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: **B/DE/05/173**

1.2 Member State of notification: **Germany**

1.3 Date of consent and consent number: **08.06.2006, Az. 6786-01-0173**

2. Report status

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

☒ a 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):

The following vectors were used: pAP2 und pAP4

3.3 Unique identifier, if available:

[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

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

Field releases 2006:

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 ...)
Werpeloh	**800**	**pAP2, pAP4**	**1755**	**14.06.2006**	**20.09.2006**
Möttingen	**300**	**pAP2, pAP4**	**480**	**14.06.2006**	**29.09.2006**
Gatersleben	**100**	**pAP2, pAP4**	**140**	**15.06.2006**	**12.10.2006**
Lohmen a	**300**	**pAP2, pAP4**	**720**	**15.06.2006**	**05.10.2006**
Sanitz a	**500**	**pAP2, pAP4**	**929**	**14.06.2006**	**11.10.2006**

Field releases 2007:

Geographical location(s)	Size of release site(s)[3] (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 ...)
Sanitz 2 (B110)	**83**	**pAP4**	**360**	**17.04.2007**	**20.09.2007**
Lohmen (Asien)	**83**	**pAP4**	**360**	**18.04.2007**	**16.10.2007**
Möttingen	**138**	**pAP4**	**600**	**19.04.2007**	**02.10.2007**
Werpeloh	**97**	**pAP4**	**420**	**18.04.2007**	**25.09.2007**

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):

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

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[4]:
- ☒ Agronomic performances (specify):

  Monitoring of general agronomic and phenotypic characteristics, such as plant height, days until flowering, tuber yield.
- ☐ Altered agronomic properties (specific):
- ☒ Altered quantitative properties (specify):

  Altered starch composition
- ☐ Stability of expression
- ☒ Multiplication of lines

  Multiplication of lines to generate material for further analyses
- ☐ Hybrid vigour study
- ☐ Molecular farming[5]
- ☐ 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):

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

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

[5] „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.

☐ 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 seed potatoes were double-bagged in mesh bags and each bag was 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):

All tuber lots were double bagged prior to transport and then placed into an outer solid crate for transportation. Potato tubers were transported separate from other commercial potatoes directly to the trial location. 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 tubers delivered were planted on the test plot.

☐ Temporal isolation (specify):

☐ Rotation (specify the previous crop(s)):

☐ others (specify):

6.1.2 During the sowing/planting

☒ Method of sowing/planting:

Tubers were planted by hand or with a potato planting machine to the prepared and marked rows.

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

The planting equipment was cleaned on the release site.

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

All tuber lots were double bagged prior to transport and then placed into an outer solid crate for transportation. On the day of planting, potato tubers were transported separate from other commercial potatoes 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:

> 20 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):

The trial site was signposted. The sign read "Versuchspflanzen, nicht zum Verzehr geeignet" ("Experimental plants, unfit for consumption or animal feed"). The release sites were electro fenced to protect the trials against damage caused by game animals.

☐ 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 sites were monitored regularly regarding deviations of the agronomic performance.

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 and partly by hand. The harvest completely destroyed the crop.

☐ Harvest/destruction before the ripeness of the seeds

☐ Effective removal of plant parts:

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

All tubers were packed directly on the release site into wired and labelled mesh bags which were then placed into a labelled box. All boxes were transported to an S1-storage facility.

☒ 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):

Tubers harvested at the different locations were transported to an S1 facility for inactivation by steaming. Dead above-ground plant material was left on the release site for composting.

☒ 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 was grubbed after harvest and surfacing tubers were removed.

☐ 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 was done at least every four weeks during the vegetation period following the harvest.

☐ Subsequent crops (specify):

☐ Crop rotation (specify):

☒ Fallow/no crop (specify):

The trial area and the buffer zone remained fallow for one year following the harvest.

☒ 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):

At least every four weeks during the vegetation period for one year following the harvest.

☐ Appropriate chemical treatment(s) (specify):

☐ Appropriate soil treatment(s) (specify):

☐ others, (specify):

6.1.6 Other(s)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): **April 2007 the trial at the location Sanitz has been destroyed partly.**

- 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:

Field releases 2006:

Geographical location(s)	Start of post-release monitoring	Finalization of post-release monitoring
Werpeloh	**01.10.2006**	**01.10.2008**
Möttingen	**01.10.2006**	**01.10.2008**
Gatersleben	**13.10.2006**	**13.10.2008**
Lohmen a	**09.10.2006**	**09.10.2008**
Sanitz a	**12.10.2006**	**12.11.2009**

Field releases 2007:

Geographical location(s)	Start of post-release monitoring	Finalization of post-release monitoring
Sanitz 2 (B110)	**01.11.2007**	**01.11.2009**
Lohmen (Asien)	**01.11.2007**	**01.11.2008**
Möttingen	**12.11.2007**	**01.11.2009**
Werpeloh	**12.11.2007**	**01.11.2009**

During the monitoring periods 2008 and 2009 no volunteers occurred at the respective locations. Therefore post-harvest monitoring has been completed for all locations.

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)

Release sites were monitored during the vegetation period at least every four weeks. Any volunteer plants were removed manually prior to flowering.

☐ Monitoring of gene flow (specify)

☒ Appropriate chemical treatment(s) and/or soil treatment(s)

Soil cultivation with a grubber.

☐ others (specify):

☐ Monitoring measures of adjacent areas:

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)/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[6] 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.

Observation plan according to application, no amendments made.

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.

An intended effect of the introduced trait is to inhibit the expression of the endogenous *gbss* gene and thereby to reduce the amylose fraction in the starch of the potato tuber. The expected decrease in amylose content and a concomitant increase in amylopectin content in tuber starch could be confirmed.

No other effects than the increased levels of amylopectin in the potato tuber starch were expected and could be observed.

6.4.3 Unexpected effect(s)[7]

“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

[6] Summary notification information format (=SNIF)
[7] Without prejudice to Article 8 of Directive 2001/18/EC as regards handling of modifications or new 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.

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 show a reduction of the amylose content in tuber starch and concomitantly an increase of the amylopectin content.

No unexpected cases of survival or persistence in untreated environments were observed. Neither the molecular nor the phenotypic analysis points to potential occurrence of any unintended effects on human or animal health.

No unforeseen or adverse effects on human or animal health or the environment were observed during the release. Therefore, no additional measures are deemed necessary for future releases.

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: 29.01.2010