

**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/10/05

1.2 Member State of notification

Spain.

1.3 Date of consent and consent number

Region of Aragón: Resolution of March 26th, 2010 by the Regional Interdepartmental Commission on Genetically Modified Organisms.

Region of Castilla-La Mancha: Resolution of March 25th, 2010, by the Regional Biosafety Commission.

Region of Castilla y León: Order of April 15st, 2010 by the Regional Council of Environment.

Region of Cataluña: Resolution of March 23rd, 2010 by the Regional Directorate-General of Agriculture and Farming.

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-00603-6 x MON-00810-6

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
Grañén (Huesca)	1.914 m²	NK603 x MON 810 hybrids 8 plants/m²	Sowing: 18/05/2010 Destruction: 20/10/2010
Daimiel (Ciudad Real)	564 m²	NK603 x MON 810 hybrids 7-9 plants/m²	Sowing: 25/05/10 Destruction: 18/11/10
Olmedo (Valladolid)	639 m²	NK603 x MON 810 hybrids 7-9 plantas/m²	Sowing: 06/05/2010 Destruction: 17/11/2010
Alcarrás (Lleida)	1.914 m²	NK603 x MON 810 hybrids 8 plants/m²	Sowing: 20/05/2010 Destruction: 15/10/2010

Notes: According with the communication of 30 July 2010, trials initially foreseen in Tauste (Zaragoza) and Ejea de los Caballeros (Zaragoza), La Puebla de Montalbán (Toledo) and Calera y Chozas (Toledo), Dueñas (Palencia) and Molacillos (Zamora), were not planted because they did not meet the necessary isolation from fields of conventional maize, or any other conditions for the successful execution of trails.

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

Development and optimization of weeds management programs. Trials have been communicated to the correspondent plant protection authorities and were carried out by Monsanto's technical staff, who is officially accredited by EOR 7/96.

5.3 Official testing

Not applicable.

5.4 Herbicide authorisation

Not applicable.

5.5 Deliberate release(s) for demonstration purposes

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

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:

- It was confirmed a minimum isolation of 200 m or 250 m (Daimiel) 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 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 temporal seed storage before planting was needed, our facilities located in Los Palacios were used, which were authorized to carry out confined operations with GM organisms (N° 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.

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 in the soil.
- To avoid involuntary dispersion, 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 with anticipation, and the planting were conducted under supervision of officials or after the permit from the Competent Authorities.
- A minimum of four lines (Grañén and Alcarrás), eight lines (Olmedo) or twelve lines (Daimiel) of conventional maize were planted surrounding the trial, 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. 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 Daimiel (Ciudad Real) location, it was installed a mesh of approximately 1-meter height in the outer perimeter of the plot to protect the trials from possible predators.
- During the performed visits it has not been observed a different effect than the conventional corn 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 corn.
- 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 and they have been conducted under their 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 surveillance of Monsanto’s technical staff.
- The trials crop residues were destroyed with tillage, chopped with 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 maize volunteers. 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 MON 810 modification 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 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 are as safe as any conventional variety for human and animal health, or the environment.

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.

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.

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 MON 810 maize plants presented no risks to human or animal health, or the environment, different from those of conventional maize.

6.4.2 Expected effect(s)

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

In these trials, it has been confirmed the tolerance to glyphosate herbicide of NK603 x MON 810 maize plants.

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 March 26th, 2010 by the Aragón Interdepartmental Commission on Genetically Modified Organisms; Resolution of March 25th, 2010, by the Castilla-La Mancha Biosafety Commission; Order of April 15st, 2010 by the Castilla y León Council of Environment and Resolution of March 23th, 2010 by the Catalanian Directorate-General of Agriculture and Farming, 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. Behaviour of NK603 x MON 810 maize has been similar to conventional maize 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 x MON 810 maize offers an alternative more compatible for the biodiversity, using herbicide formulations classified without risk pictograms and with low environmental impact.