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/12/18

1.2 Member State of notification: SPAIN

1.3 Date of consent and consent number: Resolution number 593/2012, May 25, from "Director General de Medio Ambiente del Gobierno de Navarra"

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):

pAHC25-SuSy

3.3 Unique identifier, if available:

There is not

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.

BORDER						
BORDER	**7.1**	**WT**	**10.10**	**11.6**	**11.19**	BORDER
	10.10	**7.1**	**11.19**	**WT**	**11.6**	
	11.6	**11.19**	**7.1**	**10.10**	**WT**	
BORDER						

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)
Sartaguda (Navarra)	**260 m2: 126 m2 + 134 m2 non-GM border**	**950 plants: 500 border plants, 90 WT plants and 450 pAHC25-SuSy plants**	**From 2012/05/04 to 2012/10/8**

([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

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**

5.2 Deliberate release(s) for development purposes ☐

Not proceed

5.3 Official testing ☐

Not proceed

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

5.4 Herbicide authorization ☐

Not proceed

5.5 Deliberate release(s) for demonstration purposes ☐

Not proceed

5.6 Seeds multiplication ☐

Not proceed

5.7 Deliberate release(s) for biosafety/risk assessment research ☐

Not proceed

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

(describe) : .....

Not proceed

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)

It has not been necessary to aply any risk-management measures. Everything went on as expected.

6.1.1 Before the sowing/planting:

- Clear labelling of the GM seeds (distinct from other seeds/tubers/etc.) (describe).

All maize seed types used for planting (commercial, WT(HiII) and 4 OMG lines) were transported to the field in individual paper bags (5 in total) clearly labeled outside

- 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).

All the material was transported to the field in a particular car. No other material was transported at the same time.

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

The superfluous planting material (seeds) was transported back to the Institute of Agrobiotechnology where they were kept at 4ºC for research use.

- Temporal isolation (specify).

Not proceed

- Rotation (specify the previous crop).

In the previous year (2011) commercial pepper plants were growing there.

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

Not proceed

6.1.2 During the sowing/planting activities:

- Method of sowing/planting.
  Planting was manually

- Emptying and cleaning of the sowing machinery on the field of release.
  Not proceed

- Segregation during the sowing (provide example of containment to prevent spillage during the sowing/planting).
  Not proceed

- Other(s): (specify)
  Not proceed

6.1.3 During the period of release:

- Isolation distance (x meters)

  - From sexually compatible commercial plant species.
    The distance from other maize plants growing in the same Experimental Area was higher than 120 m and there were some buildings and trees in between.
  - 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).
  The rows between lines was 0.9 m
  The distance between plants in a line was 0.3 m
  The rows between repetitions was 1.5 m
  The distance from the closet cultivated plants was higher than 120 m

- Cage/net/fence/signpost (specify).
  Each repetition was marked by using wooden sticks.
  Each experimental unit was indicated by singpost in which the name of the lines was written (border, 7.1, 10.10, ...)

- Pollen trap (specify).
  Not proceed

- Removal of GM inflorescences before flowering (indicate the frequency of removal).
  Not proceed.
  Male Inflorescences from border plants were removed in July.

- Removal of bolters/relatives/hybrid partners (indicate the frecuency of the removal, x metres around the GM field, etc).
  Not proceed

- Other(s): (specify)…….
  Not proceed

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 manually.**
  Corns were harvested separately. Each experimental unit was harvested in individual bags perfectly identified. We used 30 bags (2 per line x 5 lines(HiII + 4 OMG) x 3 repetitiones).
  Stems were cut and introduced in paper bags perfectly identified. When bags were full they were closed.

- 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).
  All harvested material (seeds and stems) was transported to the Institute of Agrobiotechnology in a particular car, in which all the transported material belonged to our experiment and was perfectly identify.
  Seeds were kept at 4ºC for their characterization.
  Stems were oven dry for their characterization.
  Border seeds were destroyed by autoclaving.

- Clean up of machinery on the release site.
  Not proceed

- Destination of the waste, treatment of waste/ surplus yield/plant residues (describe).
  Border seeds were destroyed by autoclaving the days after harvest.

- 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).
  Even after treating against corn border before planting, another three treatments against corn borer (*Ostrinia nubilanis*) were necessary. All plants were affected by this common corn pest.

- Other(s): (describe):
  On October 8th, after harvest, we cleaned up the field.

6.1.5 Post-harvest measures:

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

Frequency of visits (average) **Weekly, by the Experimental Field personal**

- Subsequent crop (specify).

Capsicum annuum (pepper)

- Crop rotation (specify).

pepper- corn - potato

- Fallow/no crop (specify).

Not proceed

- Superficial soil work / no deep ploughing.

Pass of Rotavator

- False-sowing beds.

Not proceed

- Control of volunteers (specify intervals and duration).

Not proceed

- 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: **Not proceed**

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 week after harvest**

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 field edges)). Please be aware that all post-release monitoring measures taken during the whole post-release period shall be indicated here.
Maize propagation is sexual, using seeds (grain). This join to the fact that we eliminated all the seeds no post-release monitoring will be necessary

Specify:

- Monitoring measures within site

  Duration: **from October 2012 to May 2013**

  Frequency of visits (average): **weekly**
  - Observation of resistant relatives. **Not proceed**
  - Observation of resistant insects. **Not proceed**
  - Control of volunteers (specify intervals and duration). **Every week the personal working in the experimental field will control this field.**
  - Monitoring of gene flow (specify). **Not proceed. All the seeds have been removed from field.**
  - Appropriate chemical treatment(s) and/or soil treatment(s). **Not proceed**
  - Others (specify). **Not proceed**

- Monitoring measures of adjacent areas:

Not proceed. In the surroundings there were not sexually compatible plants.

  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).
  - Appropriate chemical treatment(s) and/or soil treatment(s).
  - Others (specify).

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

We have not observed any adverse effect of the GM on either weed seeds neither pests. All the weeds and pests detected were the typical ones for maize and affected in the same way to the border (commercial maize), control (HiII: lab maize) and the GM plants.
We have not observed any effect of the GM on human health. No one persons handing with those plants (stems and seeds) had any symptom (no rash, no allergy).
We have not observed any effect of the GM on animal health.

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.
As I have already mentioned, not effect of the GM on environment either on human health was detected during the growing period.
We have either observed any effect from harvesting date till now.

6.4.2 Expected effect(s)

No effects were observed, as expected.

6.4.3 Unexpected effect(s) [2]

We have not observed any unexpected effect.

We will keep on monitoring the possible effect of the GM relased on 2012 on the growth and development of the cultivated plant placed in the same field on 2013 to confirm that this event has not effect.

6.4.4 Other information

The corn variety used in these experiments (HiII) is not good for growing on field, It has reduced vegetative growth, reduced pollen production and reduced corn production.

7 Conclusion

Taking in account the results obtained in 2012 we can conclude that:

1. **We have observed not differences between control plants (growing in the experimental field) and GM ones. However, their growth and flowering capacity was reduced comparing with border plants (commercial line).**

2. **We have observed not differences in resistance/susceptibility to pets among border, WT and GM plants.**

3. **We have observed no effects of the GM plants on environment, human health and animal health. The effect of weeds and pests was the same in both control (WT) and transgenic lines (GM). The handle of the GM did not affected human health.**

   i. **<u>The corn variety used for transformation is not good for growing in the yield</u>, therefore we will not go on working with it.**

DATE: **Pamplona, 2nd of January of 2012**

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