

**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/07/03

**1.2 Member State of notification**

Spain.

**1.3 Date of consent and consent number**

Autonomous Region of Aragón: Resolution of March 9<sup>th</sup>, by the President of the GMO Interdepartmental Commission.

Autonomous Region of Castilla La Mancha: Resolution of March 1<sup>st</sup>, 2007 by the Regional Biosafety Commission.

Autonomous Region of Castilla y León: Order of May 21<sup>st</sup>, 2007 by the Regional Directorate-General of Environmental Quality.

**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 MON 88017

**3.3 Unique identifier, if available**

MON-89Ø34-3 x MON-88Ø17-3

### 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 <sup>2</sup> )	Identity and approximate number of GM* higher plants per event actually released	Duration of the release
Almudévar (Huesca)	159 m <sup>2</sup>	MON 89034 x MON 88017 7-8 plants /m <sup>2</sup>	Sowing: April 24, 2007 Destruction: Oct 31, 2007
Grañén (Huesca)	159 m <sup>2</sup>	MON 89034 x MON 88017 7-8 plants /m <sup>2</sup>	Sowing: April 27, 07 Destruction: Oct 31, 2007
Tauste (Zaragoza)	159 m <sup>2</sup>	MON 89034 x MON 88017 7-8 plants /m <sup>2</sup>	Sowing: May 9, 2007 Destruction: Oct 30, 2007
Malpica de Tajo (Toledo)	159 m <sup>2</sup>	MON 89034 x MON 88017 7-8 plants /m <sup>2</sup>	Sowing: April 23, 2007 Destruction: Oct 22, 2007
Fuentes de Ropel (Zamora)	159 m <sup>2</sup>	MON 89034 x MON 88017 7-8 plants /m <sup>2</sup>	Sowing: June 6, 2007 Destruction: Dec 6, 2007
Toral de los Guzmanes (León)	159 m <sup>2</sup>	MON 89034 x MON 88017 7-8 plants /m <sup>2</sup>	Sowing: June 5, 2007 Destruction: Dec 5, 2007

\*GM: genetically modified

Notes:

Trials initially foreseen in *Ejea de los Caballeros (Zaragoza)*, *Porzuna (Ciudad Real)*, *Buñuel (Navarra)* and *Ribaforada (Navarra)* were not carried out, because it did not exist warranties in the necessary isolation from fields of conventional maize. Trials initially planned in *Coreses (Zamora)* were not conducted, because localities described above completed the number of sites needed for the trials program planned.

See the trials layout in the Annex.

## 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?

Yes. Application for authorization of import and use as food, feed or processing of MON 89034 x MON 88017 GM maize has been submitted in the EU in accordance with Regulation 1829/2003 (EFSA-GMO-NL-2007-39).

## 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, yield and germination capacity, plant vigour, plant height.

Protein expression and composition analysis in different plant tissues, at different growing stages.

Herbicides residue analysis in different plant tissues.

Trials destined to advance in the agronomic characterization of MON 89034 x MON 88017 maize, and its comparative development with lines not genetically modified.

These trials have been carried out in collaboration with Agrisearch Ibérica S.L., authorised to conduct trials under GLP accreditation (3/BPL03) and officially recognized testing with agrochemicals (EOR 35/98).

### ***5.3 Official testing***

Not applicable.

### ***5.4 Herbicide authorization***

Efficacy and selectivity trials with glyphosate formulations, to get the necessary data for registration by the Spanish Ministry of Agriculture.

Application times have been communicated to the correspondent Autonomous Region, and were carried out in collaboration with Agrisearch Iberica S.L., authorised to conduct trials under GLP accreditation (3/BPL03) and officially recognized testing with agrochemicals (EOR 35/98).

### ***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 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 hybrids with MON 89034 x MON 88017 have been 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). Each pack of seeds corresponded to a row of a single plot.
- 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 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.
- Trials were sown with sowing machinery modified for trials sowing and microplots, which self-cleans itself from one plot to another, keeping the ducts empty, avoiding seeds mixing.
- Remaining seed were buried in at least a 0.5 meter-deep pitch within the trial site.
- Before extracting the machinery out of the field, it was checked that all the sowing cones were cleaned.
- Competent authorities were informed of the sowing dates with anticipation, and the sowings were made under supervision of officials from the competent authority.
- The trials were surrounded by at least 6-8 lines of conventional maize, as pollen barrier.

#### ***6.1.3 During the period of release***

- The isolation of 200 m of the trials respect of other maize fields was verified during all the growing season.
- 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 trends to turn into weed, or with major susceptibility to pests and diseases that the conventional maize.
- In *Malpica de Tajo (Toledo)* location, 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 have been notified in advance to the competent authorities.
- According to the study protocol, male and female inflorescences from plants used in a self-pollination trial were bagged before flowering, while the male inflorescences were removed from plants of rows not used for this trial.
- 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 of all the fields, and the inspectors were present (see Records and photos of harvesting and destruction in the Annex enclosed).
- All the samples taken have been tagged and bagged accordingly. The samples gathered for analytical purposes were pocketed hermetically and labelled in the trial field. All operations have been carried out under standardized procedures and GLP certification.

- Trials have been harvested with combine-harvester of cereals, modified with a mill to grind the grain and to annul its viability.
- The remaining grain (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 have been destroyed with tillage, chopped (with a chopper, or an offset disc harrow) and then, buried or ploughed up with several blades passes.
- In trials located in *Malpica de Tajo (Toledo)*, general tillage to destroy and bury the crop residues were completed with additional blades passes, to ensure the buried of the remains, after verifying that in a part of the field (not harvested and ploughed directly by the farmer) some ear maize residues remained in the surface.
- 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. The commercial crop after ending the trials period will not be maize.

#### **6.1.6 Other(s) measure(s) (Describe)**

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 MON 88017 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 MON 88017 maize plants presented no risk to human or animal health or the environment.

***6.4.2 Expected effects***

MON 89034 x MON 88017 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**

Field trials were carried out as planned and in agreement with the conditions of consents.

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

Behaviour of MON 89034 x MON 88017 maize hybrids was as predicted, and it has not been observed any negative effect on the human or animal health, or on the environment, then it is considered to be as safe as conventional maize varieties.

The measures proposed in the notification and the adopted measures have been consistent with the respect to the environment, to guarantee its safety as well as the human health.

Date: January 28<sup>th</sup>, 2008.