

**REPORT 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/11/3

**1.2. Member State of notification:**

Czech Republic

**1.3. Date of consent and consent number:**

5 February 2012, 19495/ENV/12 (application number 94345/ENV/11)

***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 subsp. 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 <sup>2</sup> )	Identity and approximate number of GM higher plants per event actually released (number of seeds/plants per m <sup>2</sup> )	Duration of the release(s) (from ... (day/month/year) until...(d/m/y))
Nechanice	1440 m <sup>2</sup>	8-12 plants/m <sup>2</sup>	Sowing: 11/4/2012 Destruction:3/9/2012
Probluz	1440 m <sup>2</sup>	8-12 plants/m <sup>2</sup>	Sowing: 11/4/2012 Destruction: 3/9/2012

**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

Placing on the market of food and feed produced from genetically modified sugar beet H7-1 has been authorized in the EU in accordance with Regulation (EC) No 1829/2003 in the Commission Decision of 24 October 2007 (2007/692/EC). Application for authorisation of H7-1 sugar beet cultivation has been submitted in accordance with Regulation 1829/2003 (EFSA-GMO-DE-2008-63).

**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**

Not applicable

**5.3. Official testing**

Not applicable

**5.4. Herbicide authorisation**

Data generated from efficacy and selectivity trials are intended for authorization of glyphosate herbicide formulations in H7-1(Roundup Ready) sugar beet, genetically modified for tolerance to glyphosate.

**5.5. Deliberate release(s) for demonstration purposes**

Field trials were not used for demonstration purposes.

**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:**

- Before the sowing, it was confirmed that each selected site did show guarantees for an appropriate trial execution, including a minimum isolation of 200 m from other commercial sugar beet fields.
- Seeds of H7-1 sugar beet was triple packed and labelled as “Genetically modified organism” – KM-ØØØH71-4. Additional labelling: “not for planting, or food and feed use”, “no transfer to unauthorized personnel” H7-1 seed was packed and labelled in KWS SAAT AG, Einbeck, Germany, transported to Czech Republic by authorized personnel.

#### **6.1.2. During the sowing/planting activities:**

- Seed was transported in closed, original packages; manipulation with seed material done only by authorized and trained personnel.
- Sowing machinery was cleaned after field operation, no seed was left in the planter after planting of trials.
- Remaining seed was stored in original packages in authorized room and returned to KWS Germany.

#### **6.1.3. During the period of release:**

- Trials have been monitored during the growing season, including weekly visits during the period of June-August to ensure an early detection and destruction of inflorescences, if any, thus avoiding any pollen dispersion.
- 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:**

- Selectivity trials were harvested by sugar beet harvester. Roots were weighed in the field to determine crop yield; for laboratory analyses, approximately 60 kg of beets were sampled from each plot. Root samples were put in special labelled bags and transported to KWS Germany, accompanied by authorized personnel. Leaves and remaining roots were chopped and incorporated into soil.

- Efficacy trials were not harvested; they were destroyed by chopping by discs, with incorporation of plant material into the soil on experimental fields.
- Experimental field at Probluz was ploughed in September. Field at Nechanice will be ploughed in November. Nitrogen fertilizers were used to support biodegradation of biomass.
- Harvester, transportation means and all other equipment were carefully cleaned before leaving the experimental field.

#### **6.1.5. Post-harvest measures**

The release site will be sown with a crop different from sugar beet for one year following the trial. A field visit monitoring program has been initiated in both locations where trials were established; it will continue during vegetation period of 2013 year, in order to eliminate sugar beet regrowth, if any. Potential emerging beet plants will be destroyed 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 is ongoing.**

The post-release monitoring plan is in place since harvest of H7-1 field trials.

**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:** One year after harvest of H7-1 sugar beet trials.

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

- **Observation of resistant relatives** No
- **Observation of resistant insects** No
- **Control of volunteers (specify intervals and duration)**  
Once a month during growing season, in case that re-growth of sugar beet plants is detected, these 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)** No
- **Monitoring measures of adjacent areas**  
**Duration:** One year after harvest of H7-1 sugar beet trials.  
**Frequency of visits (average):** Once a month during growing season.  
**Area monitored:** adjacent fields and surrounding area to H7-1 sugar beet trials.
- **Observation of resistant relatives** No
- **Observation of resistant insects** No
- **Control of volunteers and/or monitoring of feral populations (specify intervals and duration)**  
Once a month during growing season, in case that re-growth of sugar beet plants is detected, these 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)** No

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

During H7-1 sugar beet 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 sugar beet trials: monitoring of re-growth of sugar beet plants during vegetation period of the next year.

### **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)**

H7-1 sugar beet plants developed normally and presented a crop cycle and yield similar to that expected for conventional sugar beet counterparts.

In these trials, tolerance to glyphosate herbicide of H7-1 sugar beet plants has been confirmed.

### **6.4.3. Unexpected effects**

No unexpected effects have been recorded.

### **6.4.4. Other information**

None

## **7. Conclusion**

The deliberate release was carried out according to the applications, approvals, and in line with specific legislation regulating GMO's.

Field trials were carried out as planned. During the release, all the measures to avoid the pollen spread of the genetically modified plants outside the trial fields were taken and appropriate management was applied to the samples collected for analytic purposes. H7-1 sugar beet behaved similarly to the conventional sugar beet. Furthermore, no negative effect on the human or animal health, or on the environment have been detected during the trials execution.

Efficacy and selectivity results are being analyzed and will be later presented to Competent Authorities to support the authorisation of the tested formulations with the a.i. glyphosate.

DATE: October 31<sup>st</sup>, 2012