1. General information

1.1. European notification number:

B/ES/10/14

1.2. Member State of notification:

Spain

1.3. Date of consent and consent number:

11/12/09

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* var. *Spunta

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

HSP(soybean)-FT(Arabidopsis) pBin19.

[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.

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3.3. Unique identifier, if available:

heat stress-tolerant

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

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 plants per event released (number of seeds/plants per m2)**	**Duration of the release(s) (from … (day/month/year… until… (d/m/y)**
Málaga E.E. La Mayora Algarrobo Mar	400 m2	9 plants/ m2. 2 events (lines #1 y # 22) for the same transgene.	from 15/05/2010 until 15/08/2010.

([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 a 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 ☒ No

If yes, indicate the country(ies) of notification:
If yes, specify for which use(s):

☐ Import
☐ Cultivation (i.e. seed/planting material production)
☐ Food
☐ Feed

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☐ Pharmaceutical use (or processing for pharmaceutical use)

☐ Processing for:

- ☐ 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	☒

Study of the transgene's ability to confer tolerance to heat stress, conditions that in potato lead to a strong reduction in tuber yield.

5.2. Deliberate release(s) for development purposes	☒

Event screening.

Proof of concept [1].

Testing previous heat-stress tolerance results obtained in confined greenhouse.

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).

Susceptibility to elevated temperatures (yield in tubers)

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

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

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Multiplication of lines

Hybrid vigor study

- Molecular farming[2].

Phyto-remediation

Others:..... (Specify).....

5.3. Official testing	☐

Variety registration on a national variety catalogue

DUS (=Distinctness, Uniformity and Stability)
VCU (=Value of Cultivation and Use)

Others: (especify).....

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.

[2] « 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.

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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. Methods and result(s) of the release, management and monitoring. Measure(s) adopted in respect to any risk to human health or to 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:

Risk management measures specified in the application were strictly followed. The GM plants were encircled by a perimeter of non-modified cultivars which served as a barrier against any possible spread of pollen (very unlikely due to the fact that commercial varieties are almost sterile). Once yield in tubers was estimated, all harvested GM tubers were inactivated byautoclave. The field was deep plowed and left fallow for 6 months. Herbicide was applied 3 months

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after harvesting, to eliminate any volunteer derived from tubers left unnoticed in the field.

6.1.1. Before the sowing/planting:

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

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).

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

Temporal isolation (specify).

Rotation (specify the previous crop).

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

The GM tubers were propagated in the greenhouses of the CNB (P1 level of containment). The commercial cultivars used as a barrier for cross-polination or as a separation between events (cultivar Désirée that produces red skin tubers, clearly distinguished from the GM tubers with white skin) were provided by HZPC. GM tubers were kept in clearly labeled containers and transported to La Mayora by specialized personnel of the company that supervised and took care of planting.

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

Only the GM material required for the field test was transported.

Temporal isolation (specify).

Rotation (specify the previous crop).

The field was left fallow for the 6 months preceding planting.

Others: (especify)

6.1.2. During sowing/planting:

Method of sowing/planting

Planting was done manually since it did not imply an elevated number of tubers.

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Emptying and cleaning of the sowing machinery on the field of release.

N/A

Segregation during the sowing (provide example of containment to prevent spillage during the sowing/planting).

The GM tubers were kept separated in individual containers appropriately labeled, which assured their unequivocal identification during planting.

Others: (especify)

6.1.3. During the period of release:

Isolation distance (x meters):

From sexually compatible commercial plant species

During the interval of the field test there were no other potato fields in the area.

From sexually compatible wild relatives.

There are not wild potato species in Europe.

Border rows (with the same crop or a different one, with a non-transgenic crop, x meters, etc).

Individual plants were grown in rows that were separated 0.5 m each other and the distance between plants in the same row was 0.3 m. Mini-plots for each event were surrounded by a row of plants of the Désirée cultivar which gives tubers of red skin, hence allowing an easy identification of the GM tubers generated by plot.

……Cage/net/fence/signpost (specify).

The field test was protected with a metal fence that remained locked during the whole assay. Only the specialized personnel of La Mayora directly implied in the assay and the scientist of HZPC had access to the field. The field was identified with a post that indicated its adscription to the E.E. La Mayora.

Pollen trap (specify).

The GM plots were surrounded by 3 rows of non-modified plants of the cultivar Spunta, which served as barrier against any eventual dispersion of pollen (highly unlikely due to the reduced fertility of the commercial potato cultivars).

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Removal of GM inflorescences before flowering (indicate the frequency of removal).

N/A

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

N/A

Others: (especify)

The assay was continuously monitored by the specialized personnel of La Mayora. One month after planting, samples of the leaves were weekly harvested to follow the pattern of expression of the transgene.

6.1.4. At the end of the release:

Harvest/destruction methods (of crop or part of it) / other means (e.g.: sampling) (describe).

Tubers were manually harvested. They were counted and weighted to estímate the yield/plant. Afterwards they were inactivated by sterilization in the autoclave.

Harvest / destruction before the ripeness of the seeds

N/A

Effective removal of plant parts.

The left over stems and dry leaves were incinerated in the dependencies of La Mayora.

Segregated storage and transport of crop/waste (provide examples of containment to prevent spillage of collected seeds/crops/wastes).

The tubers and plant wastes were separately transported in closed containers to the main building of La Mayora were suitable facilities for sterilization or incineration were available.

Clean up of machinery on the release site.

N/A

Destination of the waste, treatment of waste/ surplus yield/plant residues (describe).

.

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All tubers and plant wastes were inactivated as described above.

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).

After harvest the tubers and removal of the plant wastes the field was treated with herbicide to avoid sprouting of any tuber left unnoticed. Two applications were done, one immediately after harvest and a second one three months later, by which tubers that might be left unnoticed had lost its dormancy state.

Others (describe):.....

6.1.5. Post-harvest measures:

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

Frequency of visits (average)

Each second week.

..... Subsequent crop (specify).

N/A

Crop rotation (specify).

N/A

Fallow/no crop (specify).

The field was left fallow to 3 months following the second treatment with herbicide.

Superficial soil work / no deep ploughing.

N/A

False-sowing beds.

Control of volunteers (specify intervals and duration)

.

Double treatment with herbicide after harvesting and three months later.

Appropriate chemical treatment(s) (specify).

Roundup

Appropriate soil treatment(s) (specify).

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N/A

Others (especify):.....

6.1.6. Other(s) measure(s)(describe):

The field was protected with a fence that restricted the access to specialized personnel directly related with the assay.

6.1.7. Emergency plan(s)

Indicate:

a) If the release proceeded as planned:

Yes, except that temperatures at night were not as high as required for a correct assessment of the beneficial effects of the transgene.

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).

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The post-release monitoring plan has been completed (in the case of the final post-release monitoring report).

The yield in number and weight of tubers/plant of the GM and Mondial, Spunta and Sylvana cultivars, used as controls, was analyzed. Expression of the endogenous gene and that of the additional gene copy introduced as a transgene, under control of the soybean HSP, was as well studied. Activation of the trangene was extremely low. Weather forecast of the zone showed that temperatures did not reach 35ºC, a minimum threshold temperature required for activation of the HSP (induced by heat stress).

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:

a) Monitoring measures within site

Duration: **6 months after harvesting**

Frequency of visits (average): **each second week to monthly**

Observation of resistant relatives. **N/A**

Observation of resistant insects. **N/A**

Control of volunteers (specify intervals and duration).
During all visits along the 6 months monitoring interval.

Monitoring of gene flow (specify). **N/A**

Appropriate chemical treatment(s) and/or soil treatment(s).
Herbicide treatment directly after harvest and 3 months later.

Others (specify):

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b) Monitoring measures of adjacent areas: **N/A**

6.3. Plan for observation(s)/method(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[3] 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.

Specialized personnel of La Mayora and researchers of HZPC took care of and continuously monitored the field. They controlled any irregularity or unexpected event that may happen in the area of the release. The field test went according to the original plan and there were no incidents or external factors that affected the assay or forced to modify the methods originally proposed. Effects that potentially could be harmful to human or animal health or to the environment were not observed.

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, and

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)

[3] Summary notification information format (=SNIF)

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with respect to any risk to human health,

None.

with respect to any risk to the environment

None.

shall be reported under this section.

Particular attention shall be drawn to unexpected and unintended effect(s)

None was observed.

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)

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.

The Spunta GM plants followed an identical development pattern as the non-modified controls. A slight increase in yield was observed for one of the events. Due to temperatures were not high enough(more than 35ºC are required for activation of the transgene) it was considered pertinent to repeat the assay, but plant later the tubers such that tuberization onset coincides with the warmest months of July/August. As an alternative, GM lines in which the trangene is expressed under control of a constitutive promoter might be used.

6.4.3. Unexpected effect(s) [4]

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

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"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.

Unexpected effects or effects adverse to human or animal health or to the environment were not observed.

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.

The release developed according to the expected plan, except that temperatures did not reach the minimum threshold required for the assay. A new release application will be submitted in which tubers will be planted middle June to ensure that tuberization onset coincides with July/August, season months in which the temperatures in the area of the field trial are higher.

The information included in this report is not confidential according to the article 48 of this normative. This does not mean that the competent authorities may not ask for additional information, with a confidential character or not, to the titular of the activity.
Data of confidential character will be included in an annex to the model of the report and a non-confidential summary or a general description of the data that will be made openly accessible to the public.

Date: **30/03/2011.**

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