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)

LOGO OF THE COMPANY OR RESEARCH INSTITUTE (OPTIONAL)

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/10/2

1.2. Member State of notification:

Czech Republic

1.3. Date of consent and consent number.

31 January 2011, 89673/ENV/10

2. Report status

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

Final report

3. Characteristics of the release

3.1. Scientific name of the recipient organism:

Beta vulgaris subsp. vulgaris

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

H7-1

3.3. Unique identifier, if available:

KM-ØØØH71-4

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))
Nechanice	650 m^2	9 – 10 plants/m^2	Sowing: 1.4.2011 Harvest: 22.9. 2011
Staré Nechanice	737 m^2	9 – 10 plants/m^2	Sowing: 6.4.2012 Harvest: 17.9. 2012

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])

☒ 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) *Differences in performance for biomass yield, sugar yield and growth parameters between the herbicide treatments*

— 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

— 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)

Always, as complement to the conditions of the authorization, the work instructions of SESVanderHave have been applied

6.1.1. Before the sowing/planting:

- double packing in closed containers labelled as "Genetically modified organism" - KM-ØØØH71-4, mass value and the unified identification of SESVANDERHAVE International B.V. for genetically modified material. Extra labelling "Not determined for cultivation and consumption or feeding" and "Transfer to non-authorised persons prohibited" was used.

- Authorised transporting company was used for the transport from Belgium to the Czech Republic and back, other movements onto the field and GMO laboratory in

Nechanice were under the guidance of the trained person of the company Testing Station Nechanice.

- the subsequent crop on the experimental area and the surroundings will not be sugar beet

6.1.2. During the sowing/planting activities:

- seeds were transported from the GMO laboratory in double sealed bags with the recommended labelling, the manipulation off the material was done by the trained staff only;
- HEGE 95 seeder for accurate seeding was used;
- Seed bags were only opened on site at the appropriate plot position during drilling. The sequence and seed identification of seeds was double checked before transfer to the drilling machine
- the sowing machinery was cleaned after sowing, no seed was left in the planter;
- remaining seed was returned to the GMO laboratory and send back to Belgium via accredited transporter

6.1.3. During the period of release:

- the minimal isolation distance of 200 m from other vegetation of conventional sugar beet as demanded by the permit has been respected;
- the trial area was surrounded by 5 m wide strip of unsown land and by 8 rows of maize as a buffer strip
- the monitoring of randomly arisen plants and bolters especially was carried out at least every two weeks during the vegetation periods and according to the work instructions of SESVanderHave.;
- the trial was prevented from the entry of trespassers by four warning boards placed in all corners with notices: Attention! GMO! No Entrance! Not Determined For Feed! Not Determined for Food! Chemically Treated!

6.1.4. At the end of the release:

- the harvesting machine with the automatic line for taking the brei samples was used
- the brei samples were labelled in the harvesting machine and placed into the freezing box in the machine. After harvesting of the whole trial area, the frozen samples were double packed and transported by the authorised personnel to the GMO laboratory, where the samples were kept in the freezer and stored until transport for further analysis to Belgium;
- the harvesting machine and sampling equipment, as well as all other machinery used at the harvest, were cleaned on the release site at the place where they were used ;

- all the other plant parts were left on the experimental area, disked and deep-ploughed into the soil. Nitrogen fertiliser was applied in order to speed up the degradation of organic matter in soil

6.1.5. Post-harvest measures

- The release site will be sown with a crop different from sugar beet in the following year;
- post-harvest monitoring of randomly arisen sugar beet plants will be carried out during the whole vegetation season in the subsequent two years.

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

Not applicable.

6.1.7. Emergency plan(s)

Indicate:

(a) if the release proceeded as planned:

The release proceeded as planned.

(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:

The measures were not necessary.

6.2. Post-release monitoring measures

Please indicate whether

— **the post-release monitoring plan is ongoing** (in the case of an intermediary post-release monitoring report),

the post-release monitoring is on-going. For the trial carried out in 2011 the monitoring period had just finished in 2013, for the trial carried out in 2012 the monitoring period will finish by the year 2014. No trial was carried out in 2013.

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: Two years after the harvest season.

Frequency of visits (average): Once a month during the growing season.

— **Observation of resistant relatives** No

— **Observation of resistant insects** Not applicable

— **Control of volunteers (specify intervals and duration)**

Once a month during the next two growing seasons. In case volunteer plants are detected, they should be pulled out and left on the field. Each monitoring and its results should be recorded.

— **Monitoring of gene flow (specify)** Not applicable

— **Appropriate chemical treatment(s) and/or soil treatment(s)** Not necessary

— **Others (specify)** None

— **Monitoring measures of adjacent areas**

Duration: Two years after the harvest season.

Frequency of visits (average): Once a month during the growing season.

Area monitored:

— **Observation of resistant relatives** No

— **Observation of resistant insects** Not applicable

— **Control of volunteers and/or monitoring of feral populations (specify intervals and duration)**

Once a month during the next two growing seasons. In case volunteer plants are detected, they should be pulled out and left on the field. Each monitoring and its results should be recorded.

— **Monitoring of gene flow (specify)** Not applicable

— **Appropriate chemical treatment(s) and/or soil treatment(s)** Not necessary

— **Others (specify)** None

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.

During the release: any unexpected effect shall be recorded.

After harvest/destruction: volunteer monitoring during the two-year vegetation period after the harvest.

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.

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

No unexpected effects have been recorded.

6.4.2. Expected effect(s)

The environmental risk assessment has indicated that the environmental risk is negligible. It is concluded that H7-1 is as safe as its conventional counterpart with respect to potential direct effects on human and animal health and the environment.

No difference to the conventional sugar beet has been recorded. No adverse effects for human and animal health or environment has been observed.

6.4.3. Unexpected effects

No unexpected effects have been recorded.

6.4.4. Other information

--

---

7. Conclusion

Field trials were carried out in accordance with the applications, approvals and legislation regulating GMO´s.

All the measures to avoid potential dissemination of seed, or any other plant material were taken. All sugar beets in these trials stayed at the vegetative stage and no bolters were detected. The post-release monitoring plan has been started since the first years trials has been completed, and for the post-release monitoring of this field trial location no volunteers were observed.

No negative effects on human or animal health, or the environment, were observed.

DATE: February 26, 2014.