

**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/06/09

**1.2 Member State of notification**

Spain

**1.3 Date of consent and consent numbers**

- Autonomous Region of Aragon: Resolution of April 18<sup>th</sup> by the President of the GMO Interdepartmental Commission.
- Autonomous Region of Castilla La Mancha: Resolution of March 23<sup>rd</sup>, 2006 by the Regional Biosafety Commission.
- Autonomous Region of Castilla y Leon: Order of May 16<sup>th</sup>, 2006 by the Regional Councilor of the Environment.
- Autonomous Region of Madrid: Resolution of May 25<sup>th</sup>, 2006, by the Regional Director-General for Agriculture and Rural Development.
- Autonomous Region of Navarra: Resolution 0826 of April 4<sup>th</sup>, 2006, by the Regional Director-General for the 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 not available)**

NK603 x MON810

**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> with NK603 x MON810 event)	<b>Identity and approximate number of GM higher plants per event actually released</b>	<b>Duration of the release(s):</b>
Almudévar (Huesca)	Area occupied by GM* plants: 120 m <sup>2</sup>	NK603 x MON 810 hybrids ~8-10 plants /m <sup>2</sup>	Sowing: 27 Apr 06 Destruction: 24 Oct 06
Grañen (Huesca)	Area occupied by GM* plants: 120 m <sup>2</sup>	NK603 x MON 810 hybrids ~8-10 plants /m <sup>2</sup>	Sowing: 4 May 06 Destruction: 19 Oct 06
Torres de Berrellén (Zaragoza)	Area occupied by GM* plants: 120 m <sup>2</sup>	NK603 x MON 810 hybrids ~8-10 plants /m <sup>2</sup>	Sowing: 3 May 06 Destruction: 24 Oct 06
Toral de los Guzmanes (León)	Area occupied by GM* plants: 720 m <sup>2</sup>	NK603 x MON 810 hybrids ~8-10 plants /m <sup>2</sup>	Sowing: 25 May 06 Destruction: 23 Nov 06
Fuentes de Ropel (Zamora)	Area occupied by GM* plants: 720 m <sup>2</sup>	NK603 x MON 810 hybrids ~8-10 plants /m <sup>2</sup>	Sowing: 25 May 06 Destruction: 21 Nov 06
Corese (Zamora)	Area occupied by GM* plants: 540 m <sup>2</sup>	NK603 x MON 810 hybrids ~8-10 plants /m <sup>2</sup>	Sowing: 24 May 06 Destruction: 23 Nov 06
Aranjuez (Madrid)	Area occupied by GM* plants: 120 m <sup>2</sup>	NK603 x MON 810 hybrids ~8-10 plants /m <sup>2</sup>	Sowing: 12 Jun 06 Destruction: 30 Nov 06
Ribaforada (Navarra)	Area occupied by GM* plants: 360 m <sup>2</sup>	NK603 x MON 810 hybrids ~8-10 plants /m <sup>2</sup>	Sowing: 5 May 06 Destruction: 17 Oct 06
Balaguer (Lleida)	Area occupied by GM* plants: 900 m <sup>2</sup>	NK603 x MON 810 hybrids ~8-10 plants /m <sup>2</sup>	Sowing: 16 may 06 Destruction: 4 Sep 06
Albacete (Albacete)	Area occupied by GM* plants: 2.250 m <sup>2</sup>	NK603 x MON 810 hybrids ~8-10 plants /m <sup>2</sup>	Sowing: 3 may 06 Destruction: 12 Dec 06

\*GM: Genetically Modified

Trials layout is detailed in the Annex enclosed.

**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?**

Yes  No  Unknown, to date

**If yes, indicate the country(ies) of notification:**

The authorization for placing on the market, including cultivation, in the European Union has been submitted. Applications C/ES/04/01, according to Directive 2001/18/CE and EFSA-GMO-NL-2005-26, according to Regulation 1829/2003.

**If yes, specify for which use(s):**

- Import
- Cultivation (seeds/planting material production)
- Food
- Feed
- Pharmaceutical use (or processing for pharmaceutical use)
  - Processing for
    - Food use
    - Feed use
    - Industrial use
  - Others (Specify):

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

**5.1 Deliberate releases for research purposes**

Not applicable.

**5.2 Deliberate releases for development purposes**

Testing of different weed management programs were carried out, to improve recommendations to farmers, when they will be allowed to plant varieties with NK603 x MON 810.

**5.3 Official testing**

Trials before the application for variety Registration:

They aim at both completing the description and evaluating the Agronomic Value of a series of experimental hybrids, whose cultivation has been notified to the Spanish Office of Plant Varieties, so that they are considered to be preliminary to the new hybrids Applications for Registration next year.

The CRNPDLA06 trials protocol contains 20 varieties of FAO 600-700 cycle, from which 6 are NK603 (considered in B/ES/06/08), 2 are NK603 x MON810, and the remaining are conventional.

The CRNPDME06 trials protocol contains 30 varieties of FAO 400-500 maturity cycle, from which 9 are NK603 (considered in B/ES/06/08), 6 are NK603 x MON810, and the remaining are conventional.

The CRNPDEA06 trials protocol contains 30 varieties of FAO 200-300 cycle, from which 11 are NK603 (considered in B/ES/06/08), 6 are NK603 x MON810, and the remaining are conventional.

**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 type of deliberate releases**

Not applicable

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

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

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

- An isolation distance of minimum 200 m from other marketable maize crops was checked.
- Transgenic seeds were packed in closed bags and appropriately labelled by qualified staff.

#### **6.1.2 During the sowing/planting activities**

- Seeds were transported in closed bags and were managed by qualified staff, already warned about the preventive measures to be taken to avoid any dissemination.
- Sowing was done with a perfectly cleaned sowing machine, thus preventing seed dissemination on the soil.
- To prevent any involuntary seed release, all the remaining seed bags have been buried in a 50cm meter-deep pitch within the trial site, or they were kept in the original packages, properly re-sealed, labelled and transported by qualified staff to the original warehouse.
- Before taking the sowing machine outside the crop area, the sowing cones were verified to be clean.
- Competent authorities have been previously informed on the sowing dates and their official staff members have checked all the sowings (see enclosed Annex).
- In Balaguer location, at the sowing time a conventional maize field was noticed within the isolation perimeter of 200 m. As the field belonged to the farmer owner of the trial site he agreed to destroy the conventional maize which was done in the following days. Monsanto kept a constant communication with Catalonian authorities who checked the maize crop destruction afterwards.
- To avoid the entrance of wild animals into the trial and following the recommendations of Castilla-La Mancha authorities for B/ES/06/09, the field was surrounded with an 1-m high net.

#### **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.

- No negative effect has been observed in “non target” organisms, or in arthropofauna, or in other components of biodiversity.
- Pollen shed dates were previously notified to the competent authorities.
- No incidence occurred, except for damages caused by wild boars in several plots in Torres de Berrellén (Zaragoza); this was notified by fax on September 30th (see Annex enclosed). Maize emergence in several plots in Aranjuez was not homogeneous enough; therefore, trials intended for official testing were harvested but crop yields will not be used for further analysis. In Balaguer, adverse conditions happened during sowing and early maize stages (low humidity, early irrigation, seeds located in excessive soil depth, etc) which made difficult plant development, without any correlation to the genetic modification so they affected equally to NK603 x MON 810 hybrid, the reference hybrid with MON 810 or the conventional one.

*6.1.4. At the end of the release:*

- Authorities were informed on the harvesting dates, and they were present (see acts and photos of harvesting and destruction in the Annex enclosed).
- Trial located in Balaguer was not homogeneous for the previously described reasons, so plants were destroyed by a maize chopper machine and buried, before grain was viable.
- Every material taken away from the site has been properly packed and labelled. Trials have been harvested with a cereal combine, except in Toral de los Guzmanes, where cobs from the main plots were harvested by hand, due to excessive humidity in the soil.
- The harvested grains were buried in an approximately 1,5-2,5 metre-deep pitch. They were covered by soil at least in 0,5 m depth.
- The grains were transported to the pitch in the combine itself. If the ditch was far from the original site, the grain was then transported in a trailer, being very careful to avoid any spillage and being watched by Monsanto’s technical staff.
- The crop residues from the trials were destroyed with tillage and chopped (with a chopper or an offset disc harrow) and then, buried or ploughed up with several tillage passes.
- The combine and transport tools 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 volunteers of maize. This destruction will no longer be necessary when the NK603 X MON810 modification is authorised for cultivation in the European Union.

*6.1.6 Other(s) measure(s) (specify)*

*Emergency plan(s)*

Indicate:

- a) If the release proceeded as planned:
- Yes
  - No

b) If measures according to the emergency plan(s) [article 23.2.a) 6° of Regulation and Annex V B] should be adopted:

No

Yes

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

The monitoring results confirmed that NK603 X MON810 maize plants presented the same risk to human and animal health or the environment as the conventional varieties.

*Please specify:*

#### ***Monitoring measures within site***

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

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

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

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

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

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

No unexpected effects have been 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 did not pose any risk of adverse effects to human or animal health or to the environment different from those of conventional varieties.

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

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

Results from official testing will be sent to the Spanish Office of Plant Varieties when Registration application.

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

No unexpected effect has been observed

*6.4.4. Other information*

None

## **7. CONCLUSION**

Field trials were carried out as planned. The barrier of at least 6 rows of conventional maize planted surrounding the field acted as a pollen barrier.

NK603 X MON810 hybrids behaved as expected. Trials results from official testing will be sent to the Spanish Office of Plant Varieties when submitting the application for Registration of the tested varieties.

Weed management programs including glyphosate formulations have provided a similar or better performance than current conventional programs and full selectivity for the maize, so they would provide an alternative to reduce the use of residual herbicides.

DATE: December 19<sup>th</sup>, 2006.

Signed: Juan Alvarado  
Field Trials Specialist Lead  
Monsanto Agricultura España S.L.

Signed: Sergio García Ortiz  
Technology Development Representative  
Monsanto Agricultura España S.L.

Signed: Juan Ignacio Claver  
Development and Marketing Representative  
Monsanto Agricultura España S.L.