FORMAT FOR THE PRESENTATION OF THE RESULTS OF DELIBERATE RELEASE INTO THE ENVIRONMENT OF GENTEICALLY MODIFIED HIGHER PLANTS IN ACCORDANCE WITH ARTICLE 10 OF DIRECTIVE 2001/18/EC

The report format shall be completed by the notifier.

The notifier shall fill in the report format according to the proposed form (tick boxes and/or, as far as possible, specific keywords to use in text fields).

The notifier shall illustrate as much as possible the reported data by means of diagrams, figures and tables. Statistical data could also be provided where relevant.

In the case of multi-sites, multi-events and/or multi-annual release(s), the notifier shall provide a general overview of the measures taken and effects observed for the full duration of the consent.

The space provided after each item is not indicative of the depth of the information required for the purposes of this report.

1 General information

1.1 European notification number: **B/CZ/11/1**

1.2 Member State of notification: **Czech Republic**

1.3 Date of consent and consent number: **22.04.2011, B/CZ/11/1 (8197/ENV/11 for BASF)**
22.04.2011, B/CZ/11/1 (9037/ENV/11 for RICP)

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***

3.2 Transformation event(s) (acronym(s)) or vectors[1] used (if transformation event identity not available): **AV43-6-G7 (Modena)**

[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.

3.3 Unique identifier, if available:

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 release site(s)[2] (m^2)	Identity[3] and approximate number of GM higher plants per event actually released (number of seeds/plants per m^2)	Duration of the release(s) (from (d/m/y) until (d/m/y))
Region: Kraj Vysočina; District: Humpolec	**2011** 500 m^2	AV43-6-G7, planting density: 45000 tubers per ha	19.05.2011 until 05.10.2011

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] Vectors used

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):

  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[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 ☐

- ☐ Verticle 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) ☐

[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.

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):

Potato tubers were packed in net bags and placed in plastic containers. Each unit was clearly labelled „Genetically modified organisms, not intended for cultivation, consumption and feeding".

☒ 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 the day of planting. 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 shipped to Czech Republic were planted on the test plot.

☐ Temporal isolation (specify):

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

GM potatoes were included into crop rotation regime.

☐ others (specify):

6.1.2 During the sowing/planting

☒ Method of sowing/planting:

Tubers were planted by hand.

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

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

Transport to the rows was conducted in net bags.

☐ others (specify):

6.1.3 During the period of release

☒ Isolation distance(s):

- ☒ from sexually compatible commercial plant species:

  more than 20 m from commercially grown potatoes

- ☐ from sexually compatible wild relatives: **not applicable**

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

☒ Cage/net/fence/signpost (specify):

In the corners of the planted area warning signs have been placed „GMO – No Entry". The electric fence was used.

☐ 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:

Trials have been observed regularly during the vegetation period. General plant characteristics relating to the agronomic performance of the potato lines, any changes in susceptibility to insects and pests have been observed according to conventional agricultural practice.

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):

A single-line potato digger was used for harvesting and tubers were harvested by hand. Tubers were packed directly on the field.

☐ 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 applying Reglone.

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

Potatoes were packed in boxings inside the storage facility, transported for sorting and counting within a double containment and transported in the day of harvest to Germany for further analyses or destruction.

☒ Clean up of machinery on the release site:

Potato digger was cleaned before and after harvest.

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

All tubers harvested were transported to Germany for analysis or destruction. All remaining dead plant material was incorporated into the soil.

☒ 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 plot was grubbed after harvest.

☐ 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 on a monthly basis during the vegetation periods until one year passed without finding volunteer plants, at least for two years.

☒ Subsequent crops (specify):

Oat has been planted as subsequent crop and in the second year after the trial wheat trials were conducted.

☒ Crop rotation (specify):

Three years following the release no potatoes are planted on the same field. Crop rotation is conducted.

☐ Fallow/no crop (specify):

☒ 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(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): T**he trial was damaged by unknown person twice. Together 7 plants were destroyed.**

- 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: **After damaging of the trial the field was guarded by the security agency till time of harvest.**

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 capter 6. Please indicate whether:

☐ the post-release monitoring plan will start

☒ the post-release monitoring plan is ongoing

(for the field trial location used in 2011)

☐ 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.

Specifiy:

☒ Monitoring measures within the site

Duration: **2 years**

Frequency of visits (average): **every 4 weeks during the vegetation period**

☐ Observation of resistant relatives

☐ Observation of resistant insects

☒ Control of volunteers (specify intervals and duration)

☐ Monitoring of gene flow (specify)

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

☒ others (specify): **destruction of volunteers**

☐ 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.

The GM potato lines have been cultivated under conventional agricultural practice. Trials have been observed regularly during the vegetation period. General plant characteristics relating to the 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 events 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.

[6] Summary notification information format (=SNIF)

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)[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 unexpected effects have been 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 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 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: 280813

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