

**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/07/06

***1.2 Member State of notification***

Spain.

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

Resolution of February 14<sup>th</sup>, 2007 by the President of the GMO Interministerial Council.

***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 x MON 810

***3.3 Unique identifier, if available***

MON-ØØ6Ø3-6 x MON-ØØ81Ø-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>	<b>Duration of the release</b>
Utrera (Sevilla)	720 m <sup>2</sup>	NK603 x MON 810 hybrids 7-8 plants /m <sup>2</sup>	Sowing: March 30, 2007 Destruction: Sept 11, 2007
Fuente Palmera (Córdoba)	720 m <sup>2</sup>	NK603 x MON 810 hybrids 7-8 plants /m <sup>2</sup>	Sowing: March 29, 2007 Destruction: Sept 14, 2007
Ecija (Sevilla)	480 m <sup>2</sup>	NK603 x MON 810 hybrids 7-8 plants /m <sup>2</sup>	Sowing: March 29, 2007 Destruction: Sept 10, 2007
Almudévar (Huesca)	480 m <sup>2</sup>	NK603 x MON 810 hybrids 7-8 plants /m <sup>2</sup>	Sowing: April 23, 2007 Destruction: Oct 31, 2007
Grañén (Huesca)	960 m <sup>2</sup>	NK603 x MON 810 hybrids 7-8 plants /m <sup>2</sup>	Sowing: April 27-28, 07 Destruction: Oct 30, 2007
Tauste (Zaragoza)	480 m <sup>2</sup>	NK603 x MON 810 hybrids 7-8 plants /m <sup>2</sup>	Sowing: May 9, 2007 Destruction: Oct 30, 2007
Ejea (Zaragoza)	900 m <sup>2</sup>	NK603 x MON 810 hybrids 7-8 plants /m <sup>2</sup>	Sowing: May 8, 2007 Destruction: Oct 30, 2007
Malpica de Tajo (Toledo)	480 m <sup>2</sup>	NK603 x MON 810 hybrids 7-8 plants /m <sup>2</sup>	Sowing: April 23, 2007 Destruction: Oct 22, 2007
Fuentes de Ropel (Zamora)	480 m <sup>2</sup>	NK603 x MON 810 hybrids 7-8 plants /m <sup>2</sup>	Sowing: June 6, 2007 Destruction: Dec 6, 2007
Toral de los Guzmanes (León)	480 m <sup>2</sup>	NK603 x MON 810 Hybrids 7-8 plants /m <sup>2</sup>	Sowing: June 5, 2007 Destruction: Dec 5, 2007
Coreses (Zamora)	480 m <sup>2</sup>	NK603 x MON 810 hybrids 7-8 plants /m <sup>2</sup>	Sowing: June 4, 2007 Destruction: Nov 13, 2007
Madrigalejo (Cáceres)	480 m <sup>2</sup>	NK603 x MON 810 hybrids 7-8 plants /m <sup>2</sup>	Sowing: April 3, 2007 Destruction: May 17, 2007
Val do Dubra (A Coruña)	480 m <sup>2</sup>	NK603 x MON 810 hybrids 7-8 plants /m <sup>2</sup>	Sowing: June 7, 2007 Destruction: Dec 9, 2007

\*GM: genetically modified

Notes:

Trials initially foreseen in *Maribáñez (Sevilla)*, *Alcalá del Río (Sevilla)*, *Porzuna (Ciudad Real)*, *Lalín (Pontevedra)*, *Castro de Rey (Lugo)*, *Touro (A Coruña)*, *Ribaforada (Navarra)* y *Buñuel (Navarra)* were not carried out, because it did not exist warranties in the necessary isolation from fields of conventional maize, or water availability.

In *Madrigalejo*, because of adverse meteorological conditions and inadequate crop assistance after sowing (no herbicide application) which determined a heterogeneous emergency, trials were destroyed on May 17<sup>th</sup>.

In *Grañén*, due to adverse meteorological conditions, the crop development was not adequate to obtain necessary evaluations for their Registration, and the trials were destroyed without evaluate the production in every single plot.

See the trials layout in the Annex.

#### **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?***

Commercialization of products that contain, consist, or have been produced from NK603 x MON 810 GM maize was authorized in the EU in accordance with Regulation 1829/2003, in the Commission Decision of 24 October, 2007 (2007/701/CE). Application for authorization of NK603 x MON 810 maize cultivation has been submitted in the EU under Directive 2001/18/CE (C/ES/04/01), and Regulation 1829/2003 (EFSA-GMO-NL-2005-26).

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

##### ***5.1 Deliberate releases for research purposes***

Not applicable.

##### ***5.2 Deliberate releases for development purposes***

Not applicable.

##### ***5.3 Official testing***

The liberation is necessary to obtain the information needed by the Spanish Office of Plant Varieties Registration, to progress on the evaluation of NK603 x MON 810 varieties, which registration has been submitted to the Register of Commercial Varieties. For this purpose, it is necessary to carry out Identification trials under official supervision, as well as Agronomic Value trials in order to guarantee their stability, homogeneity, distinctness and agronomic value.

##### ***5.4 Herbicide authorization***

Not applicable.

##### ***5.5 Deliberate releases for demonstration purposes***

Not applicable.

##### ***5.6 Seeds multiplication***

Not applicable.

##### ***5.7 Deliberate releases for biosafety/risk assessment research (Please, specify)***

Not applicable.

##### ***5.8 Other types of deliberate releases***

Not applicable.

## **6. METHODS, RESULTS OF THE RELEASE, MANAGEMENT AND MONITORING MEASURES IN RESPECT OF ANY RISK TO HUMAN HEALTH OR THE ENVIRONMENT**

### **6.1 Risk management measures**

#### **6.1.1 Before the sowing**

- It was confirmed a minimum isolation of 200 m from other commercial maize fields.
- Seeds of hybrids with NK603 x MON 810 have been packed and clearly labelled by qualified staff in our installations located in *Los Palacios*, authorized to carry out confined operations with GM organisms (N<sup>o</sup> A/ES/07/I-0).
- 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, so that one bag was opened when the previous one had been placed in the sowing machine.

#### **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 lost in the soil.
- To avoid involuntary dispersion, remaining seed 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 extracting the machinery out of the field, it was checked that all the sowing cones were cleaned.
- Competent authorities were informed of the sowing dates with anticipation, and the sowings were made under supervision of officials from the competent authority.

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

- Trials have been monitored on several dates during the growing season, and have been visited by some experts and competent authorities. During the visits, besides the observations described in the studies, it has not been observed that the crop trends to turn into weed, or with major susceptibility to pests and diseases that the conventional maize.
- In *Malpica de Tajo (Toledo)* location, to protect the trials of possible predators, it was installed a mesh of approximately 1-meter height in the exterior perimeter of the plot.
- In *Madrigalejo (Cáceres)* location, once the trials were destroyed for the reasons exposed in paragraph 3.4., it was verified that the farmer had sowed conventional maize in the plot where initially the trials were located, and it was proceeded to eliminate the new crop in 3-4 leaves stage, as well as the possible new shoots that could have emerged after the first destruction. During the rest of the campaign, a detailed surveillance of the plot has been realized, without new emergencies or new shoots of maize.

- No negative effect has been observed on “non target” organisms, on arthropofauna, or for the biodiversity in general.
- Pollen shed dates have been notified in advance to the competent authorities.
- No incidences have occurred related to safety for human health and environment.

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

- Authorities were informed on the harvesting dates, and the inspectors were present (see Records and photos of harvesting and destruction in the Annex enclosed).
- All the samples taken have been tagged and bagged accordingly. Trials have been harvested with combine-harvester of cereals, modified with a mill to grind the grain and to annul its viability, except in *Val do Dubra (A Coruña)*, where the adverse climatic conditions forced to make a hand-harvest and to shell the maize ears with a shelling machine.
- The remaining grain (not ground) 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 have been destroyed with tillage, chopped (with a chopper, or an offset disc harrow) and then, buried or ploughed up with several blades passes.
- In trials located in *Malpica de Tajo (Toledo)*, general tillage to destroy and bury the crop residues were completed with additional blades passes, to ensure the buried of the remains, after verify that in a part of the field (not harvested and ploughed directly by the farmer) some ear maize residues remained in the surface.
- The combine and means of transport have been 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 volunteers of maize. This destruction will no longer be necessary when the NK603 x MON 810 modification will be authorized for cultivation in the European Union.

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

Not applicable.

#### **6.1.7 Emergency plans**

All the biosafety measures planned to avoid volunteers 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 x MON 810 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***

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

#### ***Monitoring measures in adjacent areas***

Surrounding fields 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, plant development; furthermore, no unexpected and unusual characteristic has been recorded.

### ***6.4 Observed effects***

No unexpected effects were observed

***6.4.1 All results of the deliberate releases 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 x MON 810 maize plants presented no risk to human or animal health or the environment.

#### ***6.4.2 Expected effects***

NK603 x MON 810 maize plants developed normally and presented crop cycle and yields similar to their isogenic conventional counterparts.

The results of the evaluations conducted are going to be sent to the Spanish Office of Plant Varieties Registration, for their posterior study.

#### ***6.4.3 Unexpected effects***

No unexpected effects were observed

#### ***6.4.4 Other information***

Not applicable

## ***7. CONCLUSION***

Field trials were carried out as planned and in agreement with the conditions of consent.

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

Behaviour of NK603 x MON 810 maize hybrids was as predicted, and it has not been observed any negative effect on the human or animal health, or on the environment. Results of evaluations conducted on NK603 x MON 810 varieties are going to be sent to the Spanish Office of Plant Varieties Registration, for their evaluation.

The measures proposed in the notification and the adopted measures have been consistent with the respect to the environment, to guarantee its safety as well as the human health.

Date: January 28<sup>th</sup>, 2008.