

**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/12/08

1.2 Member State of notification

Spain.

1.3 Date of consent and consent number

Resolution of April 20th, by the GMOs 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 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

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 (number of seeds/plants per m ²)	Duration of the release
Fuente Palmera (Córdoba)	81 m ²	NK603 x MON810 hybrids 8 plants/m ²	Sowing: 27/04/2012 Destruction: 21/09/2012
Dos Hermanas (Sevilla)	96 m ²	NK603 x MON810 hybrids 8 plants/m ²	Sowing: 25/04/2012 Re-sowing: 18/6/2012 Destruction: 05 /12/2012
Lebrija (Sevilla)	81 m ²	NK603 x MON810 hybrids 8 plants/m ²	Sowing: 26/04/2012 Destruction: 19/09/2012
Ejea de los Caballeros (Zaragoza)	81 m ²	NK603 x MON810 hybrids 8 plants/m ²	Sowing: 7/05/2012 Destruction: 16/11/2012
Daimiel (Ciudad Real)	81 m ²	NK603 x MON810 hybrids 8 plants/m ²	Sowing: 3/5/2012 Destruction: 10/10/2012
Alcarrás (Lérida)	81 m ²	NK603 x MON810 hybrids 8 plants/m ²	Sowing: 8/5/2012 Destruction: 18/10/2012
Valdetorres (Badajoz)	81 m ²	NK603 x MON810 hybrids 8 plants/m ²	Sowing: 2/5/2012 Destruction: 9/10/2012

Notes: trials initially foreseen in Grañén (Huesca) and Calera y Chozas (Toledo) were not planted because they did not meet the necessary isolation from fields of conventional maize, or any other guarantees for the successful execution of trials.

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?

NK603 x MON 810 maize was approved for import, feed and food use and processing, in the EU, under Regulation (EC) No. 1829/2003 (Commission Decision 2007/701/EC). The application for cultivation of NK603 x MON 810 maize was submitted according to Directive 2001/18/CE (C/ES/04/01) and subsequently under Regulation (EC) No. 1829/2003 (EFSA-GMO-NL-2005-26).

5. TYPE(S) OF DELIBERATE RELEASE(S)

5.1 Deliberate release(s) for research purposes

Not applicable.

5.2 Deliberate release(s) 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 MON810 hybrids, for their intended Registration in Spain.

5.4 Herbicide authorisation

Not applicable.

5.5 Deliberate release(s) for demonstration purposes

Not applicable.

5.6 Seeds multiplication

Not applicable.

5.7 Deliberate release(s) for biosafety/risk assessment research

Not applicable.

5.8 Other(s) type(s) of deliberate release(s)

Not applicable.

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

6.1 Risk management measure(s)

6.1.1 Before the sowing/planting:

- A minimum isolation of 200 m from other commercial maize fields was confirmed.
- Seeds of NK603 x MON810 hybrids were packed in sealed bags and clearly labelled by qualified staff in our installations located in our research centre in Peyrehorade (France), authorized to carry out confined operations with genetically modified (GM) organisms (N° 4593, April 6th 2006, Commission de Genie Genetique, France). When a transitory storage was necessary, they were stored in the facilities of Agricultura y Ensayo company, authorized for confined use of GMOs with number A-ES-12-I-06.
- Seed transport to the field was made the same day of the sowing, in the pre-prepared 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.

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 spills onto the soil.
- To avoid involuntary dispersion, once the sowing was finalized the remaining seeds were buried within the trial site.

- Before removing the machinery out of the field, it was checked that all the sowing cones had been cleaned.
- Competent Authorities were informed of the sowing dates in advance, and the plantings were executed under supervision or control by officials from the Competent Authority.
- A minimum of four lines of conventional maize were planted surrounding the trials, as pollen barrier.

6.1.3 During the period of release

- Trials have been monitored during the growing season, including visits by some experts and competent authorities. And the minimum isolation of 200 m from commercial maize fields was monitored. During these visits, and besides the observations described in the studies, it has been observed neither difference in the agronomic or environmental performance of NK603 x MON 810 varieties compared with the conventional ones, nor that the crop tends to turn into weed, or to invade non ag spaces.
- During the performed visits there was no observation of a different effect of genetically modified maize than the conventional maize on crop development, susceptibility to diseases or other pests, bees or other insects presence, birds or mammals occurrence. Therefore, it is suggested that the effect of the release on “non target” organisms”, on arthropofauna, or on the biodiversity in general has been similar to those caused by conventional maize.
- Pollen shed dates were notified in advance to the competent authorities.
- No incidences have been observed 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, which have been conducted under official supervision.
- Trials were harvested with a combine-harvester of cereals. The harvested grain was buried in an approximately 1,5-2,5 meter-deep pitch and 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 supervision of Monsanto’s technical staff.
- The trials crop residues were destroyed by tillage, chopped with an offset disc harrow and then, buried or ploughed up with moldboard.
- The combine and means of transport were cleaned before leaving the field.

6.1.5 Post harvest measures

The release site will be monitored during the year following the trials, and up to the maize flowering period, in order to destroy maize volunteers, if any. For this monitoring it is proposed to conduct one visit in winter and monthly visits during spring and summer, increasing the observations frequency during periods with higher probability of volunteers’ emergency.

The commercial crop planted in this field during the following season will be different from maize. This destruction and the restrictions for cultivation next year will no longer be necessary when the NK603 x MON810 event is authorized for cultivation in the European Union.

6.1.6 Other(s) measure(s) (Describe)

Not applicable.

6.1.7 Emergency plan(s)

All the biosafety measures planned to avoid accidental releases have been followed.

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 post release monitoring plan will start with the first visit for volunteers monitoring and elimination, if any.

According to the cases mentioned, please indicate the monitoring measures adopted

Please specify:

Monitoring measures within site

Trial plots will be visited during the following growing season to destroy the volunteer maize plants, if any. Three visits will be conducted, one by the end of winter season, one during spring, while development of a following crop, and a last one in summer.

Monitoring measures of adjacent areas

Surrounding areas to the trials will be visited during the following growing season to destroy the germinated volunteer plants, if any. Three visits will be conducted, one by the end of winter season, one during spring, while development of a following crop, and a last one in summer.

6.3 Plan for observation(s)/method(s) involved

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

6.4 Observed effect(s)

Unexpected effects were not observed

6.4.1 All results of the deliberate release(s) 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 MON810 maize plants performance were similar to conventional maize plants and no risks to human or animal health, or the environment, different from those of conventional maize were identified, confirming then the hypothesis advanced during the Environmental Risk Assessment.

6.4.2 Expected effect(s)

NK603 x MON810 maize plants developed normally and presented crop cycle and agronomic or environmental performance similar to their isogenic conventional maize counterparts.

6.4.3 Unexpected effect(s)

Unexpected effects were not observed

6.4.4 Other information

Not applicable

7. CONCLUSION

The deliberate release was carried out according to the notification proposal and in agreement with the conditions of consent in the Resolution of 20th April 2012 by the GMOs Interministerial Council, guaranteeing safety to human and animal health and the environment.

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

Trials have been executed as predicted. Performance of NK603 x MON810 maize has been similar to conventional maize and no negative effect on the human or animal health or on the environment has been detected during the trials execution. Results from the studies performed on the varieties with NK603 x MON810 will be submitted to the Spanish Variety Registration Office for their evaluation.