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/08/33**
1.2	Member State of notification: **SPAIN**
1.3	Date of consent and consent number: **04/04/08**
2.	**Report status**
2.1	Please indicate whether, according to Article 3 of the present Decision, the current report is

– ☒ **The final report**

– A post-release monitoring report

– ○ Final ○ Intermediary

3.	**Characteristics of the release**
3.1	Scientific name of the recipient organism: ***Zea Mays***
3.2	Transformation event(s) (acronym(s)) or vectors[1] used (if transformation event identity not available) **MIR604 maize**
3.3	Unique identifier, if available: **SYN-IR604**

[1] In the case of small scale field trials where several lines may be tested, the vectors used should be mentioned, which gives insight into the introduced traits and/or genetic elements. In the case of large(r) scale trials, the number of events notified is limited to only one or a few events.

3.4 Please provide the following information as well as the field(s) lay-out:

Geographical location(s) (administrative region and, where appropriate, grid reference)	**Size of the release site(s)**[2]	**Identity**[3] **and approximate number of GM higher plants per event actually released** (number of seeds/plants per m²)	**Duration of the release(s)** (from……*(day/month/year)*……until……*(d/m/y)*……)
Bellpuig-1 (Lleida)	550 m^2	~ 7 plantas/m²	31/05/08 - 12/11/08
Lleida-1 (Lleida)	550 m^2	~ 7 plantas/m²	23/05/08 - 07/11/08
Lleida-2 (Lleida)	1100 m^2	~ 7 plantas/m²	30/05/08 - 14/11/08
Alpera (Albacete)	550 m^2	~ 7 plantas/m²	28/05/08 - 12/12/08

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(s) at a later stage?

☒ **Yes** ☐ No ☐ Unknown to date

If yes, indicate the country(-ies) of notification :

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If yes, specify for which use(s):

- ☒ Import
- ☒ Cultivation (e.g. Seed/planting material production)
- ☒ Food
- ☒ Feed
- Pharmaceutical use (or processing for pharmaceutical use)
- ☒ Processing for :
  - ☒ Food use
  - ☒ Feed use
  - ☒ Industrial use
- Others (specify):

5. Type(s) of deliberate release(s)

Please select the main type(s) (in boxes) as well as sub-type(s) of the release(s). In the case of multi-sites, multi-events and/or multi-annual release(s), please provide a general overview of the type(s) of deliberate release(s) which has/have been carried out for the full duration of the consent. Please tick the appropriate type(s):

5.1 Deliberate release(s) for research purposes ☐

[2] Specify the size of the GM area and, where appropriate, the size of the non-GM area (e.g. non-GM border).

[3] Vectors used.

5.2	Deliberate release(s) for development purposes	☒

- Event screening
- Proof of concept[4]
- ☒ Agronomic performances (Specify): **Agronomic and phenotypic characteristics of maize event GA21; analyses of grain composition and protein expression.**
- ☒ Improved agronomic properties (Specify): ***Diabrotica* spp. Resistance.**
- Improved qualitative properties (prolonged shelf-life, enhanced nutritional value, modified composition, etc) (Specify)
- Stability of the expression
- Multiplication of lines
- Hybrid vigour study
- Molecular farming[5]
- Phyto-remediation
- Others (Describe)

5.3	Official testing	☒

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

5.4	Herbicide authorisation	☐

5.5	Deliberate release(s) for demonstration purposes	☐

5.6	Seeds multiplication	☐

5.7	Deliberate release(s) 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 relatives
- Observations of resistant insects
- Others (Describe)

5.8	Other(s) type(s) of deliberate release(s):	☐

[4] E.g. testing the new trait under environmental conditions.

[5] '*Molecular farming'* means the production of substances (for instance, proteins, pharmaceuticals) by plants, which have been genetically modified for a particular trait. '*Molecular farming'* could be defined as well as the production of plant-synthesised pharmaceuticals, plant-made pharmaceuticals, plant-based proteins production, etc.

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)

Please report the risk management measures, which have been used to avoid or minimise the spread of the GMO(s) outside the site(s) of release, and in particular those measures

- which were not originally notified in the application,
- which were applied in addition to the conditions in the consent,
- which the consent required only under certain conditions (e.g. dry periods, flooding),
- for which the consent allowed the notifier a choice among different measures.

Tick the examples where appropriate:

6.1.1 Before the sowing/planting:

- ☒ Clear labelling of the GM seeds/planting material lots (distinct from other seeds/tubers/etc):

  Seeds were packed in small paper bags, which remained closed until planting. Each paper bag was clearly labelled with the test entry code comparable to the code in the protocol. Each small paper bag contained the seed for one plot.
  All the paper bags composing a trial were contained into a sealed and labelled box.

- ☒ Segregation during the processing and transport of the seed/planting material (describe the method involved; provide example(s) of containment to prevent spillage during the processing and transport):

  Seeds were transported in a triple package and were managed in the trials by qualified staff. Transport of the seeds to the field was done on the day of planting.

- ☒ Destruction of superfluous seeds/planting material (Describe the method involved):

  All the prepared seeds were used for the planting, therefore there were no superfluous seeds.

- Temporal isolation (Specify)
- Rotation (Specify the previous crop(s))
- Other(s) (Specify)

6.1.2 During the sowing/planting activities:

- ☒ Method of sowing/planting:

  Sowing was carried out with a micro plot field trial planting machine.

- ☒ Emptying and cleaning of the sowing/planting machinery on the field of release:

  All equipment used to seed was free of plant material before entering the trial site. After sowing, all the equipment used for planting was cleaned on the trial site to eliminate unintended transport of any seed or plant materials from the trial site.

  Any residual seed recovered during the process of cleaning field equipment was rendered non-viable by deep burial into the soil of the trial.

- ☒ Segregation during the sowing/planting (Provide example(s) of containment to prevent spillage during the sowing/planting):

  The planting procedure with individual plot seed bags avoids seed mixing during planting operation. The micro-plot field trial planter recovers in a dedicated device all the seeds eventually non-planted in each plot.

– Other(s) (Specify)

6.1.3 During the period of release:

- ☒ Isolation distance(s) (x metres) from sexually compatible plant species, both wild relatives and crops:

  A distance of at least 200/220 m from other maize fields isolated all the fields from sexually compatible plant crops.

- ☒ Border row(s) (with the same crop or a different one, with a non-transgenic crop, x metres, etc):

  A border of at least 8 rows of conventional maize surrounded all the fields.

– Cage/net/fence/signpost (Specify)

- ☒ Pollen trap (Specify):

  The border of conventional maize plants acts as pollen trap.

– Removal of GM inflorescences before flowering (Indicate the frequency of the removal)
– Removal of bolters/relatives/hybrid partners (Indicate the frequency of the removal, x metres around the GM field, etc*)*

- ☒ Other(s) (Specify):

  Trials have been monitored on several dates during the growing season, and have been visited by some experts and competent authorities.

6.1.4 At the end of the release:

- ☒ Harvest/destruction methods (of crop or parts of it)/other means (e.g., sampling and analysis of sugar beet pulp). (Describe):

  Harvest was done with an experimental combine, which provides data automatically on grain yield and moisture. The harvested grain remains contained inside the combine until the end of the operation.

  All the harvested grain was buried inside the field trial area.

  All the remaining plant material after harvest was ploughed and incorporated into the soil.

– Harvest/destruction before the ripeness of the seeds
– Effective removal of plant parts
– Segregated storage and transport of crop/waste (Provide example(s) of containment to prevent spillage of collected seeds/crops/wastes).

- ☒ Clean up of machinery on the release site:

  The combine and all the equipment used for harvesting and plant material destruction were cleaned before leaving the field trial area.

- ☒ **Destination** of the waste, treatment of waste/surplus yield/plant residues (Describe):

  All the remaining plant materials were destroyed and incorporated into the soil.

- ☒ Post-harvest treatment and cultivation measures on the release site (Describe the method(s) for preparing and managing the release site at the end of the release, including cultivation practices):

  Field trial area was chopped several times to destroy the plant material and ploughed to incorporate the remaining plant material into the soil.

  Conventional soil cultural practices in the area were followed after the trial termination.

– Other(s) (Describe)

6.1.5 Post-harvest measures

Please indicate which measures were taken on the release site after the harvest:

- ☒ Frequency of visits (average): **one each 2 months**.

- ☒ Subsequent crop (Specify)

  Commercial maize will not be grown on the trial sites.

- ☒ Crop rotation (Specify)

  Commercial maize will not be grown on the trial sites.

– Fallow / no crop (Specify)
– Superficial soil work/no deep ploughing
– False-sowing beds

- ☒ Removal of volunteers (Specify intervals and duration):

  Specific monitoring will be implemented along the following year. Any volunteer maize appearing in the field will be eliminated before flowering. Specific monitoring will be done within the comprised period between soil preparation for planting and pre-flowering stage (from February to June)

– Appropriate chemical treatment(s) (Specify)
– Appropriate soil treatment(s) (Specify)
– Others (Please specify)

6.1.6 Other(s) measure(s): (Describe)

6.1.7 Emergency plan(s)

Indicate

a) if the release proceeded as planned

- ☒ **Yes**
- No (Describe for which reason? E.g. Vandalism, climatic conditions, etc):

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:

- ☒ **No**
- Yes (Describe):

6.2 Post-release monitoring measures

Due to the fact that the current report format can be used for the final and post-release monitoring report(s), the notifier is asked to clearly make the difference between both types of report through this section 2 of Chapter 6. Please indicate whether

- ☒ **The post-release monitoring plan will start** (in the case of a final report, **after the last harvest of the GM higher plants)**,
- The post-release monitoring plan is ongoing (in the case of an intermediary post-release monitoring report),
- The post-release monitoring plan has been completed (in the case of the final post-release monitoring report),
- No post-release monitoring plan has to be fulfilled.

According to the afore-mentioned cases, please indicate which monitoring measure(s) will be/are/were taken and where (on the release site/near the site (e.g. on fields edges)). Please be aware that all post-release monitoring measures taken during the whole post-release period shall be indicated here.
Specify:

- Monitoring measures within site
  - Duration: **one year since field trial harvesting.**
  - Frequency of visits (average): **one visit each 2 months.**
  - Observation of resistant relatives: N/A
  - Observation of resistant insects N/A
  - Removal of volunteers (specify intervals and duration) **at regular visits, special focus from February to June.**
  - Monitoring of gene flow (specify) N/A
  - Appropriate chemical treatment(s) and/or soil treatment(s) N/A
  - Others (Specify) N/A
- Monitoring measures of adjacent areas N/A
  - Duration:
  - Frequency of visits (average):
  - Area monitored:
  - Observation of resistant relatives
  - Observation of resistant insects
  - Removal of volunteers (specify intervals and duration)
  - Monitoring of gene flow (specify)
  - Appropriate chemical treatment(s) and/or soil treatment(s)
  - Others (please specify)

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

Visual monitoring on field trial sites will record any unexpected or unusual event.

No modifications or amendments to the proposed plan in the application or the SNIF have been implemented.

6.4 Observed effect(s)

6.4.1 Explanatory note

6.4.2 Expected effect(s)

The MIR604 maize hybrids have developed following good agronomic characteristics and it has been confirmed their resistance to *Diabrotica* infestation.

No adverse effect has been observed for the human health or the environment.

6.4.3 Unexpected effect(s)[6]

No unexpected effects or observations have been detected.

No adverse effect has been observed for the human health or the environment.

6.4.4 Other information

7. Conclusion

The trials proceeded as planned and no unexpected effects or observations were recording during the release.

Therefore the outcome of the risk assessment remains unchanged as a result of these trials.

DATE: 12/01/2009

[6] Without prejudice to Article 8 of Directive 2001/18/EC as regards handling of modifications or new information