

**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/10/06

**1.2 Member State of notification**

Spain.

**1.3 Date of consent and consent number**

Region of Aragón: Resolution of March 26<sup>th</sup>, 2010 by the Regional Interdepartmental Commission on Genetically Modified Organisms.

Region of Cataluña: Resolution of March 23<sup>rd</sup>, 2010 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

**3.3 Unique identifier, if available**

MON-89Ø34-3

### **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>Grañén (Huesca)</b>	<b>154 m<sup>2</sup></b>	<b>MON 89034 hybrids</b> <b>8 plants/m<sup>2</sup></b>	<b>Sowing: 18/05/2010</b> <b>Destruction: 20/10/2010</b>
<b>Ejea de los Caballeros (Zaragoza)</b>	<b>154 m<sup>2</sup></b>	<b>MON 89034 hybrids</b> <b>8 plants/m<sup>2</sup></b>	<b>Sowing: 20/04/10</b> <b>Destruction: 18/10/10</b>
<b>Alcarrás (Lleida)</b>	<b>154 m<sup>2</sup></b>	<b>MON 89034 hybrids</b> <b>8 plants/m<sup>2</sup></b>	<b>Sowing: 20/05/2010</b> <b>Destruction: 15/10/2010</b>

Notes: According with the communication of 30 July 2010, trials initially foreseen in Tauste (Zaragoza) were not planted because they did not meet the necessary isolation from fields of conventional maize, or any other conditions for the successful execution of trails.

### **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?**

MON 89034 maize was approved for import, feed and food use and processing in the EU under Regulation (EC) No. 1829/2003 (Commission Decision 2009/813/EC).

### **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**

Agronomic characterization of MON 89034 maize and efficacy evaluation against corn borers.

#### **5.3 Official testing**

Not applicable.

#### **5.4 Herbicide authorisation**

Not applicable.

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

Not applicable.

#### **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:**

- It was confirmed a minimum isolation of 200 m from other commercial maize fields.
- Seeds of MON 89034 hybrids were packed and clearly labelled by qualified staff in our installations located in our research centre in Peyrehorade (France), authorized to carry out confined operations with genetically modified (GM) organisms (N° 4593, April 6<sup>th</sup> 2006, Commission de Genie Genetique, France).
- 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.

#### **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 in the soil.
- To avoid involuntary dispersion, 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 dates with anticipation, and the planting were conducted under supervision of officials or after the permit from the Competent Authorities.
- A minimum of four lines of conventional maize were planted surrounding the trial, 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 the visits, besides the observations described in the studies, it has not been observed that the crop tends to turn into weed, or with higher susceptibility to pests and diseases than the conventional maize.
- During the performed visits it has not been observed a different effect than the conventional corn 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 corn.

- Pollen shed dates were 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 dates and they have been conducted under their supervision.
- Trials were harvested with a combine-harvester of cereals. The harvested grain was buried in an approximately 1,5-2,5 meter-deep pitch and 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 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 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 MON 89034 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 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 maize plants are as safe as any conventional variety for human and animal health, or the environment.

*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.

#### ***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.

#### ***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.***

MON 89034 maize plants presented no risks to human or animal health, or the environment, different from those of conventional maize.

#### ***6.4.2 Expected effect(s)***

MON 89034 maize plants developed normally and presented crop cycle and performance similar to their isogenic conventional 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 March 26<sup>th</sup>, 2010 by the Aragón Interdepartmental Commission on Genetically Modified Organisms and Resolution of March 23<sup>th</sup>, 2010 by the Catalanian Directorate-General of Agriculture and Farming, 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. Behaviour of MON 89034 maize has been similar to conventional maize and it has not been observed any negative effect on the human or animal health, or on the environment.