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/09/61

1.2 **Member State of notification:**

Spain

1.3 **Date of consent and consent number:**

June 10th, 2009

2 REPORT STATUS

2.1 **Please indicate whether, according to Article 3 of the present Decision, the current report is:**

- the final report

3 CHARACTERISTICS OF THE RELEASE

3.1 **Scientific name of the recipient organism:**

Zea mays L

3.2 **Transformation event(s) (acronym(s) or vectors[1] used (if transformation event identity not available):**

Bt11xMIR604 maize

3.3 **Unique identifier, if available:**

SYN-BT∅11-1 x 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-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) layout:**

Geographical location(s) (administrative region and, where appropriate, grid reference)	Size of the release site(s)[2] (m2)	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)
Lleida-3 *	1800 m^2	7 plants/m^2	19/06/09- 12/11/09

*In this location the nursery multiplication trial was not carried out.

4 ANY KIND OF PRODUCT THAT THE NOTIFIER INTENDS TO NOTIFY AT 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 :

United Kingdom

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 subtype(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):

[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

5.1 **Deliberate release(s) for research purposes** ☐

5.2 **Deliberate release(s) for development purposes** ☒

- ☐ Event screening
- ☐ Proof of concept
- ☒ Agronomic performances (e.g. efficiency/selectivity of plant protection product, yield capacity, germination capacity, crop establishment, plant vigour, plant height, susceptibility to climatic factors/diseases, etc) (Specify)
- ☐ Improved agronomic properties (e.g. disease/pest/drought/frost resistance, etc) (Specify)
- ☐ 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
- ☐ Phyto-remediation
- ☒ Others: ……**Nursery observation**

5.3 **Official testing** ☐

- ☐ Variety registration on a national variety catalogue
- ☐ DUS (=Distinctness, Uniformity and Stability)
- ☐ VCU (=Value of Cultivation and Use)
- ☐ Others: (specify)…….

5.4 **Herbicide authorization** ☐

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):** ☐

(describe) : .....

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

Without prejudice to the specific environmental risk assessment as well as to the consent conditions, the notifier shall provide the following information **in respect of any effect for human health or the environment.** 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.

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 labeling of the GM seeds (distinct from other seeds/tubers/etc.) (describe).

Seeds lots were packed in sealed paper bags in facilities authorized to carry out confined release of GMOs; the bags remained closed until planting. Each paper bag was clearly labeled with a unique identifier code and an indication that it was containing GM seeds. The name of the event was also mentioned. All the bags containing the seeds lots were contained into a sealed and labeled 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).

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

☒ Destruction of superfluous seeds/planting material (describe the method involved).

The remaining seeds from planting, when any, were buried in the soil of the alley of the trial, together with the seeds recovered during the cleaning process or they were kept in the original bags, which were re-sealed and labeled by qualified staff and returned to the original facility in a triple closing package.

☐ Temporal isolation (specify).

☐ Rotation (specify the previous crop).

☒ Other(s): (specify) .

The isolation distance was checked before initiating the planting operations.

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 material from the trial site. The residual seed recovered during the process of cleaning were buried in the soil of the alley of the trial

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

The planting procedure with identification of each seeds lot in separate bags avoids seed mixing during the planting operation. After the sowing of each seeds lot, the remaining seeds in the micro-plot planter were recovered in a dedicated device or in the seeds tank.

☐ Other(s): (specify) .....

6.1.3 During the period of release:

☒ Isolation distance (x meters)

☒ From sexually compatible commercial plant species.

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

☒ From sexually compatible wild relatives.

Not proceed. There are not compatible wild type plants.

☒ Border rows (with the same crop or a different one, with a non-transgenic crop, x meters, 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. At the end of the release, these border rows were destroyed like the rest of the trials.

☐ Removal of GM inflorescences before flowering (indicate the frequency of removal).

Not proceed

☐ Removal of bolters/relatives/hybrid partners (indicate the frequency of the removal, x meters around the GM field, etc).

Not proceed

☒ 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 part of it) / other means (e.g.: sampling)

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.

Not proceed

☐ Effective removal of plant parts.

Not proceed

☐ Segregated storage and transport of crop/waste (provide examples of containment to prevent spillage of collected seeds/crops/wastes).

Not proceed

☒ 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 harvested grain was buried.
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 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 harvest:

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

☒ Subsequent crop (specify): **Commercial maize will not be grown on the trial sites during the following year after field trial termination.**

☒ Crop rotation (specify): **Commercial maize will not be grown on the trial sites during the following year after field trial termination.**

☐ Fallow/no crop (specify): **Not proceed**

☐ Superficial soil work / no deep ploughing: **Not proceed**

☐ False-sowing beds: **Not proceed**

☒ Control 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): **Not proceed**

☐ Appropriate soil treatment(s) (specify): **Not proceed**

☐ Other(s) (specify): **Not proceed**

6.1.6 Other(s) measure(s): (describe)

6.1.7 Emergency plan(s).

Indicate:

a) If the release proceeded as planned:

☒ Yes **except for the nursery multiplication trial performed in Lleida- 3 that was not carried out due to the late authorization of the trials.**

☐ 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 results of this monitoring are meant to confirm or invalidate earlier assumptions in them risk assessment.

According to the aforementioned 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: **during the following year upon field trial termination.**

Frequency of visits (average): **1 visit each 2 months.**

☐ Observation of resistant relatives. **Not proceed**
☐ Observation of resistant insects. **Not proceed**
☒ Control of volunteers (specify intervals and duration). **at regular visits, special focus from March to June.**
☐ Monitoring of gene flow (specify). **Not proceed.**
☐ Appropriate chemical treatment(s) and/or soil treatment(s). **Not proceed**
☐ Others (specify).

- Monitoring measures of adjacent areas:

Duration: **during the following year upon field trial termination.**

Frequency of visits (average): **1 visit each 2 months.**

Area monitored:

☐ Observation of resistant relatives. **Not proceed**
☐ Observation of resistant insects. **Not proceed**
☐ Control of volunteers and/or monitoring of feral populations (specify intervals and duration). **at regular visits, special focus from March to June.**
☐ Monitoring of gene flow (specify). **Not proceed.**
☐ Appropriate chemical treatment(s) and/or soil treatment(s). **Not proceed**
☐ Others (specify). **Not proceed**

6.3 **Plan for observation(s)/methods(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.

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.
The main objectives of the information given in this section are:
- to confirm or invalidate any assumption regarding the occurrence and impact of potential effect(s) of the GMO(s) which was/were identified in the environmental risk assessment,
- to identify effect(s) of the GMO(s) which was/were not anticipated in the environmental risk assessment.
The observed **effect(s)/interaction(s)** of the GMO(s)
- with respect to any risk to human health,
- with respect to any risk to the environment
shall be reported under this section.
Particular attention shall be drawn to unexpected and unintended effect(s).
Indications as regards the effects, that the notifier may have to report, are provided hereunder.
The effects have obviously to be considered in the light of the crop, the new trait, the receiving environment as well as the conclusions of the environmental risk assessment, which is carried out on a case-by-case basis.
In order to structure the information and to facilitate and efficient search within the given information, the notifier shall use, as far as possible, specific keywords to fill in the text fields under Chapter 6, especially sections 6.4.2, 6.4.3 and 6.4.4. A most updated list of those specific keywords is available on the Internet at: http://gmoinfo.jrc.it.

6.4.2 Expected effect(s)

The Bt11x MIR604 maize hybrids have developed following good agronomic characteristics and it has been confirmed their resistance to corn borer infestation and *Diabrotica sp.*
No adverse effect has been observed for the human health or the environment.

6.4.3 Unexpected effect(s) [4]

We have not observed any unexpected or adverse effect for the human health or the environment.

6.4.4 Other information

7 CONCLUSION

Except for the nursery multiplication trial performed in Lleida- 3 that was not carried out due to the late authorization of the trials, the nursery observation trial 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: **4/15/2010**

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