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/SK/13/01

1.2. Member State of notification:

Slovakia

1.3. Date of consent and consent number:

23. April 2013, 22752/2013 (3210/2013-3.2.-18-ZZP37)

2. Report status

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

The final report

3. Characteristics of the release

3.1. Scientific name of the recipient organism:

Beta vulgaris

3.2. Transformation event(s) (acronym(s)) or vectors 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) (m^2)	Identity 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))
Borovce	560 m^2	H7-1 9 plants per m^2	Sowing: 6.5.2013 Destruction: 20.11.2013

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?

No

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

5.1. Deliberate release(s) for research purposes

Not applicable

5.2. Deliberate release(s) for development purposes

Efficacy/selectivity testing of plant protection products (herbicides). Evaluation of different herbicide treatments. Agronomic performance testing – yield, germination, plant vigour

5.3. Official testing

Not applicable

5.4. Herbicide authorisation

Data generated from the field trials is supposed to support glyphosate herbicide formulations registration according to Council Directive 91/414/EEC and Slovak plant protection legislation.

5.5. Deliberate release(s) for demonstration purposes

Some of the field trials were used for demonstration purposes to show GM sugar beet technology to farmers and technical audience.

5.6. Seeds multiplication

Not applicable

5.7. Deliberate release(s) for biosafety/risk assessment research

Not applicable

5.8. Other(s) types) of deliberate release(s):

Not applicable

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)

6.1.1. Before the sowing/planting:

- It was confirmed a minimum isolation distance of 200 m from other commercial sugar beet fields.

Seeds of H7-1 sugar beet were packed in double sealed bags and labelled as "Genetically modified organism" – KM-ØØØH71-4 seed was transported by car.

(Remaining seed after sowing was packed and sent courier to SESVanderHave, Belgium.)

6.1.2. During the sowing/planting activities:

- Seed was transported in closed bags; manipulation with seed material done only by authorized/trained staff.
- Sowing machinery was cleaned after field operation, no seed was left in the planter after planting of trials.

Remaining seed after sowing was packed and sent courier to SESVanderHave, Belgium.

- Competent authorities (Slovak Environmental Inspection) were present during sowing; planting operation was done under supervision of officials.
- A minimum of six rows of conventional sugar beet were planted and a 5 m wide strip of bare soil with no sugar beet surrounding the trial were respected as indicated in the conditions of the authorization..

6.1.3. During the period of release:

- The minimal isolation distance of 200 m from other conventional and ecological sugar beet, together with the six rows of non transgenic beet surrounding the trials, were used to prevent most of the possibility of hybridization with other sugar beet plants.
- Trials have been monitored regularly during the period of the deliberate release for potentially occurring, direct or indirect, adverse environmental effects. During the visits, no adverse environmental effects were observed. No adverse effects were recorded regarding to human or animal safety.
- Trials were labelled (in all corners) by warning : "Genetically modified organism, Do not enter, Not for feed use, Treated by chemicals"

6.1.4. At the end of the release:

- Competent authorities (Slovak Environmental Inspection) were present during harvest and trials destruction.
- Trials were terminated, plants were sugar beet – at trail termination plants were defoliated and destroyed by disking to prevent further growth.
- Trial with crop residues and plants was destroyed in the experimental site of their incorporation into the soil by plowing.
- All machinery was cleaned before leaving the field.

6.1.5. Post-harvest measures

The release site will be sown with a crop different from beet for two years following the trial and during this years, at time of vegetation period, potential volunteer plants will be controlled by mechanical destruction or non-selective herbicides.

6.1.6. Other(s) 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:

These measures were not necessary.

6.2.Post-release monitoring measures

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 on place since the termination of the H7-1 trial 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 termination of H7-1 trial.

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

— **Observation of resistant relatives** No

— **Observation of resistant insects** Not applicable

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

Once a month during growing season, in case of volunteer plants are detected, they are removed and left on the site for biodegradation.

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

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

— **Others (specify)** Rotation crop susceptible to beet conventional herbicides

— **Monitoring measures of adjacent areas**

Duration: Two years after harvest of H7-1 trials.

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

Area monitored: adjacent fields to H7-1 trials.

— **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 growing season.

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

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

— **Others (specify)** No

6.3. Plan for observation(s)/method(s) involved

During H7-1 field release: general observations of plant health, sensitivity to diseases and pests, plant development. Any unexpected effects of H7-1 shall be recorded.

After harvest/destruction of H7-1 trails: monitoring of volunteer during vegetation period of the next two years.

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.

No unexpected effects have been recorded.

6.4.2. Expected effect(s)

The environmental risk assessment has indicated that the environmental risk of these sugar beet is negligible; H7-1 is as safe as its conventional counterparts with respect to potential direct effects on human and animal health and the environment.

No difference in growing or development of H7-1 respect to its conventional counterparts has been recorded. No adverse effects have been observed for human and animal health or the environment.

6.4.3. Unexpected effects

No unexpected effects have been recorded.

6.4.4. Other information

No other information.

7. Conclusion

Field trial was carried out according to the application and in line with specific legislation regulating GMO's.

All the measures to avoid potential dissemination of seed, or any other plant material were taken. As no adverse effect from the GMO sugar beet (expected or unexpected) could be detected during this field trial, no extra measures should be taken for further releases. The monitoring plan to detect bolting plants was followed.

The post-release monitoring plan has been started since the first years GM trials has been completed, and for the post-release monitoring of this field trial location no volunteers were observed. Neither did we observe any expected or unexpected adverse effects on human health or the environment.

DATE: December 30th, 2013

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