PRESENTATION OF THE RESULTS 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: **001/MB/09**

1.2 Member State of notification: **Finland**

1.3 Date of consent and consent number: **02.03.2010, 001/MB/09**

2. Report status

2.1 Please indicate whether, according to Article 3 of the present Decision, the current report is:

☒ 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):
Transformation events EH92-527-1 (variety name "Amflora") and AM04-1020

3.3 Unique identifier, if available: **BPS-25271-9 (Amflora)**

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

Field releases 2010

Geographical location(s)	Size of release site(s)[2] (m^2)	Identity of GM higher plants	Approximate number of GM higher plants per event actually released	Duration of the release(s) (from ...)	Duration of the release(s) (until ...)
Lammi	**192**	**EH92-527-1**	**1250**	**20.05.2010**	**30.09.2010**
Lammi	**192**	**AM04-1020**	**1250**	**20.05.2010**	**30.09.2010**

[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 introduce traits and/or genetic elements. In the case of large(r)-scale field trials, the number of events notified is limited to only one or a few events

[2] Specify the size of the GM area and, where appropriate, the size of the non-GM area (e.g. non-GM border).

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 ☐ 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
  - ☐ Food use
  - ☐ Feed use
  - ☐ Industrial use
- ☐ others (please specify):

5. Type(s) of deliberate release(s)

Please select the main type(s) (in boxes) as well as the subtype(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 releases(s) which have been carried out for the full duration of the consent.

5.1 Deliberate release(s) for research purposes ☐

5.2 Deliberate release(s) for development purposes ☒

- ☐ Event screening
- ☐ Proof of concept[3]:
- ☒ Agronomic performances (specify):

  Standard agronomic evaluation of the GM lines, e.g. yield, growth behaviour has been conducted.
- ☐ Altered agronomic properties (specific):
- ☒ Altered quantitative properties (specify): **Altered starch composition**
- ☐ Stability of expression
- ☐ Multiplication of lines
- ☐ Hybrid vigour study
- ☐ Molecular farming[4]
- ☐ Phyto-remediation
- ☐ others (describe):

5.3 Official testing ☐

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

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

[4] „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-synthesized pharmaceuticals, plant-made pharmaceuticals, plant-based proteins production, etc.

5.4 Herbicide authorisation ☐

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
- ☐ Horizontal gene transfer studies (gene transfer to micro-organisms)
- ☐ Management of volunteers
- ☐ Potential changes in persistence or disposal
- ☐ Potential invasiveness
- ☐ Potential effects on target organisms
- ☐ Potential effects on non-target organisms
- ☐ Observation of resistant relatives
- ☐ Observations of resistant insects
- ☐ others: (describe)

5.8 Other(s) types(s) of deliberate release(s) ☐

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

6.1.1 Before sowing/planting:

☒ Clear labelling of the GM planting material lots (describe):

The potatoes were packaged in green plastic boxes. The boxes were clearly labelled with a sign that read „genetically modified potatoes - unfit for consumption“, and all bags were tagged with a printed plastic label identifying the specific lines and giving information on genetic modification, identity, consent holder, contact phone number, location.

☒ 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):

Potato tubers were transported separate from other commercial potatoes directly to the trial location on day of planting. All shipments were inspected on arrival to check shipping containers were intact. The amount of tubers was confirmed prior to planting according to the transport documentation.

☒ Destruction of superfluous seeds/planting material (describe method involved):

All extra potatoes were inactivated by autoclave, using 135°C and 1,5bar 20 min.

☐ Temporal isolation (specify):

☒ Rotation (specify the previous crop(s)): **The potato trial was included into crop rotation regime**

☐ others (specify):

6.1.2 During the sowing/planting

☒ Method of sowing/planting:

Tubers were planted with a potato planting machine.

☒ Emptying and cleaning of the planting machinery on the field of release:

The planting equipment was cleaned before and after the planting on the release site.

☒ Segregation during planting (provide example(s) of containment to prevent spillage during planting):

On the day of planting, potato tubers were transported by car directly to the trial location. Tubers were unpacked on the release site.

☐ others (specify):

6.1.3 During the period of release

☒ Isolation distance(s):

☒ from sexually compatible commercial plant species:

> 5 m

☐ from sexually compatible wild relatives:

Not applicable; there are no sexually compatible wild relatives of potato in Europe.

☐ Border row(s) (with the same crop or a different one, with a non-transgenic crop, x metres etc):

☐ Cage/net/fence/signpost (specify):

☐ Pollen trap (specify):

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

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

☒ other(s), describe:

The release site was monitored regularly regarding deviations concerning the expected biological characteristics of the GMO.

6.1.4 At the end of the release

☒ Harvest/destruction methods (of crop or parts of it)/other means (e.g. sampling and analysis of sugar beet pulp)(describe):

Prior to harvest the green plant parts were desiccated by herbicide application. Desiccated plant tops were chopped with a conventional mechanical topper to help ease the lifting process. The tubers were lifted onto the surface using a potato digger. The harvest completely destroyed the crop.

☐ Harvest/destruction before the ripeness of the seeds

☒ Effective removal of plant parts:

2 weeks prior to harvest the green parts of the plants have been desiccated by herbicide application.

☒ Segregation storage and transport of crop/waste (provide example(s) of containment to prevent spillage of collected seeds/crop/wastes):

All tubers were harvested directly on the release site into the green plastic boxes, of which inside was a big bag. All boxes were transported to the storage facility nearby.

☒ Clean up of machinery on the release site:

All machinery involved in the harvest process was cleaned before and after harvest.

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

All harvested tubers were transported to a storage facility. Dead above-ground plant material was left on the release site for composting. Waste potatoes that accumulated during harvest were left on the soil surface in order to destroy the tubers by frost.

☒ Post-harvest treatment and cultivation measures on the release site (describe the method(s) for preparing and managing the release site at the end of the release, including cultivation methods):

The release site has been break up once with shovel roller harrow on the November 2 to bring up the rest of tubers to the soil surface.

☐ other(s): describe:

6.1.5 Post-harvest measures

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

Frequency of visits (average):

Post-harvest monitoring is done at least every four weeks during the vegetation period until one year passed without finding volunteer plants.

☐ Subsequent crops (specify):

☒ Crop rotation (specify):

At least three years following the release no potatoes are planted on the same field. In addition planting of potatoes is allowed after one year passed without finding volunteer plants.

☒ Fallow/no crop (specify):

No crop is planted during the volunteer monitoring period.

☒ Superficial soil work/no deep ploughing:

The plot was grubbed after harvest. No deep ploughing was conducted.

☐ False-sowing beds

☒ Control of volunteers (specify intervals and duration):

Control of volunteers is done on a monthly basis during the vegetation periods until one year passed without finding volunteer plants, at least for two years.

☐ Appropriate chemical treatment(s) (specify):

☐ Appropriate soil treatment(s) (specify):

☐ others, (specify):

6.1.6 Other measure(s), describe:

6.1.7 Emergency plan(s)

Indicate:

- if the release proceeded as planned:

  ☒ Yes
  ☐ No (describe for which reason, e.g. vandalism, climatic conditions, etc):

- 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 (specify):

6.2 Post-release monitoring measures

Due to the fact that the current 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
☒ the post-release monitoring plan is ongoing
☐ the post-release monitoring plan has been completed
☐ 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 field edges)). Please be aware that all post-release monitoring measures taken during the whole post-release period shall be indicated here.

Specify:

☒ Monitoring measures within the site

Duration:

Frequency of visits (average): **At least every four weeks during the vegetation period by trained personnel.**

☐ Observation of resistant relatives
☐ Observation of resistant insects
☒ Control of volunteers (specify intervals and duration): **At least every four weeks during the vegetation period.**
☐ Monitoring of gene flow (specify)
☐ Appropriate chemical treatment(s) and/or soil treatment(s)
☒ others (specify): **Destruction of volunteer plants**

☒ Monitoring measures of adjacent areas:

Duration:

Frequency of visits (average):

Area monitored:
The periphery of at least 5 m around the release sites was monitored for potato plants at least every four weeks during the vegetation period. No potatoes were found.

☐ 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)/method(s) involved

Specify the observation plan and the methods used to collect the effects, which have to be reported in section 6.4. Any amendments or modifications to the plan as proposed in the application and the SNIF[5] part B need to be specified in detail.

NB. 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.

The GM potato lines have been cultivated under conventional agricultural practice. Trials have been observed regularly during the vegetation period, according to observation plan in the application. General plant characteristics relating to the

[5] Summary notification information format (=SNIF)

agronomic performance of the potato lines, any changes in susceptibility to insects and pests have been observed regularly.

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 anticipated in the environmental risk assessment.

The observed effect(s)/interaction(s) of the GMO(s) shall be reported:
- 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 an a case-by-case basis.

In order to structure the information and to facilitate an 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 sections “Expected effects”, that is to say, potential effects which were already identified in the environmental risk assessments 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 genetically modified potato lines show a shift of tuber starch composition to increased levels of amylopectin. No differences regarding persistence in agricultural habitats or invasiveness in natural habitats compared to conventional potato varieties were expected.

Interactions of the GM potato line with non-target species and resulting effects were expected to be comparable to those of conventional potato varieties. No toxic or allergenic effects have been expected from elevated levels of amylopectin starch.

During field release no effects in relation to effects on human or animal health or on the environment have been observed

6.4.3 Unexpected effect(s)[6]

“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.

No adverse or unexpected effects on human health or the environment were recorded during the release.

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 might also include observations of beneficial effects.

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

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 genetically modified potato events showed a shift of tuber starch composition to increased levels of amylopectin.

No effects on human or animal health or on the environment have been observed.

The information provided in this report is not considered confidential in accordance to Article 25 of Directive 2201/18/EC.

This does not prevent the competent authority from requiring additional information from the notifier, both confidential and non-confidential.

In case of confidential data, it should be provided in an Annex to the report format, with a non-confidential summary or general description of these data, which will be made available to the public.

DATE: 26.08.2013