

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/06/33

1.2 Member State of notification: SPAIN

1.3 Date of consent and consent number: 14th march of 2006, Resolution number 637 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 vectors¹ used (if transformation event identity not available):

pBIN35S-SuSy-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.

WT	35S-6	35S-5	35S-12	35S-3	35S-4	35S-7	35S-10
35S-3	35S-10	WT	35S-6	35S-4	35S-12	35S-5	35S-7
35S-4	35S-10	35S-6	35S-7	35S-5	3.5 WT	35S-3	35S-12
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)	180 m² + 32 m² non- GM border	480 plants: 60 wt plants and 420 35S- Susy plants (e plants/ m²)	From 4/05/2006 to 3/10/2006 (75% harvested) or 24/10/2006 /25% harvested)

(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) **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

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 apply 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.)

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 where it was destroyed by autoclaving.

- Temporal isolation (specify).

Not Proceed

- Rotation (specify the previous crop)

In the previous year (2005) 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 200 m.

- 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 planting lines was 0.9 m.

The rows between repetitions was 0.5 m

The distance from the closet cultivated plants (corn and fruit trees) was 6 m

- Cage/net/fence/signpost (specify).

Each repetition was indicated by using wooden sticks

Each experimental unit was indicated by signpost in which the name of the line was written (wt, 35S-SuSy 3, 35S-SuSy 4,.....)

- 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 15 days from July 24th to September 27th.

- Removal of bolters/relatives/hybrid partners (indicate the frequency of the removal, x metres around the GM field, etc).

Not proceed

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

Sprouting was irregular.

The irregular sprouting observed can not be attributed to the GM event. It happened in both wt and GM plants.

We observed that 25% of the planted tubers delayed their sprouting for nearly 3 months. We think that the delay was a consequence of the planting material that was harvested in three different dates in the institute greenhouse (due to space limitations). The last harvest was on April 2006 and those tubers were planted on May 2006 without time for taking place their endogenous dormancy.

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 harvest in an individual tray perfectly identify, both inside and outside. We use 21 trays (wt + 6 MG lines x 3 repetitions).

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 in a van, in which all the transported material belonged to our experiment and was perfectly identify.

Tubers were kept at 4°C for their characterization.

Stems were destroyed by autoclaving the day after the 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 day after the 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):

Due to the delay in the sprouting of the potatoes planted the harvest was realized in two different moments. The first harvest, on October 3rd, allowed us to harvest

nearly 75% of the field. The second harvest, on October 24th, was use to harvest all the remaining material.

On October 24th, after the harvest, we cleaned up the field (picked up all the waste – small tubers and stems – and destroyed them 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**

- Subsequent crop (specify).

It has not already been determined. Probably will be a *Brassicacea*

- Crop rotation (specify).

Corn-potato-¿brassicaceae?

- Fallow/no crop (specify).

Not proceed

- Superficial soil work / no deep ploughing.

It has not already been determined. It will depend on the planting material.

- 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 that 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 is ongoing (in the case of an intermediary post-release monitoring report).

This informs is an intermediary one. The release will be repeated next year in other place of the same experimental field. Therefore we will follow monitoring what is going on in this field.

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 the 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 expect no much forgotten tubers as the yield was very good (45.000-50.000 Kg/ha).

Specify:

- Monitoring measures within site

Duration: from November 2006 to August 2007

Frequency of visits (average):

- 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, they will inform us and we will destroy that 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 adverse effect of the GM on weeds either on pests.

All the weeds and pests detected were the typical ones for potato and affected in the same way to the control and to the GM plants.

We have not observed any effect of the GM on human health. No one of the persons handling 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.

I have already mentioned that we have observed not effect of the GM on environment either on human and animal health during the plant growth period.

We have either observed any effect from harvesting date till now.

6.4.2 Expected effect(s)

No effect was 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 effects of the GM on the environment and on the growth and development of the cultivated plants (probably a *Brassicacea*) in that field during next year.

6.4.4 *Other information*

The pest occurring previous to the harvest (September) was stronger than we expected. We think that there are two reasons for that:

- 1. We did not treat the field because we were going to harvest in two weeks time and the pesticide we normally use should be applied earlier than one month before harvest.**
- 2. In that area by the date that the pest occurred (September) there are not remaining potatoes in the field. The harvest in that area normally takes place in August.**

7 Conclusion

Taking into account the results obtained in this year (May 2006 to October 2006) we can conclude that:

- 1. To obtain a uniform sprouting we have to use potatoes harvested 4 months earlier than the planting date to be sure that the endogenous dormancy of potatoes has taken over.**
- 2. We have observed no differences between control plants (growing both in the border and in the experimental field) and GM ones.**
- 3. It seems necessary to bring forward the planting date to reduce the watering needs and the risk of low temperatures and pest occurrence.**
- 4. 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 wt and GM plants. The handling of the GM plants did not affect human health.**

DATE: Pamplona, 15th of November of 2006

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