

**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/12/05

**1.2 Member State of notification**

Spain.

**1.3 Date of consent and consent number**

Region of Aragón: Resolution of 20<sup>th</sup> April, 2012 by the Regional Interdepartmental Commission on Genetically Modified Organisms.

**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**

<b>Geographical location (s)</b> (administrative region and, where appropriate, grid reference)	<b>Size of the release site(s)</b> (m <sup>2</sup> )	<b>Identity and approximate number of GM higher plants per event actually released</b> (number of seeds/plants per m <sup>2</sup> )	<b>Duration of the release</b>
<b>Ejea de los Caballeros</b> <b>(Zaragoza)</b>	<b>360 m<sup>2</sup></b>	<b>NK603 hybrids</b> <b>8 plants/m<sup>2</sup></b>	<b>Sowing: 29/05/2012</b> <b>Destruction: 17/10/2012</b>

Notes: trials initially foreseen in Grañén (Huesca) 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 maize was approved for import, feed use and processing in the EU under Directive 2001/18/EC (Commission Decision 2004/643/EC). The food and food ingredients derived from NK603 were approved under Regulation (EC) No. 258/97 (Commission Decision 2005/448/EC). The application for cultivation of NK603 maize was submitted according to Dir 2001/18/CE (C/ES/03/01) and later under Regulation (EC) No. 1829/2003 (EFSA-GMO-NL-2005-22), and EFSA adopted a favourable scientific opinion on 29 May 2009.

#### **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**

Not applicable.

##### **5.4 Herbicide authorisation**

Not applicable.

##### **5.5 Deliberate release(s) for demonstration purposes**

Demonstrative trials for large-scale evaluation of varieties containing NK603 event.

##### **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 hybrids were packed in sealed bags and clearly labelled by qualified staff in our installations located in our research centre in Trebes

(France), authorized to carry out confined operations with genetically modified (GM) organisms (N° 4938, April 29<sup>th</sup> 2008, Ministre de l'Enseignement Supérieur et de la Recherche, France).

- 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 date in advance, and the planting were checked by officials from Aragon 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. During these visits, besides the observations described in the studies, it has been observed neither differences in the agronomic or environmental performance of NK603 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.
- The isolation from commercial maize fields was monitored as well and pollen shed date was 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 date, which has been checked by officials.
- Once the efficacy data from the different tested programs in this location were collected the maize plants were destroyed by chopping the maize plants and subsequent tillage by moldboard, which buried the plant residues.

#### **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 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. During winter, at least one visit will be performed and during spring and summer they will be conducted monthly.

##### ***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. During winter, at least one visit will be performed and during spring and summer they will be conducted monthly.

#### **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 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 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 20<sup>th</sup> April, 2012 by the Aragón Interdepartmental Commission on Genetically Modified Organisms, 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 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.