

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

1 General information

1.1 European notification number : B/ES/10/02

1.2 Member State of notification: Spain

**1.3 Date of consent and consent number : ORDEN CONSEJERÍA DE MEDIO
AMBIENTE DE LA JUNTA DE CASTILLA Y LEÓN DE 8 DE ABRIL DE 2010**

2 Report status

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

- the final report

~~— a post-release monitoring report~~

~~— intermediary: post-release monitoring still ongoing~~

3 Characteristics of the release

3.1 Scientific name of the recipient organism: Beta vulgaris

(a) Family name: Chenopodiaceae

(b) Genus: Beta

(c) Species: vulgaris

(d) Subspecies: vulgaris

(f) Common name: sugar beet

**3.2 Transformation event(s) (acronym(s) or vectors¹ used (if
transformation event identity not available):**

H7-1 Round up ready sugar beet

3.3 Unique identifier, if available:

KM-000H71-4

¹ 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:

| Geographical location(s) (administrative region and, where appropriate, grid reference) | Size of the release site(s) (²) (m ²) | Identity (³) 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) |
|--|---|--|---|
| Villamediana, Palencia | 1000 m ² | H7-1 event; 4600 before thinning 4000 plants after thinning | From 17/05/2010 until 25/10/2010 |

(²) Specify the size of the GM area and, where appropriate, the size of the non-GM area (e.g. non-GM border)

(³) Vectors used

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 (by another juridical entity of the group) 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 pour.
 - 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 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.) 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 : (specify)

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.

5.2 Official testing



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

5.3 Herbicide authorization



5.4 Deliberate release(s) for demonstration purposes



5.5 Seeds multiplication



5.6 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.
- Observation of resistant insects.
- Others: (describe)
-

5.7 Other(s) type(s) 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)

Please report the risk-management measures, which have been used to avoid or minimise 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,

The trial was surrounded by a sugar beet field on one side and with a barley field on the other side. The field was surrounded by a 5 m border of naked soil as recommended by the operating procedures of SESVanderHave. This area was kept clean during the whole duration of the trial.

The beets in the trial and in the surrounding field were all at the vegetative stage and were not allowed to flower. Like in normal weather conditions, all the beets in the yield trial remained vegetative.

Regular visits of the trial by experienced staff were conducted to ensure the early detection of any bolting plant. Procedures were put in place to ensure that the bolting plant if any would be destroyed long before flowering.

- 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 (distinct from other seeds/tubers/etc.) (describe)
At sowing time, the seeds were packed in closed bags and the bags were handled in a closed container as required by the SESVanderHave standard operating procedures.
The bags and the container were clearly labeled with the GMO label and the dedicated GM seed codes as defined in the standard operating procedures of SESVanderHave.

- 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).
Seeds were transported in so-called triple packaging: double-walled inner packaging in a rigid outer container. The packaging as a whole was leak or sifts proof. The outer packaging could not break, disrupt or open when dropped.
- Destruction of superfluous seeds/planting material (describe the method involved).
All left-over seeds were collected and packed as described above. These seeds were sent back to SESVANDERHAVE NV in Tienen, Belgium with the appropriate movement traceability forms.
- Temporal isolation (specify).
- Rotation (specify the previous crop). BARLEY
- Other(s): (specify)

6.1.2 During the sowing/planting activities:

- Method of sowing/planting.
A drilling machine was used on the site. 200 seeds were drilled on each plot.

Emptying and cleaning of the sowing machinery has been performed on the release field . The drilling machine used on the site was carefully cleaned at the trial site according to the standard operating procedures of SESVanderhave before and after the sowing tasks were completed and before leaving the site, to remove any remaining seed.
- Segregation during the sowing (provide example of containment to prevent spillage during the sowing/planting).
Seeds were packaged in the required amount in individual envelopes per plot. These envelopes were only opened on site, at the appropriate plot position during drilling. The sequence of envelopes was checked prior to drilling by two persons to ensure the correct sequence as determined on the field layout.
- Other(s): (specify)

6.1.3 During the period of release:

- Isolation distance (x meters)

From sexually compatible commercial plant species. Because the plants in the trial were kept at the vegetative stage and surrounded by vegetative sugar beet and because any sign of bolting was monitored during the trial, there was no need for isolation distances

From sexually compatible wild relatives. Because the plants in the trial were kept at the vegetative stage and because any sign of bolting was monitored during the trial, there was no need for isolation distances.

- Border rows (with the same crop or a different one, with a non-transgenic crop, x meters, etc).
One border row of sugar beets was surrounding the field trial. All these plots (research and border plots) were surrounded by at least 5 m of bare soil.
- Cage/net/fence/signpost (specify).
- Pollen trap (specify).
- Removal of GM inflorescences before flowering (indicate the frequency of removal).

No flowering was detected as the trial was monitored regularly for bolters.

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

No bolters were detected during the whole release period. During the whole campaign, the trial was visited not less than once every two weeks.

- 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) (describe).
Sugar beet plots were harvested with the SESVanderhave mobile beet harvester. For each plot, harvested beets were weighted and brei samples prepared from the sugar beets. These brei samples were labeled and stored properly as determined in the SESVanderHave standard operating procedures and sent to Tienen, Belgium, for further analysis.
All the remaining beet leaves, tops, pieces of roots were left in the trial site. They have been buried in a very big hole and covered with Quick lime as requested by the authorization
- Harvest / destruction before the ripeness of the seeds.
Roots were harvested, and as explained before left on the field. The beets were at the vegetative stage and there was no seed produced from any of the plant of the trial as the beet were not allowed to bolt nor to flower.
- Effective removal of plant parts.
Not applicable.
- Segregated storage and transport of crop/waste (provide examples of containment to prevent spillage of collected seeds/crops/wastes).
Brei samples have been packed in double walled bags to prevent spillage. As the beets were only vegetative plants, no flower has been detected and no seed has

been produced on the release site. Only the collected brei samples made from samples of the root tissue did leave the release site.

All the remaining beet leaves, tops, pieces of roots, both GM and conventional, were left in the trial site. They have been buried in a very big hole and covered with Quick lime as requested by the authorization. No waste did leave the trial site.

- Clean up of machinery on the release site.

The mobile harvester was cleaned before the start of the harvest and after harvesting of the trial. Cleanings have been done on the release site and recorded in the field logbook.

- Destination of the waste, treatment of waste/ surplus yield/plant residues (describe).

After the brei samples have been prepared, all the remaining beet leaves, tops, pieces of roots were left in the trial site. They were buried in a big hole and covered with quick lime as requested in the authorization..

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

Standard works have been already done before to sow new crop-barley, basically with subsoling works, Chissel machine and rotary cultivation.

6.1.5 *Post-harvest measures:*

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

Superficial soil work / no deep ploughing.

Frequency of visits (average)

The trial site started to be monitored immediately after harvest and for a 2 years period after harvesting to detect and destroy any sugar beet which would be growing in the trial area. Three visits per year are required to ensure that any beet is detected prior to flowering.

No sugar beets will be grown for 2 years on this location.

- Subsequent crop (specify).

Barley

- Crop rotation (specify).

Potatoes/sugar beets/barley

- Fallow/no crop (specify).

- False-sowing beds.

- Control of volunteers (specify intervals and duration).

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

6.1.6 *Other(s) 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 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 post-release monitoring plan is ongoing** (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.

Specify:

- Monitoring measures within site

Duration: 2 years

Frequency of visits (average): at least 3 times a year, during the growing season

- Control of volunteers (specify intervals and duration).
- Appropriate chemical treatment(s) and/or soil treatment(s).
- Others Rotation crop susceptible to Beet conventional herbicides

- Monitoring measures of adjacent areas:

Duration: 2 years

Frequency of visits (average): at least 3 times a year, during the growing season

Area monitored: field site and adjacent field site.

- Control of possible volunteers.

6.3 Plan for observation(s)/methods(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 SNIF⁴ 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.

No modifications to the original plan and protocol of the trial were made nor applied.

The development of The GMO herbicide resistant sugar beet in natural agronomical conditions was observed. Special care was given to all steps of development (color, shape and freshness of the leaves, morphology of the plants, stability of the phenotype all over the season, development of the root) and to notice any abnormal or different behavior.

Also the presence of weeds was scored during this field trial.

At the end of the season the GMO sugar beets have been collected and harvested on the site for testing of agronomic and quality parameters, like root yield and sugar yield are

⁴ Summary notification information format (=SNIF)

determined. Except brei samples, all parts of the beets were left and buried on the trial site.

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)

This section concerns « expected effects », that is to say, potential effects which were already identified in the environmental risk assessment of the notification and could therefore be anticipated.

Notifiers should supply data from the deliberate release(s) which validate the assumptions made in the environmental risk assessment.

No bolters were observed during the trial.

6.4.3 *Unexpected effect(s)*⁵

“Unexpected effects” refer to effects on human health or the environment which were not foreseen or identified in the environmental risk assessment of the notification. This part of the report should contain any information with regard to unexpected effects or observations relevant for the initial environmental risk assessment. In case of any observed unexpected effects or observations, this section should be as detailed as possible to allow a proper interpretation of the data.

No unintended effects were detected during this field trial.

6.4.4 *Other information*

Notifiers are encouraged to supply information, which is outside the scope of the notification but which might be relevant to the field trials in question. This may also include observations of beneficial effects.

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 GM Release referenced B/ES/10/02 was managed as expected and without any unexpected effect. All the sugar beets in this yield trial stayed at the vegetative stage, no bolter was detected

During drilling and harvest, authorization requirements, SESVANDERHAVE SOPs and dedicated protocols were properly followed to manage the risk of spillage of GMO material. SESVanderHave issued standard operating procedures covering all aspects of the release management. These procedures and working instructions were instructed to all people working with GMO material for this trial.

For further releases, similar measures will be taken to manage the trials in the same confidence. No extra measures should be taken for further releases. Sesvanderhave SOPs are fully relevant and no change in these Sops is foreseen for the time being.

The burying of all harvested beet roots and other harvest wastes and the use of quick lime is a highly severe measure that is understandable and economically acceptable in the case of a new event not yet authorized in the EU. In the case of H7-1(KM-ØØØH71-4), which is deregulated for food and feed in the EU, and for its further

⁵ Without prejudice to Article 8 OF Directive 2001/18/EC as regards handling of modifications or new information.

releases like registration trials that will occur in bigger acreages and higher number of locations in the coming years, it could be proposed to destroy the crop harvest residues by simply incorporating them in the soil by rotavation and monitoring any possible regrowth within one year after release end.

DATE: 25 March 2011