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/09/50**

**1.2 Member State of notification: SPAIN**

**1.3 Date of consent and consent number: Resolution number 2606, 21st december of 2009, 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:**

***Solanum tuberosum* L.**

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

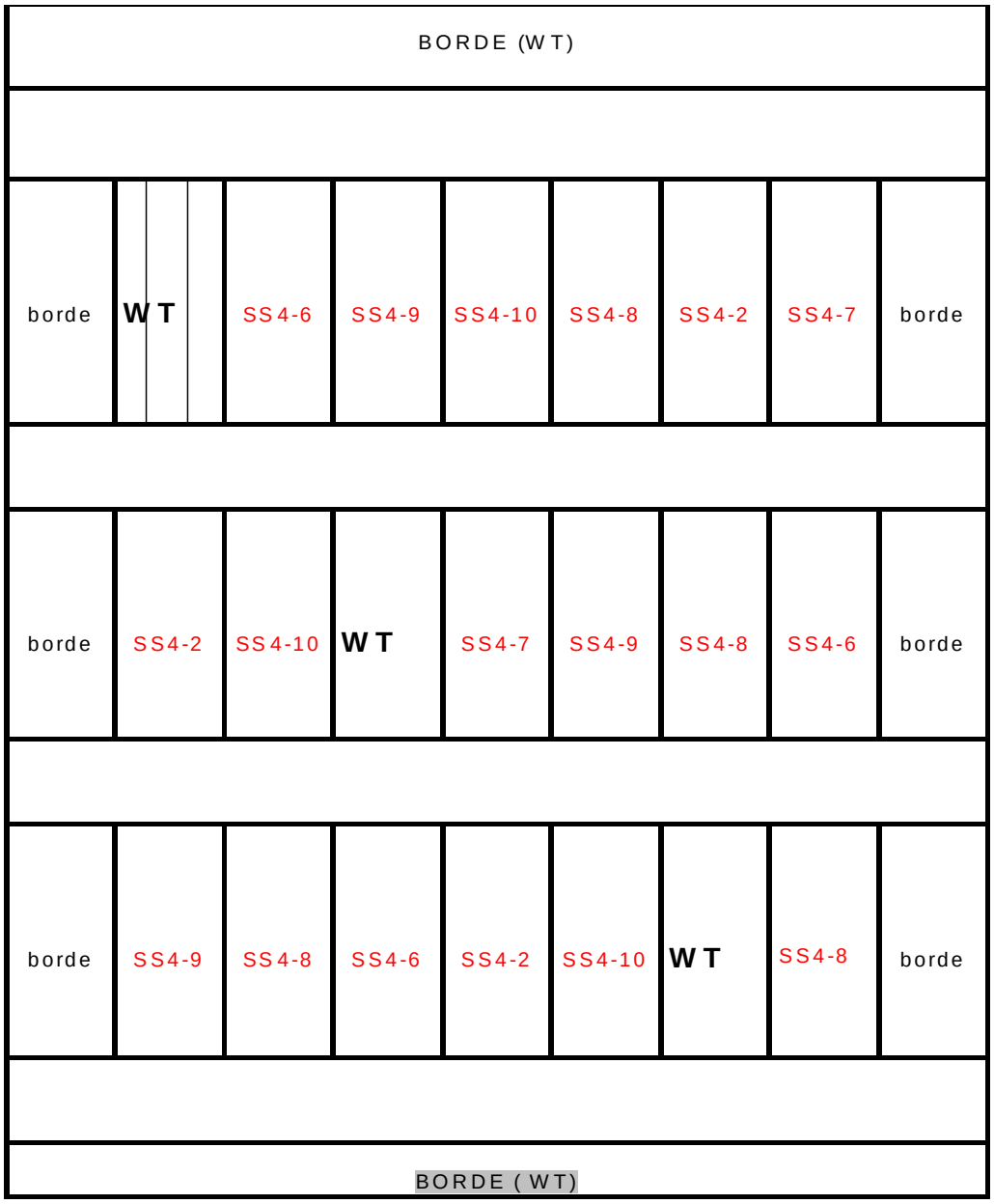
**P35S-AtSS4-NOS**

**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.




| **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)** | **110 m2 + 45 m2 non-GM border** | **420 plants: 60 WT plants and 360 35S-AtSS4 plants (3 pl/m2)** | **From 2009/06/26 to 2009/11/28** |

([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 tuber types used for planting (WT and 6 OMG lines) were transported to the field in individual trays ( 7 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 the institute 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).

**In the previous year (2008) corn 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 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 (corn and prunus trees) was 3 m**

- Cage/net/fence/signpost (specify).
  **Each repetitons was marked by using wooden sticks.**
  **Each experimental unit was indicated by singpost in which the name of the lines was written ( WT, 35S-AtSS4-2,...)**

- 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 August 4$^{th}$ to September 18$^{th}$**

- 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.**
  **Tubers were harvested separately. Each experimental unit was harvested in individual trays perfectly identified. We used 42 trays (2 per line x 7 lines ( wt + 6 OMG) x 3 repetitiones).**
  **Stems were cut and introduced in autoclaving bags. 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 (tubers and stems) 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.**
  **Stems were destroyed by autoclaving the days after harvest.**

- 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 November 28$^{th}$, 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).

**Corn- 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: **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 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 November 2009 to May 2010**

  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 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

**We have not observed any adeverse effect of the GM on weed seeds either pests.**
**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 persons 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.

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 (B/ES/09/50), 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.**

**Nevertheless, we will keep on monitoring the possible effect of the GM relased on 2009 on the growth and development of the cultivated plant placed in the same field on 2010 to confirm that this event has not effect.**

*6.4.4 Other information*

# 7 Conclusion

**Taking in account the results obtained in 2006, 2007, 2008, 2009 and this release (2009) we can conclude that:**

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

2. **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, 23st of November of 2009**

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