

**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**

<b>1 GENERAL INFORMATION</b>
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**1.1 European notification number:**

B/ES/12/13

**1.2 Member State of notification:**

Spain

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

16/02/2012

<b>2 REPORT STATUS</b>
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**2.1 Please indicate whether, according to Article 3 of the present Decision, the current report is:**

**The final report**

<b>3 CHARACTERISTICS OF THE RELEASE</b>
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**3.1 Scientific name of the recipient organism:**

*Beta vulgaris*

**3.2 Transformation event(s) (acronym(s) or vectors<sup>1</sup> used (if transformation event identity not available):**

SBVR111xH7-1 sugar beet

**3.3 Unique identifier, if available:**

Not available

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<sup>1</sup> 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-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:**

<b>Geographical local location or places (administrative region and coordinates of reference when it proceeds)</b>	<b>Local surface or places (m<sup>2</sup>)</b>	<b>Identity and approximate number of top plants MG liberated really by every event (N<sup>o</sup> of seeds / plants for m<sup>2</sup>)</b>	<b>Duration of her or the liberations: (Of... (day / month / year) up to (day / month / year</b>
Burgos, Villaquirán de los Infantes Pol 507 Parc 340	Not planted		
Burgos, Villaquirán de los Infantes Pol 505 Parc 10206	Not planted		
Valladolid, Valladolid Pol 1 Parc43	Not planted		
Valladolid, Villanueva de Duero, Pol 2 Parc28	Not planted		
Valladolid, Vega de Valdetronco, Pol 3 Parc 192	Not planted		
Valladolid, Vega de Valdetronco, Pol 3 Parc 193	Not planted		
Palencia, Magaz de Pisuerga, Pol 2 Parc 73	Not planted		
Palencia, Magaz de Pisuerga, Pol 2 Parc 20057	175,5 m2 (GM). Total surface: (GM + conventional): 877.5 m2	30 plants/m2	10/04/12 – 27/09/2012
Palencia, Magaz de Pisuerga, Pol 1 Parc 10018	Not planted		
Leon, Villamorico, Pol 9 Parc33	Not planted		

**4 ANY KIND OF PRODUCT THAT THE NOTIFIER INTENDS TO NOTIFY AT 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(s) for development purposes

- Event screening
- Proof of concept
- 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)
- Improved agronomic properties (e.g. disease/pest/drought/frost resistance,etc) (Specify: **rhizomania resistance**)
- Improved qualitative properties (prolonged shelf-life, enhanced nutritional value, modified composition, etc) (Specify)
- Stability of the expression
- Multiplication of lines
- Hybrid vigour study
- Molecular farming
- Phyto-remediation
- Others: .....

**5.3 Official testing**

- Variety registration on a national variety catalogue
- DUS (=Distinctness, Uniformity and Stability)
- VCU (=Value of Cultivation and Use)
- Others: (specify).....

**5.4 Herbicide authorization**

**5.5 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) type(s) of deliberate release(s):**

(describe) :

<b>6 METHOD(S), RESULT(S) OF THE RELEASE, MANAGEMENT AND MONITORING MEASURE(S) IN RESPECT OF ANY RISK TO HUMAN HEALTH OR THE ENVIRONMENT.</b>
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Without prejudice to the specific environmental risk assessment as well as to the consent conditions, the notifier shall provide the following information **in respect of any effect for human health or the environment**. 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.

### 6.1 Risk management measure(s)

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 labeling of the GM seeds (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 identifier code and an indication that it was containing GM seeds. 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 inside of a triple closing package and were managed in the trials by qualified staff.**

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

**The remaining seeds after the field trial sowing were buried inside the perimeter of the field release area.**

- Temporal isolation (specify).

- Rotation (specify the previous crop).

Other(s): (specify) ..

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

Method of sowing/planting.

**The sowing has been carried out by means of a pneumatic drill specially adapted for agricultural experimentation**

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. The residual seed recovered during the process of cleaning were buried in the soil of the alley of the trial**

**The drill is equipped with an automatic system to avoid mixtures, separating in a specific container all the seeds not sowed in his corresponding plot. The remaining seeds of the sowing have been buried inside the perimeter of the test.**

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 (x meters)

From sexually compatible commercial plant species.

**A distance of at least 5 m from conventional sugar beet fields.**

From sexually compatible wild relatives.

**No wild relatives are present in the zone of the field release.**

Border rows (with the same crop or a different one, with a non-transgenic crop, x meters, etc).

Cage/net/fence/signpost (specify).

Pollen trap (specify).

Removal of GM inflorescences before flowering (indicate the frequency of removal).

**Visual monitoring once every 4 weeks: No bolting sugar beet plants were detected.**

Removal of bolters/relatives/hybrid partners (indicate the frequency of the removal, x meters around the GM field, etc).

Other(s): (specify).....

**6.1.4 At the end of the release:**

Harvest/destruction methods (of crop or part of it) / other means (e.g.: sampling)

**Sugar beet roots were harvested by hand. All the roots were introduced in closed containers, weighted and prepared for its transport to the laboratory and final destruction. At the field site, the plant materials remaining in the field trial area suffered mechanical grinding and were mechanically incorporated into the soil immediately after the harvest.**

**The root material after analysis was buried into a big hole and treated with calcium oxide.**

Harvest / destruction before the ripeness of the seeds. (describe).

**All the roots and remaining material after analysis was buried into a big hole and treated with calcium oxide.**

**All the other plant materials remaining in the field trial area suffered mechanical grinding and were mechanically incorporated into the soil.**

Post-harvest treatment and cultivation measures on the release site (describe the method 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 harvest:

Frequency of visits (average): **One each 4 weeks during the periods when seed potential could germinate.**

Subsequent crop (specify): **Sugar beet will not be grown on the trial sites during the following year after field trial termination.**

Crop rotation (specify): **Sugar beet will not be 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).

**Specific monitoring will be implemented along the following year. Any volunteer sugar beet appearing in the field will be eliminated before flowering.**

- Appropriate chemical treatment(s) (specify):
- Appropriate soil treatment(s) (specify):
- Other(s) (specify):

**6.1.6 Other(s) measure(s): (describe)**

**Not applicable**

**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 plan(s) (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 results of this monitoring are meant to confirm or invalidate earlier assumptions in them 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: **along the following year upon field trial termination focusing on the periods when sugar beet plants could grow.**

Frequency of visits (average): **1 visit each 4 weeks during the periods when sugar beet plants could grow.**

- Observation of resistant relatives.
- Observation of resistant insects.
- Control of volunteers (specify intervals and duration). **1 visit each 4 weeks during the periods when sugar beet plants could grow (spring)**
- Monitoring of gene flow (specify).
- Appropriate chemical treatment(s) and/or soil treatment(s).
- Others (specify).

- Monitoring measures of adjacent areas:

Duration: **not applicable. Monitoring within the site includes the fallow zone around the field release area.**

Frequency of visits (average):

Area monitored:

- Observation of resistant relatives.
- Observation of resistant insects.
- Control of volunteers (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)/methods(s) involved

**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 at least one survey every four weeks during the release timelines.**

**No unexpected or adverse effects have been detected.**

### 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.*

*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 and 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>.

#### **6.4.2 Expected effect(s)**

**The SBVR111xH7-1 sugar beet plants have developed showing good agronomic characteristics.**

**No adverse effect has been observed for the human health or the environment.**

#### **6.4.3 Unexpected effect(s)<sup>2</sup>**

**No unexpected or adverse effects for the human health or the environment have been observed.**

#### **6.4.4 Other information**

## **7 CONCLUSION**

**The field trials have developed as it was foreseen and has not been observed any unexpected or adverse effect. In consequence the conclusions of the environmental risk assessment have been confirmed**

**DATE: 29/01/2013**

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<sup>2</sup> Without prejudice to Article 8 of Directive 2001/18/EC as regards handling of modifications or new information.