

**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/06/08

***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 Counselor 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

***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> (Type of deliberate release)	<b>Identity and approximate number of GM higher plants per event actually released</b>	<b>Duration of the release(s):</b>
<b>Almudévar (Huesca)</b>	Area occupied by GM* plants: 360 m <sup>2</sup> (2)	NK603 hybrids ~8-10 plants /m <sup>2</sup>	Sowing: 27 Apr 06 Destruction: 24 Oct 06
<b>Grañen (Huesca)</b>	Area occupied by GM* plants: 630 m <sup>2</sup> (1) + 360 m <sup>2</sup> (2) + 3.000 m (3) + 2.400 m <sup>2</sup> (4)	NK603 hybrids ~8-10 plants /m <sup>2</sup>	Sowing: 4 May 06 Destruction: 19 Oct 06
<b>Torres de Berrellén (Zaragoza)</b>	Area occupied by GM* plants: 630 m <sup>2</sup> (1) + 360 m <sup>2</sup> (2)	NK603 hybrids ~8-10 plants /m <sup>2</sup>	Sowing: 3 May 06 Destruction: 24 Oct 06
<b>Tauste (Zaragoza)</b>	Area occupied by GM* plants: 2.500 m (3) + 2.400 m <sup>2</sup> (4)	NK603 hybrids ~8-10 plants /m <sup>2</sup>	Sowing: 28 Apr 06 Destruction: 25 Oct 06
<b>Malpica de Tajo (Toledo)</b>	Area occupied by GM* plants: 630 m <sup>2</sup> (1) + 3.000 m (3)	NK603 hybrids ~8-10 plants /m <sup>2</sup>	Sowing: 28 Apr 06 Destruction: 21 Oct 06
<b>Toral de los Guzmanes (León)</b>	Area occupied by GM* plants: 630 m <sup>2</sup> (1) + 1.200 m <sup>2</sup> (2)	NK603 hybrids ~8 plants /m <sup>2</sup>	Sowing: 25 May 06 Destruction: 23 Nov 06
<b>Fuentes de Ropel (Zamora)</b>	Area occupied by GM* plants: 630 m <sup>2</sup> (1) + 1.200 m <sup>2</sup> (2)	NK603 hybrids ~8-10 plants /m <sup>2</sup>	Sowing: 25 May 06 Destruction: 21 Nov 06
<b>Corese (Zamora)</b>	Area occupied by GM* plants: 1.030 m <sup>2</sup> (2)	NK603 hybrids ~8-10 plants /m <sup>2</sup>	Sowing: 24 May 06 Destruction: 23 Nov 06
<b>Aranjuez (Madrid)</b>	Area occupied by GM* plants: 630 m <sup>2</sup> (1) + 360 m <sup>2</sup> (2) + 2.500 m (3) + 1.080 m <sup>2</sup> (4)	NK603 hybrids ~8-10 plants /m <sup>2</sup>	Sowing: 12 junio 06 Destruction: 30 Nov 06
<b>Ribaforada (Navarra)</b>	Area occupied by GM* plants: 600 m <sup>2</sup> (2) + 1.320 m <sup>2</sup> (4)	NK603 hybrids ~8-10 plants /m <sup>2</sup>	Sowing: 5 may 06 Destruction: 17 Oct 06

\*GM: Genetically Modified

Notes:

- (1): Deliberate releases for development (protein expression, agronomic equivalence, and reference material) and herbicide authorisation (herbicide residues).
- (2): Deliberate releases for official testing (trials before the varieties register application)
- (3). Deliberate releases for development (study on weed management programs) and herbicide authorisation (efficacy and selectivity)
- (4) Deliberate releases for development (testing of weed management programs in bigger, non replicate plots)

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 EU has authorized NK603 maize import and consumption, according to Directive 2001/18/EC (Decision of the Commission on July 19<sup>th</sup>, 2004; OJEU of 19/09/04). The uses of NK603 maize and its fractions have also been authorized according to Regulation EC/258/97 (October 26<sup>th</sup>, 2004). The application for cultivation has been submitted according to Directive 2001/18/EC (C/ES/03/01) and Regulation 1829/2003 (EFSA-GMO-NL-2005-22)

**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**

- Evaluation of agronomic performances, yield capacity, germination capacity, plant vigour, plant height.
- Determination of the expression of proteins and the composition in different plant tissues, at different growing stages.
- Determination of the level of residues of several herbicides, in different plant tissues.
- Testing of different weed management programs were carried out to improve recommendations for farmers, when they will be allowed to plant varieties with NK603. In a group of 4 locations a detailed study with a large number of treatments, replicate and small plots were conducted, whereas in another group of 4 locations testing on bigger and non replicated plots were conducted, in order to assess the most appropriate program for each region.
- Others (Describe): Additional data taken on genetically modified maize, including its comparative development with non-genetically modified inbred. Reference

material and buffer lines for trials reported in B/ES/06/02 and B/ES/06/03.

Some trials have been carried out in collaboration with Agrisearch Ibérica S.L., authorised to undertake GLP trials (05/3/BPL03).

### **5.3 Official testing**

#### Trials before the Register application:

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 can be considered as preliminary to the new hybrids Application for Registration next year.

The CRNPDLA06 trials protocol contained 20 varieties of FAO 600-700 maturity cycle, from which 6 were NK603, 2 were NK603 x MON810 (considered in B/ES/06/09), and the remaining were conventional.

The CRNPDME06 trials protocol contained 30 varieties of FAO 400-500 cycle, from which 9 were NK603, 6 were NK603 x MON810 (considered in B/ES/06/09), and the remaining were conventional.

The CRNPDEA06 trials protocol contained 30 varieties of FAO 200-300 cycle, from which 11 were NK603, 6 were NK603 x MON810 (considered in B/ES/06/09), and the remaining were conventional.

### **5.4 Herbicide authorization**

#### Residues:

Two residue trials were carried out with several herbicides, and they were reported to the correspondent competent authority with the following codes: AF/10287/ME/8 and AF/10288/ME/8 (Autonomous Region of Aragon), AF/10287/ME/7 and AF/10288/ME/7 (Autonomous Region of Castilla La Mancha), AF/10287/ME/11 and AF/10288/ME/11 (Autonomous Region of Castilla y Leon) and AF/10287/ME/10 and AF/10288/ME/10 (Autonomous Region of Madrid). These trials were carried out in collaboration with the company Agrisearch Ibérica S.L., authorised to undertake GLP trials (05/3/BPL03) and trials with officially accredited plant protection products (EOR 35/98).

#### Efficacy and Selectivity:

Trials were carried out to study the efficacy and selectivity of MON 79.545 formulation, which contains glyphosate as active ingredient, and communicated to the correspondent authority in each Autonomous Region (Monsanto is officially accredited by EOR 7/96). Agronomic results about the maize development are detailed in the Annex enclosed.

### **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**

- Clear labelling of the GM seeds batches/planting material. Each GM seed was stored in a closed paper bag, and it was labelled with its correspondent identification.
- Segregation during the processing and transport of the seeds/planting material: seeds were transported to the field 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 case of fields with deliberate releases intended for development purposes (protein expression), herbicides authorisation and/or official testing, an experimental sowing machine were used and to avoid confusion or seeds mixing, the bags were opened sequentially, so that one paper bag was opened when the previous one had been placed in the sowing machine.
- Destruction of surplus seeds/planting material: All seeds prepared for the trial were placed in the sowing cones, following the previously detailed process.
- Temporal isolation
- Rotation
- Others (specify): Before sowing, it was determined that the plot isolation was appropriate, and that no other maize crop was at less than 200 m from the trial.

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

- Method of sowing/planting: trials with different varieties or events were sown with a special planter for trials sowing and micro plots; this machine self-cleans itself from one plot to another, keeping the ducts empty, avoiding seeds to be mixed. Others were sown with a conventional seed drill.
- Emptying and cleaning of the sowing/planting machinery on the field of release. When a special planter was used, the seeds deposits and the ducts were emptied at the end of each elemental plot; when a conventional planter was used, sowing was done with a perfectly clean sowing machine, avoiding losses in the soil and before taking it outside the crop area, the sowing cones were verified to be clean.
- Segregation during sowing/planting: All seeds were kept and transported in individual paper bags, adequately identified. As explained above, a paper bag was not open until the previous seed was placed in the machine: it was not possible to mix seeds from two different paper bags.
- Others: Competent authorities have been informed on the sowing dates and their official staff members have checked the sowings.  
Only authorised Monsanto people could access the seeds for the trial. Seeds were transported in closed bags and were managed in the trials by qualified staff, already warned about the preventive measures to be taken to avoid any dissemination. The planter's ducts and deposits were cleaned after sowing the trial, to avoid any seed remaining could leave the trial area. To prevent any involuntary seed release, all the remaining seed were been buried in at least a 0.5 meter-deep pitch within the trial

site, or were kept in the original bags, which were re-sealed, labelled and transported by qualified staff to the origin warehouse.

### 6.1.3 During the period of release

- Isolation distance(s) (meters)
  - From sexually compatible commercial plant species: an isolation distance of more than 200 m was kept from other maize crops.
  - From sexually compatible wild relatives: none present in Europe.
- Border(s) rows: at least 6 rows of non-genetically modified maize of the same maturity surrounded each trial. At the end of the release, these non-GM maize rows were chopped like the rest of the trial.
- Cage/net/fence/signpost: In the plot of Malpica de Tajo, to avoid the entrance of wild animals into the trial, all the field was surrounded with a 1-m high net.
- Pollen trap: Surrounding each trial, at least 6 rows of non-genetically modified maize of the same maturity were sown, to act as pollen traps. At the end of the release, these non-GM maize rows were chopped like the rest of the trial.
- Removal of GM inflorescences before flowering.
- Removal of volunteers/wild relatives/ hybrids collaborators
- Others: Trials were monitored on several dates during the growing season, and have been visited by some experts and competent authorities.

Pollen shed dates have been notified to the competent authorities.

According to the study protocol, male and female inflorescences from some plants were packed before flowering (self pollinated plants), while the male inflorescences were removed in other plants.

No negative effect has been observed in “non target” organisms, or in arthropofauna, or in other biodiversity parameter.

No incidence has 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). In Tauste (Zaragoza), poor weeds emergence caused no relevant differences concerning efficacy and positioning (testing of different herbicides/weed management programs) studies so only the selectivity study was completed in this location. On the other hand, due to the late authorisation and technical difficulties (as water availability), maize emergence in several plots in Aranjuez was not homogeneous enough; therefore, trials intended for official testing (trials before Registration application) were harvested but not used for further analysis, and the trials intended for selectivity, efficacy and positioning only were considered to assess efficacy (see Annex enclosed).

### 6.1.4. At the end of the release:

- Destruction/harvest methods (of crop or part of it)/other means: In each site, the kernels were harvested, weighted and buried in soil at least with 0,5 m depth. The crop debris were chopped and incorporated into the soil. During the season, no viable samples of several tissues were taken for analytical purposes as well as some grain samples at harvest time. The samples were hermetically packed in a double package, adequately labelled and watched over while transported to authorized laboratories to be analysed, and then destroyed according to certified GLP procedures. All the crop debris but samples for the analyses, were incorporated into the soil.

- Harvest/destruction before seeds maturity
- Effective removal of plant parts
- Segregated storage and transport of crops/debris: Samples for analytical purposes were hermetically packed at the trial site. Every action was done following standard and certified GLP procedures.
- Clean up of machinery on the release site. Every machinery used in any stage from harvest to destruction was carefully cleaned at each trial site.
- Destination of the debris, treatment of waste/surplus yield/crop debris: harvested grains were buried at least at 0,5-m-depth in each trial site. Waste plants were destroyed, chopped and incorporated in the soil at the end of the trial.
- Post-harvest treatment and cultivation measures on the release site: at the end of the trial, crop waste was chopped and incorporated in the soil.
- Other(s):

Authorities were informed on the harvesting dates, and they were present (see Records and photos of harvesting and destruction in the Annex enclosed).

The grains were transported to the pitches in the combine itself. If the ditch was far from the original site, the grains were then transported in a trailer, being very careful to avoid any spillage and being watched by Monsanto's technical staff.

#### 6.1.5 Post-harvest measures

The trial field will be visited during the following growing season and up to the maize flowering period, in order to check that marketable maize has not been planted, and to destroy any eventual volunteers. This destruction will no longer be necessary when the NK603 modification is authorised for cultivation in the European Union.

- Subsequent crop: any crop different from marketable maize
- Crop rotation: the following year any crop (except no marketable maize) will be grown.
- Fallow/no crop
- Superficial soil work/no deep ploughing
- False-sowing beds
- Control of volunteers: In the season following the trial, each trial field will be visited to check any maize volunteer in the subsequent crop.
- Appropriate chemical treatment(s) (specify)
- Appropriate soil treatment(s) (specify)
- Others: In case of volunteers in the field, they will be destroyed mechanically or chemically; the most appropriate means will be chosen according to the kind and number of volunteers observed in the field. Monitoring will be conducted until achieving two consecutive observations without presence of volunteers.

#### 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 destruction of the trials was made on the dates indicated in 3.4 (see details in the Annex enclosed). The post-release monitoring plan will start once trials are harvested and destroyed, and will last until the following maize growing season.

*Specify:*

- Monitoring measures within the release site
  - Duration: trial fields will be visited during the following growing season to detect and destroy any maize volunteer.
  - Control of volunteers: regular visits, more frequent if some volunteers are detected and destroyed
  
- Monitoring measures in adjacent areas: adjacent areas to the trial field will be visited during the subsequent season, to destroy potential maize volunteers, if any.

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

Different parameters on the agronomic behaviour of plants have been observed and registered. Different herbicide formulations have been applied and the treated plants response has been observed visually. Efficacy of different weed management programs was evaluated.

### **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 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 maize plants developed normally and presented a crop and yield cycle similar to their isogenic conventional maize counterparts.

Tolerance to glyphosate formulations was confirmed.

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

#### *6.4.3. Unexpected effects*

Neither damage nor any kind of negative effects that could impact or have an effect on human health or the environment were observed.

#### *6.4.4. Other information*

None

## **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.

No negative effect of any kind was observed that had or could have effects on the human health or the environment; therefore, NK603 maize is considered to be as safe as conventional maize varieties.

No risks other than those of conventional varieties for human health or the environment was identified as a result of the deliberate release of genetically modified maize in these trials.

Due to the glyphosate tolerance, the weeds can be controlled in post-emergence of maize, providing an alternative more compatible with biodiversity and using an herbicide without risk pictograms. Weed management programs including glyphosate formulations provided a similar or better performance than current conventional programs.

NK603 hybrids in official testing behaved as expected. Results on NK603 hybrids will be sent to the Spanish Office of Plant Varieties to support application for Registration.

The measures proposed in the notification and the control measures are consistent with the purpose of respect to the environment, and guarantying the safety of the environment and human health.

DATE: December 18<sup>th</sup>, 2006.

Signed: Concepción Novillo  
Regulatory Affairs Specialist  
Monsanto Agricultura España S.L.

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