

**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/08/12

**1.2 Member State of notification**

Spain.

**1.3 Date of consent and consent number**

Autonomous Region of Cataluña: Resolution of March 19<sup>th</sup>, 2008 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)**

MON 89034 x NK603

**3.3 Unique identifier, if available**

MON-89034-3 x 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>	<b>Duration of the release</b>
Alcarrás (Lleida)	4.320 m <sup>2</sup>	MON 89034 x NK603 hybrids 7-9 plants /m <sup>2</sup>	Sowing: 6/6/08 Destruction: 20/11/08

\*GM: genetically modified

Notes:

According to the communication to Competent Authorities on 07/14/2008, trials initially foreseen in Aragón Region (Peñalba and Ejea de los Caballeros) and in two locations in Gimennells (Lleida) with MON 89034 x NK603 maize, were not carried out, after fitting them to those locations with more probability of appropriate isolation and successful execution.

#### **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?**

Application for authorization of MON 89034 x NK603 maize for food, feed, import and processing has been submitted in EU according with the Regulation 1829/2003 (EFSA-GMO-NL-2007-38).

#### **5. TYPE(S) OF DELIBERATE RELEASES**

**5.1 Deliberate releases for research purposes**

Not applicable.

**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.

**5.3 Official testing**

Not applicable.

**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)**

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 MON 89034 x 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 (Nº 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.
- The trials were surrounded by 8 lines of conventional maize, 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.
- 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.
- 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.
- 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.
- All the trials have been harvested with a harvester of cereal.
- 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 MON 89034 x 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 MON 89034 x 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.**

MON 89034 x 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**

MON 89034 x NK603 maize plants developed normally and presented crop cycle and yields similar to their isogenic conventional counterparts.

**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 Authority from Cataluña, Resolution of March 19<sup>th</sup>, 2008 by the Regional Directorate-General of Agriculture and Farming, 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 MON 89034 x 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.