

**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/06/03

1.2 Member State of notification: Spain

1.3 Date of consent and consent number:

- Autonomous Region of Aragon: Resolution of April 18th by the President of the GMO Interdepartmental Commission.
- Autonomous Region of Castilla La Mancha: Resolution of March 23rd, 2006 by the Regional Biosafety Commission.
- Autonomous Region of Castilla y Leon: Order of May 16th, 2006 by the Regional Counselor of the Environment.
- Autonomous Region of Madrid: Resolution of May 25th, 2006, by the Director-General for Agriculture and Rural Development.
- Autonomous Region of Navarra: Resolution 0826 of April 4th, 2006, by the Director-General for the Environment

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 vectors used (if transformation event identity not available): MON 88017 x MON 810.

3.3 Unique identifier, if available.

MON-88017-3 x MON-00810-6

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) (m²)	Identity and approximate number of GM higher plants per event actually released (number of seeds)	Duration of the release(s): (from...(day/month/year) to...(day/month/year)
Grañén (Huesca)	Area with GM plants*: 154 m ²	MON 88017 x MON 810 maize (1470 seeds)	From 04/05/2006 to 19/10/2006
Torres de Berrellén (Zaragoza)	Area with GM plants*: 154 m ²	MON 88017 x MON 810 maize (1470 seeds)	From 03/05/2006 to 24/10/2006
Malpica de Tajo (Toledo)	Area with GM plants*: 154 m ²	MON 88017 x MON 810 maize (1470 seeds)	From 28/04/2006 to 21/09/2006
Toral de los Guzmanes (León)	Area with GM plants*: 154 m ²	MON 88017 x MON 810 maize (1470 seeds)	From 25/05/2006 to 23/11/2006
Fuentes de Ropel (Zamora)	Area with GM plants: 154 m ²	MON 88017 x MON 810 maize (1470 seeds)	From 25/05/2006 to 21/11/2006
Aranjuez (Madrid)	Area with GM plants*: 154 m ²	MON 88017 x MON 810 maize (1470 seeds)	From 12/06/2006 to 30/11/2006

*GM: genetically modified

The locations selected in Navarra were not sown, as it was found out that maize was planted, or was intended to be planted, in plots closer than 200 m.

See the trial layout in the Annex.

4 ANY KIND OF PRODUCTS 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 No Unknown, to date

If yes, indicate the country(ies) of notification: An authorization for import and use as food, feed or processing in the EU has been submitted at the Czech Republic.

If yes, specify for which use(s):

- Import
- Cultivation (seeds/planting material production)
- Food
- Feed
- Pharmaceutical use (or processing for pharmaceutical use)
- Processing for
 - Food use
 - Feed use
 - Industrial use

5 TYPE(S) OF DELIBERATE RELEASES

5.1 Deliberate releases for research purposes

5.2 Deliberate releases for development purposes

- Evaluation of agronomic performances, yield capacity, germination capacity, plant vigour, plant height.
- Determination of the expression of proteins and the composition in different plant tissues, at different growing stages.
- Determination of the level of residues of several herbicides, in different plant tissues.
- Others (Describe): Additional data taken on genetically modified maize, including its comparative development with non-genetically modified inbred.

Trials have been carried out in collaboration with Agrisearch Ibérica S.L., authorised to undertake GLP trials (05/3/BPL03).

5.3 Official testing

- Variety registration on a national catalogue
 - DUS (= Distinctness, Uniformity and Stability)
 - VCU (= Value of Cultivation and Use)
- Others (Specify)

5.4 Herbicide authorization

Two trials were carried out with several herbicides, and they were reported to the correspondent competent authority with the following codes AF/10287/ME/9 and AF/10288/ME/9 (Autonomous Region of Aragon), AF/10287/ME/7 and AF/10288/ME/7 (Autonomous Region of Castilla La Mancha), AF/10287/ME/14 and AF/10288/ME/14 (Autonomous Region of Castilla y Leon) and AF/10287/ME/10 and AF/10288/ME/10 (Autonomous Region of Madrid). These trials were carried out in collaboration with the company Agrisearch Ibérica S.L., authorised to undertake GLP trials (05/3/BPL03) and trials with officially accredited plant protection products (EOR 35/98).

5.5 Deliberate release(s) for demonstration purposes

5.6 Seeds multiplication

5.7 Deliberate releases for biosafety/risk assessment research

Vertical gene transfer studies

Out-crossing with conventional crops

Out-crossing with wild relatives

Horizontal gene transfer studies (gene transfer to micro-organisms)

Management of volunteers

Potential changes in persistence or dispersal

Potential invasiveness

Potential effects on target organisms

Potential effects on non-target organisms

Observation of resistant parents

Observation of resistant insects

Others (Describe)

5.8 Other types of deliberate releases

6 METHOD(S), RESULT(S) OF THE RELEASE, MANAGEMENT AND MONITORING MEASURES IN RESPECT OF ANY RISK TO HUMAN HEALTH AND THE ENVIRONMENT

6.1 Risk management measures

6.1.1 Before the sowing/plantation activities

- Clear labelling of the GM seeds batches/planting material. Each GM seed was stored in a closed paper bag, and it was labelled with its correspondent identification. Each paper bag corresponded to an elemental plot row.
- Segregation during the processing and transport of the seeds/planting material: seeds were transported to the field 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. To avoid confusion or seeds mixing, the bags were opened sequentially, so that one paper bag was opened when the previous one had been placed in the sowing machine.
- Destruction of surplus seeds/planting material: All seeds prepared for the trial were placed in the sowing cones, following the previously detailed process.
- Temporal isolation
- Rotation
- Others (specify): Before sowing, it was determined that the plot isolation was appropriate, and that no other maize crop was closer than 200 m from the trial.

6.1.2 During the sowing/planting activities

- Method of sowing/planting: trials were sown with a special planter for trials sowing and micro plots; this machine self-cleans itself from one plot to another, keeping the ducts empty, avoiding seeds to be mixed.

- Emptying and cleaning of the sowing/planting machinery on the field of release. At the end of each elemental plot, the seeds deposits and the ducts were emptied; the potential seed mixing was therefore avoided.
- Segregation during sowing/planting: All seeds were kept in individual paper bags, properly identified. As explained above, a paper bag was not open until the previous seed was placed in the machine: it was not possible to mix seeds from two different paper bags.
- Others: Only authorised Monsanto people could access the trial seeds. The planter's ducts and deposits were cleaned after sowing the trial, to avoid any seed remaining could leave the trial area. Monsanto's technical staff re-packed the remaining seeds, properly labelled them and transported them to the original warehouse.

6.1.3 *During the release period*

- Isolation distance(s) (metres)
 - From sexually compatible commercial plant species: an isolation distance of more than 200 m was kept from others maize crops.
 - From sexually compatible wild relatives
- Border(s) rows: at least 6 rows of non-genetically modified maize of the same maturity were sown surrounding each trial. At the end of the release, these non-GM maize rows were chopped like the rest of the trial.
- Cage/net/fence/signpost: In the plot of Malpica de Tajo, to avoid the entrance of wild animals into the trial, all the field was surrounded with an about 1-m high net.
- Pollen trap: Surrounding each trial, at least 6 rows of non-genetically modified maize of the same maturity were sown, to act as pollen traps. At the end of the release, these non-GM maize rows were chopped like the rest of the trial.
- Removal of GM inflorescences before flowering.
- Removal of volunteers/wild relatives/ hybrid collaborators
- Others: According to the study protocol, male and female inflorescences from some plants were bagged before flowering (self pollinated plants), while the male inflorescences were removed in other plants.

6.1.4 *At the end of the release*

- Destruction/harvest methods (of crop or part of it)/other means: In each site, the kernels were harvested, weighted and buried in soil at least at 0,5 m depth. The crops debris were chopped and incorporated into the soil. During the season, no viable samples of several tissues were taken for analytical purposes as well as some grain samples at harvest time. The samples were hermetically packed in a double package, properly labelled and watched over while transported to authorized laboratories to be analysed, and then destroyed according to certified GLP procedures. All the crops debris but samples for the analyses, were incorporated into the soil.
- Harvest/destruction before seeds maturity
- Effective removal of plant parts
- Segregated storage and transport of crops/debris: Samples for analytical purposes were hermetically packed and labelled at the trial site. Every action was done following standard and certified GLP procedures.
- Clean up of machinery on the release site. Every machinery tool used in any stage from harvest to destruction was carefully cleaned at each trial site.
- Destination of the debris, treatment of waste/surplus yield/crop debris: harvested grains were buried in soil at least at 0,5-m-depth in each trial site. Waste plants were destroyed, chopped and incorporated in the soil at the end of the trial.

- Post-harvest treatment and cultivation measures on the release site: at the end of the trial, crop waste was chopped and incorporated in the soil.
- Other(s):

6.1.5 *Post-harvest measures*

The trial field will be visited during the following growing season to check marketable maize has not been planted, and to destroy any undesired volunteers.

- Subsequent crop: any crop different from marketable maize
- Crop rotation: the following year any crop (except marketable maize) will be grown.
- Fallow/no crop
- Superficial soil work/no deep ploughing
- False-sowing beds
- Control of volunteers: In the season following the trial, each trial field will be visited to check any maize volunteer in the subsequent crop.
- Appropriate chemical treatment(s) (specify)
- Appropriate soil treatment(s) (specify)
- Others: In case of volunteers in the field, they will be destroyed mechanically or chemically; the most appropriate means will be chosen according to the kind and number of volunteers observed in the field.

6.1.6 *Other(s) measure(s) (specify)*

6.1.7 *Emergency plan(s)*

Indicate:

- a) If the release proceeded as planned:
 - Yes
 - No
- b) If measures according to the emergency plan(s) [article 23.2.a) 6° of Regulation and Annex V B] should be adopted
 - No
 - Yes

6.2 **Post-release monitoring measures**

The destruction of the trials was made on the dates indicated in 3.4 (see details in the Annex enclosed). The post-release monitoring plan will start once trials are harvested and destroyed, and will last until the following maize growing season.

Specify:

- Monitoring measures within the release site
 - Duration: trial fields will be visited during the following growing season to detect and destroy any maize volunteer.
 - Control of volunteers: regular visits, more frequent if some volunteers are detected and destroyed

- Monitoring measures in adjacent areas: adjacent areas to the trial field will be visited during the subsequent season, to destroy potential maize volunteers, if any.

6.3 Plan for observation(s)/method(s) involved (s)

Different parameters on the agronomic behaviour of plants have been observed and registered. Different herbicide formulations have been applied and the treated plants response has been observed visually.

6.4 Observed effect(s)

No unexpected effects have been 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 88017 x MON 810 maize plants do not pose any risk to human or animal health, or the environment different from those of conventional varieties.

6.4.2 Expected effects

MON 88017 x MON 810 maize plants developed normally and presented a crop and yield cycle similar to their isogenic conventional maize counterparts.

6.4.3 Unexpected effects

Neither damage nor any kind of negative effects that could impact or have an effect on human health or the environment were observed.

6.4.4 Other information

None

7 CONCLUSION

Field trials were carried out as planned.

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

No negative effects of any kind have been observed that has or could have effects on the human health or the environment; therefore, MON 88017 x MON 810 maize is considered to be as safe as conventional maize varieties.

No risks different from those of conventional varieties for human health or the environment have been identified as a result of the deliberate release of genetically modified maize in these trials.

The measures proposed in the notification and the control measures are consistent with the purpose of being friendly with the environment, and guarantying the safety of the environment and human health.

DATE: December 18th, 2006.

Signed: Concepción Novillo
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Monsanto Agricultura España S.L.

Signed: Gonzalo Valencia
Trials Co-ordinator
Agrisearch Ibérica S.L.