

**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/07/01

1.2 Member State of notification

Spain.

1.3 Date of consent and consent number

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

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

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

Autonomous Region of Cataluña: Resolution of February 12th, 2007 by the Regional Directorate-General of Agriculture, Livestock and Innovation.

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

Geographical location (s) (administrative region and, where appropriate, grid reference)	Size of the release site(s) (m ²)	Identity and approximate number of GM* higher plants per event actually released	Duration of the release
Almudévar (Huesca)	375 m ²	Hybrids with MON 89034 7-8 plants /m ²	Sowing: April 23, 2007 Destruction: Oct 31, 2007
Grañén (Huesca)	375 m ²	Hybrids with MON 89034 7-8 plants /m ²	Sowing: April 27-28, 07 Destruction: Oct 31, 2007
Tauste (Zaragoza)	135 m ²	Hybrids with MON 89034 7-8 plants /m ²	Sowing: May 9, 2007 Destruction: Oct 30, 2007
Bujaraloz (Zaragoza)	240 m ²	Hybrids with MON 89034 7-8 plants /m ²	Sowing: May 9, 2007 Destruction: Oct 25, 2007
Malpica de Tajo (Toledo)	135 m ²	Hybrids with MON 89034 7-8 plants /m ²	Sowing: April 23, 2007 Destruction: Oct 22, 2007
Tarazona de la Mancha (Albacete)	240 m ²	Hybrids with MON 89034 7-8 plants /m ²	Sowing: May 7, 2007 Destruction: Nov 28, 2007
Toral de Los Guzmanes (León)	135 m ²	Hybrids with MON 89034 7-8 plants /m ²	Sowing: June 5, 2007 Destruction: Dec 5, 2007
Fuentes de Ropel (Zamora)	135 m ²	Hybrids with MON 89034 7-8 plants /m ²	Sowing: June 6, 2007 Destruction: Dec 6, 2007
Gimenells (Lleida)	240 m ²	Hybrids with MON 89034 7-8 plants /m ²	Sowing: May 16, 2007 Destruction: Oct 26, 2007

*GM: genetically modified

Notes:

Trails initially foreseen in *Ejea de los Caballeros (Zaragoza)*, *Porzuna (Ciudad Real)*, *Bell-Lloch d'Urgell (Lleida)*, *Albesa (Lleida)*, *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 GM maize has been submitted in the EU in accordance with Regulation 1829/2003 (EFSA-GMO-NL-2007-37).

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.

Trials destined to advance in the agronomic characterization of MON 89034 maize, and to evaluate its efficiency against lepidopterous of agronomic importance.

Some trials have been carried out in collaboration with Agrisearch Ibérica S.L., under GLP accreditation (3/BPL03).

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)

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 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).

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 lost in the soil.

- To avoid involuntary dispersion, remaining seed 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 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.
- 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)* and *Tarazona de la Mancha (Albacete)* locations, 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.
- No incidences have occurred related to safety for human health and environment. As unique agronomic incident, it must be mentioned a breakdown in the irrigation system in *Tarazona de la Mancha (Albacete)*, that cause a lack of homogeneity in the development of the crop and disabled the evaluation of efficacy in the trials that were placed in this location.

6.1.4 At the end of the release

- Authorities were informed on the harvesting dates, 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 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 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 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 maize plants presented no risk to human or animal health, or the environment.

6.4.2 Expected effects

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

The proposed measures 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 28th, 2008.