to the correspondent Competent Authority in each Region and were carried out by Monsanto's technical staff, who is officially accredited by EOR 7/96.

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

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

### **5.6 Seeds multiplication**

Characterization, self-fertilization and selection of inbred lines and hybrids, resultant of directed crossings.

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

Study to confirm the safety for non target organisms.

### **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:**

- It was confirmed a minimum isolation of 200m from other commercial maize fields in locations of Aragón, Cataluña and Navarra regions. For locations in Castilla-La Mancha region, a minimum isolation of 250m from other commercial maize fields was confirmed. For locations in Castilla y León region a minimum isolation of 400m from other commercial maize fields was confirmed.
- Seeds of NK603 hybrids were packed and clearly labelled by qualified staff in our installations located in *Los Palacios*, authorized to carry out confined operations with GM organisms (N° A/ES/07/I-0). Seeds of NK603 inbred lines were packed and clearly labelled by qualified staff in our research centre in Peyrehorade (France), authorized to carry out confined operations with 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 paper 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 spill in the soil.
- To avoid involuntary dispersion, the remaining seeds were buried in at least a 0.5 meter-deep pitch within the trial site, or there were kept in the original bags, which were re-sealed, labelled and transported by qualified staff to the origin warehouse.
- 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 with anticipation, and the planting were conducted under supervision of officials from the Competent Authority.
- A minimum of eight lines of conventional maize were planted surrounding the trial, as pollen barrier in locations from Aragón, Castilla y León, Cataluña and Navarra regions. In locations from Castilla-La Mancha a minimum of twelve rows of conventional corn were planted surrounding the trial, 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.

- In Calera y Chozas (Toledo) and Daimiel (Ciudad Real) locations, it was installed a mesh of approximately 1-meter height in the exterior perimeter of the plot for protecting the trials of possible predators.
- No negative effect has been observed on “non target” organisms, on arthropofauna, or for the biodiversity in general.
- Pollen shed dates were notified in advance to the competent authorities.
- No incidences have occurred related to safety for human health and environment.
- As agronomic incidence it has to be mentioned that trials located in Alcarrás (Lleida) were performing as expected, but on August 1<sup>st</sup> there was a severe hailstorm, which seriously damaged the maize plants and limited the plant evaluations forecasted in the last crop stages.

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

- Authorities have been informed in advance on the harvesting dates and they have been conducted under their supervision.
- All the samples taken were tagged and bagged accordingly. The samples harvested for analytics purposes were bagged and tagged in the trial field. All the procedures were carried out under standard procedures, with full traceability, and watched over, guaranteeing that they could not end up into the human or animal food chain. The harvest of seeds in Milagro (Navarra) location has been conducted under supervision of Competent Authority and in the presence of inspectors. The transport from the field to the research centre in Peyrehorade (France) has been subjected to a chain of custody provided to the Competent Authority.
- Trials were harvested with a combine-harvester of cereals.
- The grains not grounded were buried in an approximately 1,5-2,5 meter-deep pitch. They were 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 surveillance of Monsanto’s technical staff.
- The trials crop residues were destroyed with tillage, chopped (with a chopper, or an offset disc harrow) and then, buried or ploughed up with several blades passes.
- The combine and means of transport were cleaned before leaving the field.

#### ***6.1.5 Post harvest measures***

The release site will be watched on 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 modification will be 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 applied

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 present the same risk to human and animal health, or the environment, as any conventional variety.

*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, it has been confirmed the tolerance to glyphosate herbicide of NK603 maize plants. The results from efficacy and selectivity trials with glyphosate formulations will be included in their submission for registration by Spanish Authorities.

#### **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 March 13<sup>th</sup>, 2009 by the Aragón Interdepartmental Commission on Genetically Modified Organisms; Resolution of March 25<sup>th</sup>, 2009, by the Castilla-La Mancha Biosafety Commission; Order of April 21<sup>st</sup>, 2009 by the Castilla y León Council of Environment; Resolution of March 6<sup>th</sup>, 2009 by the Catalanian Directorate-General of Agriculture and Farming and the Resolution 1240/2009, of June 1<sup>st</sup>, 2009, by the Navarra Directorate-General of Environment & Water, guaranteeing safety to human and animal health and the environment.

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

Trials have been executed as predicted. Behaviour of NK603 maize was similar to conventional maize and it has not been observed any negative effect on the human or animal health, or on the environment. It is remarkable that a postemergence weed control in NK603 maize offers a more compatible alternative for the biodiversity, using herbicide formulations classified without pictograms and with low environmental impact.