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/10/16

1.2 **Member State of notification:**

Spain

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

26/03/2010

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 mais

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

Bt11maize

3.3 **Unique identifier, if available:**

SYN-BTØ11-1

[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 local location or places (administrative region and coordinates of reference when it proceeds)	**Local surface or places (m^2)**	**Identity and approximate number of top plants MG liberated really by every event (N º of seeds / plants for m^2)**	***Duration of her or the liberations: (Of … (day / month / year)up to (day / month / year***
Alforque	Not planted	Not planted	Not planted
Sastago-1	467 m^2	8 plants/m^2	19/05/2010-03/11/2010
Sastago-2	Not planted	Not planted	Not planted

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 :

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):

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: …….

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 of the sowing have been buried inside the perimeter of the test.

☐ Temporal isolation (specify).

☐ Rotation (specify the previous crop).

☐ Other(s): (specify) ..

6.1.2 During the sowing/planting activities:

☒ Method of sowing/planting.

The sowing has been carried out by means of a pneumatic drill specially adapted for agricultural experimentation

☒ 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
The drill is equipped with an automatic system to avoid mixtures, separating in a specific container all the seeds not sowed in his corresponding plot. The remaining seeds of the sowing have been buried inside the perimeter of the test.

☒ 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 commercial maize fields .

☒ From sexually compatible wild relatives.

In the zone there does not exist risk of transfer of genes to wild relatives.

☐ Border rows (with the same crop or a different one, with a non-transgenic crop, x meters, etc). **8 rows**

☐ Cage/net/fence/signpost (specify). **Not proceed**

☐ Pollen trap (specify). **Not proceed**

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

Visual monitoring once every 3 weeks.

☐ 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 into a big hole in the area.

All the remaining plant material after harvest has been subjected to mechanical grinding 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 remaining plant material after harvest has been subjected to mechanical grinding 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).

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 6 weeks.**

☒ 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 plant 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.

☐ 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

☐ 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 6 weeks .**

☐ Observation of resistant relatives. **Not proceed**
☐ Observation of resistant insects. **Not proceed**
☒ Control of volunteers (specify intervals and duration). **at regular visits.**
☐ 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 6 weeks .**

Area monitored:

☐ Observation of resistant relatives. **Not proceed**
☐ Observation of resistant insects. **Not proceed**

☐ Control of volunteers (specify intervals and duration). **at regular visits.**
☐ Monitoring of gene flow (specify). **Not proceed.**
☐ Appropriate chemical treatment(s) and/or soil treatment(s). **Not proceed**

☐ Others (specify).

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

With the aim to detect any unexpected effect on non-target organisms, a monitoring program has been implemented through a series of systematic observations in the field trial

No unexpected or adverse effects have been detected.

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 GM maize plants have developed following good agronomic characteristics.
No adverse effect has been observed for the human health or the environment.

6.4.3 Unexpected effect(s) [2]

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

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

6.4.4 Other information

7 CONCLUSION

The tests have developed since it was foreseen and has not been observed any unexpected or adverse effect. In consequence the conclusions of the Risk environmental evaluation have been confirmed

DATE: **14/04/2011**