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/15/02

1.2 Member State of notification: SPAIN

1.3 Date of consent and consent number: Resolution number 356/2015, 27 May of 2014, from "Director General de Medio Ambiente y Agua 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:

***Solanum tuberosum* L.**

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

pB33-G6PDH-as

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.

BORDE (WT)						
borde	**WT**	G6PDH-as-2	G6PDH-as-5	G6PDH-as-6	G6PDH-as-7	borde
borde	G6PDH-as-2	G6PDH-as-5	**WT**	G6PDH-as-7	G6PDH-as-6	borde
borde	G6PDH-as-6	G6PDH-as-7	G6PDH-as-2	**WT**	G6PDH-as-5	borde
BORDE (WT)						

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)	**150 m2 + 82 m2 non-GM border**	**450 plants: 90 WT plants and 360 B33-G6PDH-as plants (3 pl/m2)**	**From 2015/06/04 to 2015/10/15**

([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

5.2 Deliberate release(s) for development purposes ☐

Not proceed

- 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) .....

5.3 Official testing ☐

Not proceed

- Variety registration on a national variety catalogue

[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.

- 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

- 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): ☐

Not proceed

(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:
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 tuber types used for planting (WT and 4 OMG lines) were transported to the field in individual boxes (5 in total) clearly labelled, both inside and 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 my private car. No other material was transported at the same time.
- Destruction of superfluous seeds/planting material (describe the method involved).
  The superfluous planting material (tubers) was transported back to the Institute of Agrobiotechnology where it was destroyed by autoclaving.
- Temporal isolation (specify).
  Not proceed
-
- Rotation (specify the previous crop).
  No crop
- 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 potato plants growing in the same Experimental Area was 300m.
  - 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 rows between repetitions was 0.3 m
  The distance between repetitions was 1 m
  The distance from the close cultivated plants (borraja, apple and prunus trees) was more than 3 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 (WT, G6PDH-as2,...)

- Pollen trap (specify).
  Not proceed

- Removal of GM inflorescences before flowering (indicate the frequency of removal).
  Inflorescences from all plants (GM and WT) were removed every 14 days from July 2nd to September 3rd
- Removal of bolters/relatives/hybrid partners (indicate the frecuency of the removal, x meters 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) (describe).
  Harvest was manually.
  Tubers were harvested separately. Each experimental unit was harvested in individual trays perfectly identified. We used 30 trays (2 per line x 5 lines (WT + 4 OMG) x 3 repetitions).

- 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 was transported to the Institute of Agrobiotechnology in a van, in which all the transported material belonged to our experiment and was perfectly identify.
  Tubers were kept at 4ºC for their characterization.

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

- Destination of the waste, treatment of waste/ surplus yield/plant residues (describe).
  The stems 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).
  No treatments were necessary.
  The only cultivation practice realized was the pass of a Rotavator.

- Other(s): (describe):
  On October 15, after harvest, we cleaned up the field (picked up all the waste-small tubers and stems- and destroyed by autoclaving)

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).
  Corn

- Crop rotation (specify).
  No plant-Potato-Corn

- Fallow/no crop (specify).
  Not proceed

- Superficial soil work / no deep ploughing.
  Two Passes of Rotavator

- False-sowing beds.
  Not proceed

- Control of volunteers (specify intervals and duration).
  Every week the personal working in the experimental field will control if any potato is growing. If it is so, they will inform us and we will destroy the material by autoclaving.

- 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 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.**

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.
Potato propagation is asexual, using tubers (vegetative organs). This join to the fact that we eliminated all the inflorescences the only post-release monitoring will be the control of sprouting of small tubers that could be forgotten in the field. We expected no much forgotten tubers as we clean up the field after harvest.

Specify:

- Monitoring measures within site

  Duration: **from October 2010 to May 2011**

  Frequency of visits (average):

  - Observation of resistant relatives. **weekly**
  - Observation of resistant insects. **Not proceed**
  - Control of volunteers (specify intervals and duration). **Every week the personal working in the experimental field will control if any potato is growing. If it is so, thy will inform us and we will destroy the material by autoclaving.**

  - Monitoring of gene flow (specify). **Not proceed. Potato has a vegetative propagation.**

  - Appropriate chemical treatment(s) and/or soil treatment(s). **Not proceed**
  - Others (specify). **Not proceed**

- Monitoring measures of adjacent areas:
  Not proceed. In the surrounding 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

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.
We have not observed any adverse effect of the GM on weed seeds either pest.
All the weeds and pests detected were the typical ones for potato and affected in the same way to the control and the GM plants.
We have not observed any effect of the GM on human health. No one person handing with those plants (stems and tubers) 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.

[4] Summary notification information format (=SNIF)

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, and as we expected (previous released potato OMGs), 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)

This section concerns « expected effects », that is to say, potential effects which were already identified in the environmental risk assessment of the notification and could therefore be anticipated.

Notifiers should supply data from the deliberate release(s) which validate the assumptions made in the environmental risk assessment.
No effects were observed, as expected.

6.4.3 Unexpected effect(s) [5]

"Unexpected effects" refer to effects on human health or the environment which were not foreseen or identified in the environmental risk assessment of the notification. This part of the report should contain any information with regard to unexpected effects or observations relevant for the initial environmental risk assessment. In case of any observed unexpected effects or observations, this section should be as detailed as possible to allow a proper interpretation of the data.

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

We have not observed any unexpeccted effect.

Nevertheless, we will keep on monitoring the possible effect of the GM release on 2015 on the growth and development of the crop (maize) placed in the same field on 2016 to confirm that this event has not effect.

6.4.4 Other information

Notifiers are encouraged to supply information, which is outside the scope of the notification but which might be relevant to the field trials in question. This may also include observations of beneficial effects.

7 Conclusion

In this chapter, the notifier should specify the conclusions drawn and the measures taken or to be taken on the basis of the results of the release with regard to further release(s) and where appropriate, make reference to any kind of product the notifier intends to notify at a later stage.

Taking in account the results obtained in 2006, 2007, 2008, 2009 (2 releases), 2010, 2014 and this release (2015) we can conclude that:

i. **We have observed not differences between control plants (growing both in the border and in the experimental field) and GM ones.**

ii. **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.**

DATE: Pamplona, 21st of January 2016