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

(COMMISSION DECISION 2003/701/EC)

1. General information

1.1. European notification number: B/CZ/10/3

1.2. Member State of notification: Czech Republic

1.3. Date of consent and consent number. 07/04/2011 – 109280/ENV/10

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: *Beta vulgaris L.*

3.2. Transformation event(s) (acronym(s)) or vectors ([1]) used (if transformation event identity not available): SBVR111, H7-1, SBVR111xH7-1

3.3. Unique identifier, if available:

H7-1: KM-ØØØ71-4

SBVR111: not 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 introduced traits and/or genetic elements. In the case of large(r)-scale 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.

Geographical location(s) (administrative region and, where appropriate, grid reference)	Size of the release site(s) ([1]) (m^2)	Identity ([2]) and approximate number of GM higher plants per event actually released (number of seeds/plants per m^2)	Duration of the release(s) (from ... (day/month/year) until...(d/m/y))
Nosislav 1510/1	Total surface: 2909 m2 GM area: 1172 m2	9 plants/m2	From 20/04/2011 until 14/10/2011
Unkovice 1667/26	Total Surface: 1345 m2 GM area: 565 m2	9 plants/m2	From 20/04/2011 until 14/10/2011
Troubelice 1227/36	Not planted		

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

([2]) 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 ☒ 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 (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 ☐

5.2. Deliberate release(t) for development purposes ☒

— Event screening

— Proof of concept ([2])

X 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)

X Altered agronomic properties (e.g. disease/pest/drought/frost-resistance, etc.) (specify)

The objective of the field releases was to gain information relating to:

- **the agronomic performance of these event sugar beet products under European conditions,**
- **the production of sugar beet for comparative and protein analyses and the study on agronomic traits,**
- **gaining further information relating to the resistance against target pests under European conditions,**
- **allowing further assessment of the events in the environment**

— Altered qualitative properties (prolonged shelf-life, enhanced nutritional value, modified composition, etc.) (specify)

— Stability of the expression

— Multiplication of lines

— Hybrid vigour study

— Molecular farming ([3])

— Phyto-remediation

— Others: .....(describe).....

5.3. Official testing ☐

— Variety registration on a national variety catalogue

  — DUS (**D**istinctness, **U**niformity and **S**tability)

  — VCU (**V**alue of **C**ultivation and **U**se)

— Others: (specify).....

5.4. Herbicide authorisation ☐

5.5. Deliberate release(s) for demonstration purposes ☐

5.6. Seeds multiplication ☐

([2]) For example, testing the new trait under environmental conditions.

([3]) '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 pharmaceuticals, plant-based proteins production, etc.

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
— Potential changes in persistence or dispersal
— 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) of deliberate release(s): ☐

(describe) .....

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.

Tick the examples where appropriate:

6.1.1. Before the sowing/planting:

— Clear labelling of the GM seeds/planting material lots (distinct from other seeds/tubers/etc.) (describe)

Seeds lots were packed in sealed paper bags in facilities authorized to carry out confined release of GMOs; the bags remained closed until planting. Each paper bag was clearly labeled with a unique identifier code and as "Contains genetically modified material, not to be used for commercial cultivation, food or feed". The name of the event was also mentioned. All the bags containing the seeds lots were contained into a sealed and labeled box

— 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)

Seed were transported in a triple closing package and were managed in the trials by qualified staff. Transport of the seeds to the field trial site was done on the day of planting.

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

All the remaining seeds after planting were collected then burned and destroyed by burying into the field release site.

— Temporal isolation (specify)

— Rotation (specify the previous crop(s))

— Other(s): (specify).....

6.1.2. During the sowing/planting activities:

— Method of sowing/planting

Sowing was carried out with a microplot field trial machine.

— Emptying and cleaning of the sowing/planting machinery on the field of release

All equipment used to seed was free of plant material before entering the trial site. After sowing, all the equipment used for planting was cleaned on the trial site to eliminate unintended transport of any seed or plant material from the trial site.

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

The planting procedure with identification of each seeds lot in separate bags avoids seed mixing during the planting operation. After the sowing of each seeds lot, the remaining seeds in the micro-plot planter were recovered in a dedicated device or in the seeds tank

— Other(s) (specify).....

6.1.3. During the period of release:

— Isolation distance(s) (x metres)

— from sexually compatible commercial plant species,

The trials were surrounded by no less than 5 metre wide zone of a cultivated fallow.

— from sexually compatible wild relatives.

— 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.)

The trial sites were regularly monitored (once every 3 weeks at a minimum).

— Other(s): (specify):.....

Trials have been monitored on a bi-weekly basis (in average) during the growing season; additionally have been inspected by experts and competent authorities.

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) Harvest /destruction before the ripeness of the seeds

Sugarbeet roots were harvested by hand. All the roots were introduced in labelled, closed bags, and prepared for its transport to the Syngenta laboratory of Semcice. All the roots and remaining material after analysis was transported to the waste dump of the AVE s.r.o company in Benátky nad Jizerou. The material was buried into a big hole. All the other plant material remaining in the field trial area after harvest (not required for further analysis) was destroyed by crushing down, and application of a nitrogen fertilizer will be conducted before its integration into the soil to accelerate decomposition of the biomass

— Effective removal of plant parts

For the purpose of the experiment, all beetroots produced in the field trials have been harvested and transported for analyses to Syngenta beet laboratory of Semčice.

— Segregated storage and transport of crop/waste (provide example(s) of containment to prevent spillage of collected seeds/crops/wastes)

The harvested material was placed into closed bags appropriately labelled and transported in a heavy lorry with trained driver to the Syngenta beet laboratory of Semcice.

— Clean up of machinery on the release site

All the equipment used for harvesting and plant material destruction were cleaned before leaving the field trial area

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

All the roots and remaining material after analysis at Syngenta beet laboratory were transported to the waste dump of the AVE s.r.o company in Benátky nad Jizerou. The material was buried into a big hole. All the other plant material remaining in the field trial area after harvest (not required for further analysis) was destroyed by crushing down, and application of a nitrogen fertilizer was conducted before its integration into the soil to accelerate decomposition of the biomass.

— 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 practices)

Conventional soil cultural practices in the area were followed after the trial termination.

— Other(s): (describe).....

6.1.5. Post-harvest measures

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

Frequency of visits (average):

Post-harvest monitoring visits were conducted in the following 2 years after the end of the release according to the monitoring plan: in one month interval the first year – 2012 (focusing on the periods when sugar beet plants could grow) and in the second year - 2013, an only inspection was conducted in June.

— Subsequent crop (specify)

Sugar beet was not grown on the trial sites during the following year after field trial termination.

— Crop rotation (specify)

Sugar beet was not grown on the trial sites during the following year after field trial termination

— Fallow/no crop (specify)

— Superficial soil work/no deep ploughing

— False-sowing beds

— Control of volunteers (specify intervals and duration)

Post-harvest monitoring visits were conducted in the following 2 years after the end of the release according to the monitoring plan: in one month interval the first year - 2012 (focusing on the periods when sugar beet plants could grow) and in the second year – 2013, an only inspection was conducted in June.

No volunteers were found.

— Appropriate chemical treatment(s) (specify)

— Appropriate soil treatment(s) (specify)

— Others (specify)

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

.....
.....

6.1.7. Emergency plan(s)

Indicate:

(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 plans) (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),~~
- **the post-release monitoring plan has been completed** (in the case of the final post-release monitoring report),
- ~~**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:

— Monitoring measures within site

Duration:

Post-harvest monitoring visits were conducted in the following 2 years after the end of the release according to the monitoring plan.

Frequency of visits (average):

In one month interval the first year – 2012 (focusing on the periods when sugar beet plants could grow) and in the second year – 2013, an only inspection was conducted in June. No volunteers were found

— Observation of resistant relatives

Resistant relatives have not been observed

— Observation of resistant insects

Resistant insect have not been observed

— Control of volunteers (specify intervals and duration)

Post-harvest monitoring visits were conducted in the following 2 years after the end of the release according to the monitoring plan: in one month interval the first year – 2012 (focusing on the periods when sugar beet plants could grow) and in the second year – 2013 only one inspection was conducted in June

— Monitoring of gene flow (specify)

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

— Others (specify).....

— Monitoring measures of adjacent areas **Not requested**

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

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 ([4]) 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.

No amendment was requested for the application and SNIF of Part B. No additional scientific insights or methods have been developed that would have recommended to change the methods and processes used in these investigations.

6.4. Observed effect(s)

6.5. 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.

([4]) Summary notification information format (= SNIF).

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 not anticipated in the environmental risk assessment.

The observed effect(s)/interaction(s) of the GMO(s)

— 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 on 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.

6.5.1. 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 GM sugar beet events, approved as indicated above in this report for environmental release, differ only for its resistance to Rhizomania and tolerance to the herbicide active ingredient glyphosate compared to conventional sugar beet. Non-transgenic, near isogenic control sugar beet with the same genetic background was grown for comparison. No other phenotypic difference was observed between GM and non-GM sugar beet.

6.5.2. Unexpected effects ([5])

'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.

With the aim to detect any unexpected effect on non-target organisms, a monitoring program has been implemented through a series of systematic observations in the field trial
No unexpected or adverse effects have been detected.

6.5.3. 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.

The trials proceed as planned and no unexpected effects or observation were detected. Therefore the outcome of the risk assessment remains unchanged as a result of these trials.

([5]) 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 information provided in this report is not considered confidential in accordance with Article 25 of Directive 2001/18/EC. This does not prevent the competent authority from requiring additional information from the notifier, both confidential and non-confidential. In the 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: 24/09/2013

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