

**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/06/06

1.2 Member State of notification

Spain

1.3 Date of consent and consent numbers

Resolution of March 6th, 2006 by the President of the Spanish Inter-ministerial GMO 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 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

Geographical location(s) (administrative region and, where appropriate, grid reference)	Size of the release site(s) (NK603 maize event m ²)	Identity and approximate number of GM higher plants per event actually released	Duration of the release(s):
Almudévar (Huesca)	400 + 80 + 160= 640 m ²	NK603 hybrids ~7 plants /m ²	Sowing: 27 April 06 Destruction: 24 Oct 06
Grañen (Huesca)	400 + 80 + 160= 640 m ²	NK603 hybrids ~7 plants /m ²	Sowing: 4 May 06 Destruction: 19 Oct 06
Torres de Berrellén (Zaragoza)	400 + 80 + 160= 640 m ²	NK603 hybrids ~7 plants /m ²	Sowing: 3 May 06 Destruction: 24 Oct 06
Aranjuez (Madrid)	400 m ²	NK603 hybrids ~7 plants /m ²	Sowing: 12 junio 06 Destruction: 30 Nov 06
Maribáñez- Los Palacios – Utrera (Sevilla)	400 + 150 + 45= 595 m ²	NK603 hybrids ~7 plants /m ²	Sowing: 14 May 06 Destruction: 7 Oct 06
Carmona (Sevilla)	400 + 150 + 45= 595 m ²	NK603 hybrids ~7 plants /m ²	Sowing: 7 April 06 Destruction: 8 Oct 06
Villagonzalo (Badajoz)	400 m ²	NK603 hybrids ~7 plants /m ²	Sowing: 10 April 06 Destruction: 12 sept 06
Fuentes de Ropel (Zamora)	80 + 160= 240 m ²	NK603 hybrids ~7 plants /m ²	Sowing: 25 May 06 Destruction: 21 Nov 06
Toral de los Guzmanes (León)	80 + 160= 240 m ²	NK603 hybrids ~7 plants /m ²	Sowing: 25 May 06 Destruction: 22 and 23 Nov 06
Corese (Zamora)	80 + 160= 240 m ²	NK603 hybrids ~7 plants /m ²	Sowing: 24 May 06 Destruction: 23 Nov 06

Notes:

The site at Las Cabezas de San Juan (Sevilla) was not planted, because of lack of irrigation water, due to the drought.

Trials previously planned in this notification for Navarra were not planted, as the sites selected did not keep a-200-m-isolation distance.

Please, see the trial layout 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?

The EU has authorized NK603 maize import and consumption, according to Directive 2001/18/EC (Decision of the Commission on July 19th, 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 26th, 2004). The authorization for cultivation has been submitted according to Directive 2001/18/EC (C/ES/03/01) and EC Regulation 1829/2003 (EFSA-GMO-NL-2005-22)

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

Releases provide information to fulfil the data required by the Spanish Office of Plant Varieties regarding maize varieties derived of NK603, and whose register has been applied for. Therefore, it is necessary to carry out Identification trials under official supervision, as well as Agronomic Value Trials, in order to guarantee stability, homogeneity, distinctness and agronomic value of NK603 varieties compared to other varieties.

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. METHODS AND 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 sowing

- An isolation distance of minimum 200 m from other marketable maize crops was checked.
- Transgenic seed was 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 clean 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 50 cm-deep pitch within the trial site or they were kept in the original packages, properly resealed, 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, except for Villagonzalo (Badajoz). (Detailed information in the Annex enclosed)

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 on “non target” organisms, to the arthropofauna, or for biodiversity in general.
- Pollen shed dates have been previously notified to the competent authorities.
- 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). On the other hand, in several plots in Aranjuez, emergence was not homogeneous enough; therefore, trials were harvested but they will not be used for further analysis (see Annex enclosed).

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), except for Villagonzalo.
- Every material taken away from the site has been properly packed and labelled. Trials have been harvested with a cereal combine, except for 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 at 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 then transported in a trailer, being very careful to avoid any spillage and being watched by Monsanto's technical staff.
- The trials crop residues have been 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 have been 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 modification is authorised for cultivation in the European Union.

6.1.6 Other(s) measure(s) (please, describe)

Not relevant

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 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

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

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

General observations on plants health, illness sensitivity, plants development; furthermore, any unexpected and unusual characteristic were recorded.

6.4 Observed effects

No unexpected effect was 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.

Maize NK603 presented the same risk to human or animal health or the environment as conventional maize varieties.

6.4.2 Expected effects

NK603 maize plants developed normally and presented crop cycle and yields similar to their isogenic conventional counterparts.

Results were sent to the Spanish Office of Plant Varieties for further studies.

6.4.3 Unexpected effect(s)

No unexpected effect has been observed

6.4.4 Other information

Not appropriate

7. CONCLUSIÓN

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

NK603 hybrids behaved as expected. NK603 hybrids results were sent to the Spanish Office of Plant Varieties for evaluation.

Date: December 19th 2006

Signed: Juan Alvarado Aldea