

**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/08/07

1.2 Member State of notification

Spain.

1.3 Date of consent and consent number

Resolution of April 4th, 2008 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

Geographical location (s) (administrative region and, where appropriate, grid reference)	Size of the release site(s) (m ²)	Identity and approximate number of GM* higher plants per event actually released	Duration of the release
Villalón-Fuente Palmera (Córdoba)	820 m²	NK603 x MON810 hybrids 7-9 plants/m²	Sowing: 29/04/2008 Destruction: 18/09/2008
El Cuervo (Sevilla)	1120 m²	NK603 x MON810 hybrids 7-9 plants/m²	Sowing: 28/04/2008 Destruction: 17/09/2008
Grañén (Huesca)	1630 m²	NK603 x MON810 hybrids 7-9 plants/m²	Sowing: 08/05/2008 Destruction: 11y12/11/2008
Ejea de los Caballeros (Zaragoza)	1390 m²	NK603 x MON810 hybrids 7-9 plants/m²	Sowing: 07/05/2008 Destruction: 10/11/2008
Yunquera (Guadalajara)	1420 m²	NK603 x MON810 hybrids 7-9 plants/m²	Sowing: 25/04/2008 Destruction: 18/11/2008
Peñarandilla (Salamanca)	1170 m²	NK603 x MON810 hybrids 7-9 plants/m²	Sowing: 10/06/2008 Destruction: 18/12/2008
Dueñas (Palencia)	640 m²	NK603 x MON810 hybrids 7-9 plants/m²	Sowing: 09/06/2008 Destruction: 17/12/2008
Coreses (Zamora)	1170 m²	NK603 x MON810 hybrids 7-9 plants/m²	Sowing: 08/06/2008 Destruction: 16/12/2008
Santovenia de Pisuerga (Valladolid)	930 m²	NK603 x MON810 hybrids 7-9 plants/m²	Sowing: 06/05/2008 Destruction: 18/12/2008
Alcarrás (Lleida)	720 m²	Híbridos NK603 x MON810 7-9 plantas/m²	Sowing: 05/06/2008 Destruction: 14/11/2008
Valdetorres (Badajoz)	400 m²	NK603 x MON810 hybrids 7-9 plants/m²	Sowing: 25/04/2008 Destruction: 24/09/2008
Arteixo (A Coruña)	640 m²	NK603 x MON810 hybrids 7-9 plants/m²	Sowing: 12/06/2008 Destruction: 19/12/2008

*GM: genetically modified

Notes:

According with the communication of July 10th 2008, trials initially foreseen in Jeréz de la Frontera (Sevilla), Lebrija (Sevilla), Tauste (Zaragoza), Zuera (Zaragoza), Ejea de los Caballeros 2 (Zaragoza), Yunquera de Henares 1 (Guadalajara), La Cisterniga (Valladolid), Toral de los Guzmanes (León), Lleida, Gimenezells (Lleida), Oliva de Mérida (Badajoz) and Marcilla (Navarra) were not carried out, because they did not meet the necessary isolation from fields of conventional maize, other conditions for the successful execution of trails, or trials adjustment to suitable area, after fitting of other notifications.

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

DUS and Agronomic Value trials under official supervision, to progress on the technical evaluation of NK603 x MON 810 varieties, for their intended Registration in the Spanish Variety Catalogue.

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 NK603 x MON 810 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 (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 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.
- The Competent Authorities were informed of the sowing dates with anticipation, and the plantings were made under supervision of officials from the Competent Authority.
- A minimum of four lines of conventional maize were planted surrounding the trial, 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 tends to turn into weed, or with higher susceptibility to pests and diseases than the conventional maize.
- In one monitoring visit to *Arteixo* (A Coruña) field, some maize plants in neighboring fields were detected, inside the 200 m isolation perimeter. To guarantee the trial isolation, actions were taken immediately and before maize flowering. The maize plants in the isolation perimeter were removed, after negotiation with the owners of the orchards located in the isolation ring, and a part of the trial was destroyed, when agreement was not achieved. Plant Variety Registration Authorities were informed about the incident and the measures taken; afterwards they verified the compliance with trial isolation.
- 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.

6.1.4 At the end of the release

- Authorities have been informed in advance on the harvesting dates.
- 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.
- Trials were harvested with combine-harvester of cereals, modified with a mill to grind the grain and to destroy their viability.
- The remaining grains (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 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 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 different from those of conventional maize..

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 according to the notification proposal and in agreement with the conditions of consent in the Resolution of April 14th, 2008 by the President of the GMO Interministerial Council, guaranteeing safety to human or animal health or 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 x MON 810 maize hybrids was similar to conventional corn 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.