FORMAT FOR THE PRESENTATION OF THE RESULT OF DELIBERATE RELEASE INTO THE ENVIRONMENT OF GENETICALLY MODIFIED HIGHER PLANTS IN ACCORDANCE WITH ANNEX XI OF ROYAL DECREE 178/2004

1 General information

1.1 European notification number: B/ES/13/19

1.2 Member State of notification: Spain

1.3 Date of consent and consent number: 27-05-2013 Authorization n°2013 001 0030701

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 **X**

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): maíz Bt11 x MIR604 x GA21

3.3 Unique identifier, if available:

3.4 Please provide the following information as well as the field(s) layout:

[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.

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)
Alcalá de Henares	Two hectares of which 0.96 ha are Bt11xMIR604xG21 maize	7-8 plants by m2	From 13 June 2013 until March 27, 2014

([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

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 (by another juridical entity of the group) **X** 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 pour.
    - 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 **X**

Within the same reporting a similar test will be conducted in 2014

5.2 Deliberate release(s) for development purposes ☐

- Event screening.

- Proof of concept [2].

- 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).

- Altered agronomic properties (e.g. disease/pest/drought/frost-resistance, etc.) (specify).

- Altered qualitative properties (prolonged shelf-life, enhanced nutritional value, modified composition, etc.) (specify).

- Stability of the expression.

- Multiplication of lines.

- Hybrid vigour study.

- Molecular farming[3].

- Phyto-remediation.

- Others : (specify) .....

[2] For example, testing the new trait under environmental conditions.

[3] « 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 pharceuticals, plant-based proteins production, etc.

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.
- Observation 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.

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 (distinct from other seeds/tubers/etc.) (describe).
  The seed lots came labeled and remained so until planting
- 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).
  The seeds were kept locked in a room in which there was no other seed. They were never in contact with other seeds and kept in closed boxes (A) who got into resistant bags (B) that were introduced in other cases also closed (C) (see Figure). The transport was under the custody of INIA researchers in a closed vehicle the day of sowing
- Destruction of superfluous seeds/planting material (describe the method involved).
  The remaining seeds were buried at a depth of 30 cm in a plot planted with GM material. The area was marked with blue flags. Any plant that germinated was manually destroyed
  .
- Temporal isolation (specify).
  No temporal isolation was performed

- Rotation (specify the previous crop).
  The previous crop in the plot were winter cereal, being oat the previous one

- Other(s): (specify) .....

6.1.2 During the sowing/planting activities:

- Method of sowing/planting.
  The trial was sown with a precision sowing machine, which was carefully cleaned before planting. The plots had been previously tagged

- Emptying and cleaning of the sowing machinery on the field of release.
  We turned to clean the drill when the seeds were changed at the end of planting. All the cleaning process but the first was performed within the test plot. The remaining seed was collected and buried in a GM plot

- Segregation during the sowing (provide example of containment to prevent spillage during the sowing/planting).
  All seeds are kept in the closed boxes until needed. Both types of seeds are never used or manipulated simultaneously. The GM seed was seeded first

- Other(s): (specify)

6.1.3 During the period of release:

- Isolation distance (x meters)

    - From sexually compatible commercial plant species.
      The assay was isolated more than 200 m from any other corn as shown in the picture
    - From sexually compatible wild relatives.
      There are no wild relatives in the area

- Border rows (with the same crop or a different one, with a non-transgenic crop, x meters, etc).
  The trial was surrounded by a three meter area free of plants followed by between 4 and 8 rows of conventional maize and more than two hundred meters of oat crop that was harvested at maturity since then this area was a vegetation-free zone

- Cage/net/fence/signpost (specify).
  Several signs of "no trespassing" on the outside of the trial were placed

- Pollen trap (specify).

Between 4 and 8 rows of conventional maize isogenic line provided by the breeder

- Removal of GM inflorescences before flowering (indicate the frequency of removal).
  No

- Removal of bolters/relatives/hybrid partners (indicate the frecuency of the removal, x metres around the GM field, etc).
  There was no regrowth as the previous crop in recent years were always winter cereals

- Other(s): (specify)…….
  Because the presence of some boar specimens was observed an electric fence that was active until harvest, was placed around the trial outside the pollen trap lines.

6.1.4 At the end of the release:

- Harvest/destruction methods (of crop or part of it) / other means (e.g.: sampling) (describe).
  The assay was collected in full with a harvester combine for trials that stores the grain in a closed container

- Harvest / destruction before the ripeness of the seeds.
  No plant material was collected before maturation

- Effective removal of plant parts.
  All plants once the grain was harvested were chopped by a mincer hammer (A), two disc harrow passes (B) and a moldboard plow (C) were given

- Segregated storage and transport of crop/waste (provide examples of containment to prevent spillage of collected seeds/crops/wastes).
  The grain was transported in the closed container of the harvester combine and downloaded into a ditch 1.5 meter deep. Plants were treated in the plot itself

- Clean up of machinery on the release site.
  The harvester combine was cleaned in the plot and the remains were removed in the ditch

- Destination of the waste, treatment of waste/ surplus yield/plant residues (describe).
  The grain was transported in the closed container of the harvester combine to a ditch 1,5 m deep in which it was downloaded. The ditch was half filled with grain to and completely covered with 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).
  When you go to plant next season will again deep plow if necessary and disc harrow plus proceed to the fertilization of the parcel

- 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) every 15 days until the next site preparation

- Subsequent crop (specify). If we have seeds this trial shall be repeated
- Crop rotation (specify). If no seed, winter cereals or other crop that allows control volunteers will be planted
- Fallow/no crop (specify). No
- Superficial soil work / no deep ploughing. Disk arrow
- False-sowing beds. No
- Control of volunteers (specify intervals and duration). All regrowth appears from this time will be pulled up. The field will be visited every 15 days during the year following the GM crop
- Appropriate chemical treatment(s) (specify). Treatment with herbicide metolachlor and terbuthylazine in the right plots and in interplots and borders, following the lay out of the trial.
- Appropriate soil treatment(s) (specify). Fertilization 15:15:15.
- Other(s) (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.)
  The continuous rain from mid-December delayed harvest

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 **X**
- 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 monitoring plan is initiated at this time after harvest and soil treatment

- **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.**

The results of this monitoring are meant to confirm or invalidate earlier assumptions in the 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: 2 years

  Frequency of visits (average):

  - Observation of resistant relatives. not applicable
  - Observation of resistant insects. yes
  - Control of volunteers (specify intervals and duration). Every 15 days for two years
  - Monitoring of gene flow (specify). There is no presence of corn crop or related species
  - Appropriate chemical treatment(s) and/or soil treatment(s). The corresponding treatments for a repetition of the trial
  - Others (specify).

- Monitoring measures of adjacent areas:

  Duration:

  Frequency of visits (average):

Area monitored:

- Observation of resistant relatives.
- Observation of resistant insects.
- Control of volunteers and/or monitoring of feral populations (specify intervals and duration).
- Monitoring of gene flow (specify). There is neither upcoming corn crop nor related species. The only gene flow could be related to our trial and our volunteer plants that will be controlled.
- Appropriate chemical treatment(s) and/or soil treatment(s). In principle the volunteers would be controlled if any manual or mechanical if necessary.
-
- Others (specify).

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

In this section the observation plan and the methods used to collect the effects which have to be reported under the next section (section 6.4) need to be specified. Any amendments or modifications to the plan as proposed in the application and the SNIF[4] part B need to be specified in detail.

During the time between the notification and the final report submission, new scientific insights or methods may be developed which cause a change in the methods used. In particular these modifications need to be specified under this section.

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)

[4] Summary notification information format (=SNIF)

- 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)

Throughout the trial, no risk to health human neither animal nor on the environment was detected. Plants and arthropods sampling provided data for the purposes of studying effects of crop management. The analysis carried out in the field data obtained will provide this type of information at end of trial

6.4.3 Unexpected effect(s) [5]

Throughout the growing season we have not detected unforeseen effects. It is unlikely that a trial of two years can detect such effects unless these are very prominent in whose case it would be possible

7 Conclusion

Although small deviations were mentioned the release has occurred successfully. In principle if seed are available this trial will be repeated in 2014

DATE: 31 march 2014

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