

**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/08/09

1.2 Member State of notification

Spain.

1.3 Date of consent and consent number

Autonomous Region of Castilla La Mancha: Resolution of February 20th, 2008 by the Regional Biosafety Commission.

Autonomous Region of Castilla y León: Order of April 22st, 2008 by the Regional Directorate-General of Environment.

Autonomous Region of Cataluña: Resolution of March 19th, 2008 by the Regional Directorate-General of Agriculture and Farming.

Autonomous Region of Navarra: Resolution 1008 of May 20th, 2008 by the Regional Directorate-General of Environment & Water.

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

3.3 Unique identifier, if available

MON-00603-6

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
Yunquera de Henares (Guadalajara)	2.364 m²	NK603 hybrids 7-9 plants /m²	Sowing: 28/4/08 Destruction: 18/11/08
Calera y Chozas (Toledo)	2.400 m²	NK603 hybrids 7-9 plants /m²	Sowing: 29/4/08 Destruction: 20/11/08
Dueñas (Palencia)	4.000 m²	NK603 hybrids 7-9 plants /m²	Sowing: 13/6/2008 Destruction: 17/12/2008
Peñarandilla (Salamanca)	4.000 m²	NK603 hybrids 7-9 plants /m²	Sowing: 10/6/2008 Destruction: 18/12/2008
Gimenells (Lleida)	300 m²	NK603 hybrids 7-9 plants /m²	Sowing: 7/5/08 Destruction: 14/11/08
Alcarrás (Lleida)	4.320 m²	NK603 hybrids 7-9 plants /m²	Sowing: 6/6/08 Destruction: 20/11/08
Marcilla (Navarra)	2.213 m²	NK603 inbred lines 5 plants /m²	Sowing: 22-Abril Destruction: 19 Noviembre

*GM: genetically modified

Notes:

According with communication to Competent Authorities, trials initially foreseen in the Autonomous Region of Aragon (Tauste, Zuera, Grañén, Peñalba y Ejea de los Caballeros) and in other localities as La Gineta (Albacete), La Cisterniga (Valladolid), Coreses (Zamora), Santovenia de Pisuerga (Valladolid), Toral de los Guzmanes (León), Lleida and Gimenells (2) (Lleida) with NK603 maize, were not carried out, because they did not meet the necessary isolation from fields of conventional maize, any other conditions for the successful execution of trails, or due to trials adjustment, after fitting other notifications in suitable area.

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?

Importation and consumption of NK603 maize are authorized in the EU in accordance with Directive 2001/18/CE (Commission Decision of July, 19th 2004, OJEU of 19/09/04). The use of NK603 maize and its fractions has been also authorized in accordance with Regulation CE/258/97 (October 26th, 2004). Application for authorization of NK603 maize cultivation has been submitted in accordance with Directive 2001/18/CE (C/ES/03/01), and Regulation 1829/2003 (EFSA-GMO-NL-2005-22).

5. TYPE(S) OF DELIBERATE RELEASES

5.1 Deliberate releases for research purposes

Evaluation of agronomic performance of the genetically modified inbred lines (yield and germination capacity, plant vigour, plant height, flowering and morphology description of several characters) and comparison with the conventional parental lines (not genetically modified), from which they derive. The lines genetically modified more similar to the conventional equivalent ones, will be useful to obtain genetically modified hybrids.

5.2 Deliberate releases for development purposes

Evaluation of agronomic performance of genetically modified maize (including yield, germination capacity, plant vigour and plant height) and its comparative development with lines not genetically modified.

Development and optimization of weeds management programs.

5.3 Official testing

Not applicable.

5.4 Herbicide authorization

Efficacy and selectivity trials with glyphosate formulations, to get the necessary data for their registration by Spanish Authorities.

Application times have been communicated to the correspondent Competent Authority in each Autonomous Region. The trails were carried out by Monsanto's technical staff, who is officially recognized by EOR 7/96.

5.5 Deliberate releases for demonstration purposes

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

5.6 Seeds multiplication

Characterization, self-fertilization and selection of pure lines and hybrids, resultant of directed crossings.

5.7 Deliberate releases for biosafety/risk assessment research (Please, specify)

Study to confirm the safety for non target organisms.

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 inbred lines were packed and clearly labelled by qualified staff in our installations at the Investigation Center located in Peyrehorade (France) and authorized to carry out confined operations with GM organisms (N° 4593 6 April 2006 Commission de Genie Genetique, France).
- Seeds of NK603 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 (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, 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.
- Competent Authorities were informed of the sowing dates with anticipation, and the plantings were made under supervision of officials from the Competent Authority.
- The trials were surrounded by at least 6 lines of conventional maize (8 lines in Castilla y León and Cataluña locations), 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 a weed, or with higher susceptibility to pests or diseases than the conventional maize.
- In Yunquera de Henares (Guadalajara) and Calera y Chozas (Toledo), locations, to protect the trials of possible predators, it was installed a mesh of approximately 1-meter height in the exterior perimeter of the plot.
- 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. In the location of Marcilla (Navarra), technical staff, responsible of the trial, has done several visits and field work previously to flowering dates and at later dates.
- No incidences have occurred related to safety for human health and environment.

6.1.4 At the end of the release

- Authorities were informed on the harvesting dates, and the inspectors were present.
- All the samples taken have been tagged and bagged accordingly. The samples gathered for analytical purposes were closed hermetically and labelled in the trial field. All operations were carried out under standardized procedures, guaranteeing that they could not end up into the human or animal food chain. Harvesting of samples in Marcilla (Navarra) have been carried out under the supervision of the Competent Authority and in presence of inspectors. The transportation to the Investigation Center, in Peyrehorade (France), was made under chain of custody, which has been sent to the Competent Authority.
- All the trials have been harvested with a harvester of cereal. In Marcilla (Navarra), trials have been harvested with combine-harvester of cereals, modified with a mill to grind the grains and 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 maize volunteers. The commercial crop after ending the trials will not be maize. This destruction and the restrictions for cultivation next year will no longer be necessary when the NK603 modification will be authorized for cultivation in the European Union.

6.1.6 Other(s) measure(s)

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 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 maize plants presented no risk to human or animal health, or the environment different than those of conventional varieties.

6.4.2 Expected effects

NK603 maize plants developed normally and presented crop cycle and yields similar to their isogenic conventional counterparts. In the trials, it has been confirmed the tolerance to glyphosate herbicide of NK603 maize plants.

The results of efficacy and selectivity trials with glyphosate formulations will be used to support their registration by Spanish Authorities.

6.4.3 Unexpected effects

No unexpected effects were observed

6.4.4 Other information

Not applicable

7. CONCLUSION

The voluntary release was carried out in agreement with the measures proposed in the notification and established by the Competent Authorities from each Autonomous Region (Resolution of February 20th, 2008 by the Regional Biosafety Commission of Castilla-La Mancha, Order of April 22st, 2008 by the Regional Directorate-General of Environment of Castilla y León, Resolution of March 19th, 2008 by the Regional Directorate-General of Agriculture and Farming of Cataluña, and Resolution 1008 of May 20th, 2008 by the Regional Directorate-General of Environment and water of Navarra) guaranteeing safety to human or animal health, or to the environment.

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

Field trials were carried out as planned. Behaviour of NK603 maize hybrids was as predicted, 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 maize offers a more compatible alternative for the biodiversity, using herbicide formulations classified without pictograms and with low environmental impact.