

**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/07/07

**1.2 Member State of notification**

Spain.

**1.3 Date of consent and consent number**

Autonomous Region of Aragón: Resolution of March 9<sup>th</sup>, by the President of the GMO Interdepartmental Commission.

Autonomous Region of Castilla La Mancha: Resolution of March 1<sup>st</sup>, 2007 by the Regional Biosafety Commission.

Autonomous Region of Castilla y León: Order of May 21<sup>st</sup>, 2007 by the Regional Directorate-General of Environmental Quality.

Autonomous Region of Navarra: Resolution 0633 of April 2<sup>nd</sup>, 2007 by the Regional Directorate-General of Environmental.

**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>	<b>Duration of the release</b>
Almudévar (Huesca)	573 m <sup>2</sup>	NK603 7-8 plants /m <sup>2</sup>	Sowing: April 24, 2007 Destruction: Oct 31, 2007
Grañén (Huesca)	1.053 m <sup>2</sup>	NK603 7-8 plants /m <sup>2</sup>	Sowing: April 27-28, 07 Destruction: Oct 31, 2007
Tauste (Zaragoza)	2.713 m <sup>2</sup>	NK603 7-8 plants /m <sup>2</sup>	Sowing: May 9, 2007 Destruction: Oct 30, 2007
Malpica de Tajo (Toledo)	3.673 m <sup>2</sup>	NK603 7-8 plants /m <sup>2</sup>	Sowing: April 23, 2007 Destruction: Oct 22, 2007
Tarazona de la Mancha (Albacete)	500 m <sup>2</sup>	NK603 7-8 plants /m <sup>2</sup>	Sowing: May 7, 2007 Destruction: Nov 28, 2007
Fuentes de Ropel (Zamora)	2.105 m <sup>2</sup>	NK603 7-8 plants /m <sup>2</sup>	Sowing: June 6, 2007 Destruction: Dec 6, 2007
Toral de los Guzmanes (León)	963 m <sup>2</sup>	NK603 7-8 plants /m <sup>2</sup>	Sowing: June 5, 2007 Destruction: Dec 5, 2007
Corese (Zamora)	780 m <sup>2</sup>	NK603 7-8 plants /m <sup>2</sup>	Sowing: June 4, 2007 Destruction: Nov 13, 2007
Santovenia de Pisuerga (Valladolid)	3.580 m <sup>2</sup>	NK603 7-8 plants /m <sup>2</sup>	Sowing: June 5, 2007 Destruction: Dec 3, 2007
Buñuel	435 m <sup>2</sup>	NK603 7-8 plants /m <sup>2</sup>	Sowing: May 10, 2007 Destruction: Nov 6, 2007

\*GM: genetically modified

**Notes:**

Trials initially foreseen in *Ejea de los Caballeros (Zaragoza)*, *Bujaraloz (Zaragoza)*, *Villabrágima (Valladolid)* and *Porzuna (Ciudad Real)* were not carried out, because it did not exist warranties in the necessary isolation from fields of conventional maize. Trials initially planned in *Navarra* have been reorganized in a unique plot located in *Buñuel*, to accomplish with the isolation required.

In *Grañén*, due to adverse meteorological conditions, the development of the field in some assays was not uniform, and the affected assays were finished without evaluate the production in every single plot.

In *Tauste*, soil class and adverse climatic conditions impeded the suitable and homogeneous development of the pure lines in the trial destined for their characterization, then observations and crossings initially planned could not be conducted.

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?**

Importation and consumption of NK603 maize are authorized in the EU in accordance with Directive 2001/18/CE (Commission Decision of July, 19<sup>th</sup> 2004, OJEU of 19/09/04). The use of NK603 maize and its fractions has been also authorized in accordance with Regulation CE/258/97 (October 26<sup>th</sup>, 2004). Application for authorization of NK603 maize cultivation has been submitted in accordance with Directive 2001/18/CE (C/ES/03/01), and Regulation 1829/2003 (EFSA-GMO-NL-2005-22).

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

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

Not applicable.

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

Evaluation of agronomic performance, yield and germination capacity, plant vigour, plant height.

Protein expression and composition analysis in different plant tissues, at different growing stages.

Herbicides residue analysis in different plant tissues.

Additional evaluations on maize genetically modified and its comparative development with lines not genetically modified. Development and optimization of weeds management programs. Characterization of pure lines and hybrids, resultant of directed crossings.

Some trials have been carried out in collaboration with Agrisearch Ibérica S.L., authorised to conduct trials under GLP accreditation (3/BPL03) and officially recognized testing with agrochemicals (EOR 35/98).

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

Trials before application for varieties Registration: they aim was to complete the characterization and Agronomic Value of a group of experimental hybrids, previously notified to the Spanish Office of Plant Varieties Registration, in order to fulfil the preliminary testing for the Registration Application of new hybrids. See details of the protocol in the Annex.

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

Efficacy and selectivity trials with glyphosate formulations, to get the necessary data for registration by the Spanish Ministry of Agriculture.

Application times have been communicated to the correspondent Competent Authority in the Autonomous Region. Some of them were carried out in collaboration with Agrisearch Iberica S.L., authorised to conduct trials under GLP accreditation (3/BPL03), and the

remaining trials was carried out by Monsanto's technical staff, who is officially accredited by EOR 7/96.

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

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

#### ***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 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 (Nº 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.
- The trials were surrounded by at least 6-8 lines of conventional maize, as pollen barrier.

### **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)* and *Tarazona de la Mancha (Albacete)* locations, to protect the trials of possible predators, it was installed a mesh of approximately 1-meter height in the exterior perimeter of the plot.
- 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. As unique agronomic incident, it must be mentioned a breakdown in the irrigation system in *Tarazona de la Mancha (Albacete)*, that cause lack of homogeneity in the development of the crop and disabled the evaluation of final yield in demonstrative trials that were placed in this location.

### **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. The samples gathered for analytical purposes were pocketed hermetically and labelled in the trial field. All operations have been carried out under standardized procedures and GLP certification.
- Trials have been harvested with combine-harvester of cereals, modified with a mill to grind the grain and to annul its viability.
- 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 ears 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. The commercial crop after ending the trials period will not be maize. This destruction and the restrictions for cultivation next year will no longer be necessary when the NK603 modification will be authorized 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 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 maize plants presented no risk to human or animal health or the environment.

**6.4.2 Expected effects**

NK603 maize plants developed normally and presented crop cycle and yields similar to their isogenic conventional counterparts. In the trials, it has been confirmed the tolerance to glyphosate herbicide of NK603 maize plants.

The results of the evaluations carried out on NK603 hybrids are going to be sent to the Spanish Office of Plant Varieties while submitting their registration application.

Likewise, the results of trials for efficacy, selectivity and residues with glyphosate formulations will be useful to support their registration by the Ministry of Agriculture.

**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.

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

Behaviour of NK603 maize hybrids was as predicted, 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 of low environmental impact.

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 16<sup>th</sup>, 2008.