

REPORT ON RESULTS

Notification B/ES/04/17

(In accordance with Annex XI of RD 178/2004, of 30th January)

1. GENERAL INFORMATION

1.1 European notification number

B/ES/04/17

1.2 Member State of Notification

Spain

1.3 Date of consent and consent number

4th March 2005 (number 2183).

2. REPORT STATUS

2.1 Please indicate whether, according to Article 3 of the present Decision, the current report is:

a **FINAL** post-release monitoring report

3. CHARACTERISTICS OF THE RELEASE

3.1 Scientific name of the recipient organism

Zea mays

3.2 Transformation events [acronym(s) or vector(s) used (if transformation event identity 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) (event NK603 m2)	Identity and approximate number of GM higher plants per event actually released	Duration of the releases
Maribañez (LosPalacios y Villafranca, Sevilla)	460 m2	NK603 hybrids ~7-8.5 plants /m2	Sowing: 14 April 2005 Destruction: 30 August 2005
Fuente Palmera (Cordoba)	460m2	NK603 hybrids ~7-8.5 plants /m2	Sowing: 15 April 2005 Destruction: 29 August 2005
Almudevar (Huesca)	320m2	NK603 hybrids ~7-8.5 plants /m2	Sowing: 3 May 2005 Destruction: 2 November 2005
Estadilla (Huesca)	320m2	NK603 hybrids ~7-8.5 plants /m2	Sowing: 25 April 2005 Destruction: 2 November 2005
Malpica (Toledo)	320m2	NK603 hybrids ~7-8.5 plants /m2	Sowing: 27 April 2005 Destruction: 6-7 October 2005
Buñuel (Navarra)	320m2	NK603 hybrids ~7-8.5 plants /m2	Sowing: 26 April 2005 Harvest: 25 October Destruction: see comments.

Comments

- Huerto (Huesca) was rejected because of non-sufficiently uniform irrigation.
- Torrijos was replaced by Malpica.
- This type of trial was not finally planted neither in Cisterniga (Valladolid) nor in Fuentes de Ropel (Zamora), as there was no hybrid of these cycles in the Commercial Variety Register of maize at the moment of sowing, although it was initially expected.
- Guadiana del Caudillo was rejected because the plot was not uniform enough.
- On October, 25th Buñuel's field was ploughed and harrowed. But crops and grains residues were not buried enough, so, as soon as the weather allows it, the field will be tilled again.

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?

An authorisation for placing on the market, including cultivation, in the European Union has been submitted.

5. TYPE(S) OF DELIBERATE RELEASES

5.1 Deliberate releases for research purposes

N/A.

5.2 Deliberate releases for development purposes

N/A.

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 compared to other varieties.

5.4 Herbicide authorization

N/A

5.5 Deliberate releases for demonstration purposes

N/A

5.6 Seeds Multiplication

N/A

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

N/A

5.8 Other type of deliberate releases

N/A

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 the sowing

- An isolation distance of minimum 200m has been checked.
- Genetically modified seeds were packed in two closed bags and were appropriately labelled by qualified staff.

6.1.2 During the sowing and planting

- Seeds were transported in closed bags and were managed in the trials 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, avoiding losses in the soil.
- To prevent any involuntary seed release, all the remaining seed bags have been buried in a 1 meter-deep pitch within the trial site. Before taking the sowing machine outside the crop area, the sowing cones were verified to be clean.
- Competent authorities have been informed on the sowing dates and their official staff members have checked the sowings.
- A minimum of 6-8 rows of maize free of this genetic modification has been sown around the trial sites, to act as a 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.
- Although specific counting has not been done, no negative effect has been observed in “non target” organisms, or in arthropofauna, or in biodiversity generally.
- Pollen shed dates have been notified.
- Incidences, if any, have been notified. The facts mentioned below referring to the trial of Malpica de Tajo are the only incidence worthy of mention:

07/09/05 – During a control visit, Monsanto technicians noticed two fields of sorghum (species incompatible with maize) at less than 200 m from the trials and a maize field at near 70-80 m of the GM maize trials. These fields seem to come from sowings in July 2005, when GM maize was at the beginning of the pollen shed period.

09/09/05 – Although pollen transference between GM maize to the conventional maize field seems impossible, the competent authorities were faxed and informed about it (National Biovigilance Committee and the autonomous government of Castilla-La Mancha, Junta de Castilla-La Mancha).

14/09/05 – Field visit with the Head of the Variety Register Service of the Spanish Office of Plant Varieties (Ministry of Agriculture, Fisheries and Food), during which the advanced ripeness state of GM field trials could be observed, whereas there was no evidence of ears with pollen-receiving silks in the nearby maize field.

16/09/05 – After reaching a compensation deal with the field owner, the conventional maize field sown at 70-80 m from the GM varieties trials was destroyed.

6.1.4 At the end of the release

- Authorities were informed on the harvesting dates, and they were present.
- Every material taken away from the site has been kept separately and clearly identifiable.
- Trials have been harvested with a cereal combine.
- The grains have been buried in an approximately 2,5 metre-deep pitch and has been covered with a minimum of 75 cm earth layer.
- The grains were transported to the pitch in the combine itself. If the ditch was far from the original site, the grain was then transported in a trailer.
- The trials crop residues have been destroyed with tillage, chopped (with a chopper, a land clearing machine 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.
- The same day of the harvest, samples were taken for germination and one thousand grains weight studies.

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, except for the detection, on September 7th, in Malpica (Toledo), of a maize silage field in second harvest, in the vicinity (around 75-80 m distant from the trial sites). After notifying it to the competent authorities, on September 9th, and having reached an agreement with the maize field's owner, the field was chopped and destroyed before pollen release and receiving silks appeared on September 16th.

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 confirm that NK603 maize plants present the same risk to human and animal health or the environment as any conventional varieties.

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

Please specify:

Monitoring measures within site

Field trials during the following growing season to destroy any germinated plants.

Monitoring measures in surrounding areas

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

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

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

6.4 Observed effect(s)

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 no risk to human or animal health or the environment.

6.4.2 Expected effect(s)

NK603 maize plants grew normally and presented a crop and yield cycles similar to their isogenic conventional counterparts. Results are 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

N/A

7. CONCLUSION

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 are sent to the Spanish Office of Plant Varieties for evaluation.

Date:

A handwritten signature in blue ink that reads "Juan Alvarado Aldea". The signature is written in a cursive style with a large, sweeping initial "J".

Signed: Juan Alvarado Aldea