

ANNEX

THE FORM TO PRESENT THE RESULTS OF INTENDED RELEASE INTO THE ENVIRONMENT 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/PL/09/02-06**

1.2. **MemberState of notification: Poland**

1.3. **Date of consent and consent number: 22.02.2010 nr 02.01./2010**

2. **Reporting status**

2. Report status

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

— **the final report**

— a post-release monitoring report

— final indirect

3. **Characteristics of the release**

Scientific name of the recipient organism:: Sugar beet (Beta vulgaris L.)

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

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 the release site(s) ⁽¹⁾ (m ²)	Identity ⁽²⁾ and mean number of GM higher plants really released per given case (number of seeds/plants per m ²)	Duration of the release(s) (from ... (day/month/year) until...(d/m/y))
Province Dolnośląskie, municipality Wrocław, Agricultural Experimental Station of Department of Agroecosystems and Green Areas Management	666 m ² - total plots area for GM beets cultivation	Plasmid PV- BVGTO8 28 pieces of seeds / m ² (Before thinning) 8-9 pieces of plants m ² (after thinning)	20.04.2010- 2.09.2010 and 19.04.2011- 31.08.2011

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

²Vectors 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)

5.1. **Deliberate release(s) for research purposes**

5.2. **Deliberate release(t) for development purposes**

- Event screening
- Proof of concept (²)
- Agronomic activities (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)
- 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 in 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

5.4 Deliberate release(s) for demonstration purposes

5.6 Seeds multiplication

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)

The fields, which deliberate release of genetically modified sugar beet H7-1 were done were spatially isolated from other fields. The spread of sugar beet H7-1 was effectively constrained by the strict control of the seed during and after sowing. Excess seeds were sent to the producer.

Please report the risk-management measures, which have been used to avoid or minimize 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)
KWS SAAT AG delivered the seed material in years 2010-2011 in a clearly marked and sealed cardboard 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)
- Destruction of superfluous seeds/planting material (describe the method involved)

The seed that was not used to the experiment was sent back to the KWS SAAT AG. producer

- Temporal isolation (specify)
Fields with sugar beet H7-1 were sown with spring wheat belt with a width not less than 10 m. Other beet crops were distant at least 100 meters from the place of release.

- Crop rotation (specify the previous crop(s))
For the experiment in 2010, the previous crop was spring wheat Monsumvariety, but for the experiment in 2011 –it was winter wheat Trendvariety.

- Other(s): (specify)

6.1.2. During the sowing/planting activities:

- Method of sowing/planting
Sowing in 2010 and 2011 was conducted with a spacing drill belonging to Agricultural Experimental Station where the release of sugar beet H7-1 took place in.

- Emptying and cleaning of the sowing/planting machinery in the field of release
After sowing of the seed material for this purpose the machinery was accurately drained and cleaned off residual material.
- Segregation during the sowing/planting (provide example(s) of containment to prevent spillage during the sowing/planting)
- Other(s) (specify)

6.1.3. *During the period of release:*

- Isolation distance(s) (x metres)
 - from sexually compatible commercial plant species,- at least 100 meters
 - from sexually compatible wild relatives - not less than 100 meters
- Border row(s) (with the same crop or a different one, with a non-transgenic crop, x metres, etc.)

Each year the field of sugar beet H7-1 was distant, at least 100 meters from other beet crops.

- Cage/net/fence/signpost (specify)
The place of the release of sugar beet H7-1 to the environment was in a closed area of the Agricultural Experimental Station.
- Pollen trap (specify)
- Removal of GM inflorescences before flowering (indicate the frequency of the removal)**X**
- Removal of bolters/relatives/hybrid partners (indicate the frequency of the removal, x metres around the GM field, etc.)
- Other(s) (specify):

6.1.4. *At the end of the release:*

Between 01 – 02. 09. 2010 and 29 – 31. 09. 2011 the harvest of sugar beet roots was done. The harvest time took place in the same way: the roots are harvested by hand bridle and then digging the roots from each plot. Samples intended for the study were weighed, packaged and shipped. The individual samples for biometric measurements were also performed. Any plant remains left on the field were chopped and plowed down All activities were done in the presence of the committee.

- 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 Harvest followed on 01-02.09.2010 and 29-31.09.2011 in the presence of the committee. Material (samples) was packed and labeled, and then sent to the laboratory. Sugar beet H7-1 does not generate the generative organs - so there was no seed material.
- Effective removal of plant parts
Plant remains left in the field were accurately chopped and then plowed down to a depth of 35 cm.- Segregated storage and transport of crop/waste (provide example(s) of containment to prevent spillage of collected seeds/crops/wastes)
Collected samples of roots were weighed, packed and clearly labeled as GMO material, then sent to the laboratory.
- Cleaning up of machinery on the release site
All machines and tools used during the harvest in 2010 and 2011 were accurately cleaned.
- Destination of the waste, treatment of waste/surplus yield/plant residues (describe)

Any plant remains (leaves and roots) were chopped and plowed down in the field.

- 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)
- Other(s): (describe):

1.1.1. 6.1.5. Post-harvest measures

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

Frequency of visits (average):

- Subsequent crop (specify) Maize (2010), Winter triticale (2011)
- Crop rotation (specify) Maize – Spring triticale - Canola (2010) Winter triticale - Canola (2011)
- Fallow/no crop (specify)
- Superficial soil work/no deep ploughing - Harrowing, seedbed preparation, sowing.
- False-sowing beds
- Control of volunteers (specify intervals and duration)
- 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 NIE WIEM CO ZAZNACZYC bo w oryginalne polskim tez nie wiem pan Prof. miał sie o to zapytac**

- **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 going (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.

Sugar beet is a biennial plant producing inflorescences shoots in the second year. Sugar beet H7-1 because of the annual use of both the 2010 and 2011 was unable to produce the generative (can not produce pollen - no possibility of uncontrolled spread). There was no need for such a detailed inspection of the area and adjacent areas. For this reason, monitoring of the experimental field after release took place at intervals of 4-7 days.

After completion of the harvest and after harvest, samples for laboratory testing, plant remains left in the field were accurately chopped and plowed down.

Specify:

- Monitoring measures within site
 - Duration: min. about 30 minutes
 - Frequency of visits (average): (average of 2-3 visits / week)
 - Observation of resistant relatives - It is not necessary
 - Observation of resistant insects — Control of volunteers (specify intervals and duration) - It is not necessary
 - Monitoring of gene flow (specify)- It is not necessary
 - Appropriate chemical treatment(s) and/or soil treatment(s) - It is not necessary
 - Others (specify).....
- Monitoring measures of adjacent areas
 - Duration: min. about 30 minutes
 - Frequency of visits (average): (average of 2-3 visits / week)
 - Area monitored:
 - Observation of resistant relatives- It is not necessary
 - Observation of resistant insects- It is not necessary
 - Control of volunteers and/or monitoring of feral populations (specify intervals and duration)- It is not necessary
 - Monitoring of gene flow (specify)- It is not necessary
 - Appropriate chemical treatment(s) and/or soil treatment(s) - It is not necessary
 - Others (specify)

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

All activities and observations in the experimental field were held in accordance with the originally defined methodology.

6.4. Observed effect(s)

Sugar beet H7-1 in 2010-2011 was unable to produce pollen, as its cultivation was confined to produce vegetative stage. There were no adverse effects to human health and the environment.

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 whole process of the release of sugar beet H7-1 to the environment in 2010-2011 was held in accordance with the provisions set out in the methodology. As a result of security used on the same seed as the crop, there was no inadvertent spread of sugar beet.

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.