

FORMAT FOR THE PRESENTATION OF THE RESULT OF DELIBERATE
RELEASE INTO THE ENVIRONMENT OF GENETICALLY MODIFIED
HIGHER PLANTS IN ACCORDANCE WITH ANNEX XI
OF ROYAL DECREE 178/2004

1 General information

1.1 European notification number: B/ES/13/03

1.2 Member State of notification: SPAIN

1.3 Date of consent and consent number: 12/12/12 Ministerio de Agricultura y Medio Ambiente – Consejo Interministerial de ORGANISMOS GENÉTICAMENTE MODIFICADOS

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 vectors¹ used (if transformation event identity not available):

H7-1 Round up Ready sugar beet

3.3 Unique identifier, if available:

KM-ØØØH71-4 sugar beet

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)
Laguna de Negrillos León	1.000 m ²	H7-1 5040 plants	From 24/04/13 Until 10/10/13
Magaz Palencia	1.000 m ²	H7-1 5040 plants	From 22/04/13 Until 08/10/13
Tordesillas Valladolid	1.000 m ²	H7-1 5040 plants	From 23/04/13 Until 10/10/13
Villalazán Zamora	1.000 m ²	H7-1 5040 plants	From 23/04/13 Until 09/10/13
Toro Zamora	1.000 m ²	H7-1 5040 plants	From 23/04/13 Until 10/10/13

(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

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.) (specify). Yield capacity
- Others : (specify)

5.3 Official testing

- Variety registration on a national variety catalogue
- Others: (specify):

5.4 Herbicide authorization

² For example, testing the new trait under environmental conditions.

5.5 Deliberate release(s) for demonstration purposes

5.6 Seeds multiplication

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

- Others: (describe)

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5.8 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)

6.1.1 Before the sowing/planting:

- Clear labelling of the GM seeds (distinct from other seeds/tubers/etc.) (describe). –

Always, as complement of the conditions of the authorization, the work instructions of SESVANDERHAVE have been applied.

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 sealed bags and sealed container were clearly labeled with the GMO label and the dedicated GM seed codes as defined in the standard operating procedures of SESVanderHave. Additionally the seeds were coated with a color specific for GMO seeds 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 sift proof. The outer packaging could not break, disrupt or open when dropped.

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

Burned and buried

- Other(s): (specify)

6.1.2 *During the sowing/planting activities:*

- Method of sowing/planting.

Direct sowing with specific essays seed drill

Emptying and cleaning of the sowing machinery on the field of release.

Automatic cleaning of the seed drill

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).

The seed corresponding to every plot settles in the corresponding hopper of the seed drill

Seeds were packed 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 and seed identification of envelopes was checked prior to drilling by two persons to ensure the correct sequence and seed identification as determined on the field layout.

- Other(s): (specify)

6.1.3 *During the period of release:*

- Isolation distance (x meters)

The conditions specified in the Communication and later Authorization to maintain 5m of clean soil and to eliminate bolting plants have been respected.

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

6.1.4 *At the end of the release:*

The treatment of the harvested beets, leaves and residues of harvest have been managed in accordance with the notification/consent

Manual harvest helped mechanically

Cleaning have been done at the place where the machinery was used.

The shoots were buried at the trial site and plowed to 30cm deep as requested by the authorization.

The rest of the production – properly labeled – were moved to the AIMCRA facilities.

All the residues, after the analyses were buried with quicklime as requested by the authorization.

- Other(s): (describe):

6.1.5 Post-harvest measures:

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

The post-harvest monitoring will be realized by AIMCRA technical staff in accordance with the notification / authorization.

The cultivation of sugar beet will not be allowed for a two years period after the release.

In the cultivation following the release, lethal herbicides for the sugar beet will be used.

Periodic visits will be realized to prevent the appearance of any volunteer.

- 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

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

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

- **X 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): Once a month

- Monitoring measures of adjacent areas:

There were no bolting plants, therefore it is not foreseen

Area Others (specify).

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 SNIF³ part B need to be specified in detail.

³ Summary notification information format (=SNIF)

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.

The AIMCRA technical staff has dealt with the practical achievement of the fields. All the remarks realized by the technical staff responsible for the essay in its visits have been noted down in the field notebook of every essay: Vegetative development of the cultivation, weeds, plagues and illnesses.

S.A. MARISA SESVANDERHAVE notifier and Company responsible of the release, by its technical staff, has been present in all the phases of the release and has carried out its visits and remarks, exchanging its points of view with the AIMCRA staff.

6.4 Observed effect(s)

6.4.1 Explanatory note.

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.

As expected effects there existed the possibility of dispersion of pollen from bolting GMO plants. Never the flowering of bolting plants was allowed

6.4.3 Unexpected effect(s)⁴

“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.

Unexpected effects were not observed

6.4.4 Other information

⁴ Without prejudice to Article 8 OF Directive 2001/18/EC as regards handling of modifications or new 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.

The plants of GMO sugar beets have been always perfectly integrated in the field of essay together with the control conventional varieties. It was impossible to distinguish between GMO and conventional sugar beets, even for a technical specialist in the cultivation of sugar beet whom did not know the scheme of the design.

All the remarks indicate that the presence of these GMO sugar beet plants in the environment is equivalent to the presence of plant of cultivated conventional sugar beet.

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 of the notification B/ES/13/03 was managed as expected and without unexpected events. All the sugar beets in this trial stayed at the vegetative stage and 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.

The sowing, cultivation, treatments and harvest was made by the technical team of AIMCRA in accordance with the specifications in the Notification / Authorization. All these specifications were joined to the ones of SESVANDERHAVE, and records were maintained in a field book for every field of the essay that the AIMCRA technical staff was handling.

S.A. MARISA SESVANDERHAVE, by its technical personnel and by means of periodic visits, has stated that AIMCRA has fulfilled with the stipulations for the practical achievement of these fields of essay.

The Authorities of the Ministerio de Agricultura y Medio Ambiente , the technical staff of the OFFICE OF VEGETABLE VARIETIES, was present at the trial during sowing, harvest, burial of remains, ... etc. and during the control visits, corresponding Minutes were made and signed.

The release and the way in which it has been carried out by the AIMCRA staff experienced in this kind of field essays with sugar beet, has been satisfactory and indicates that the way of operating must be continued.

For further releases, similar measures will be taken to manage the trials in the same way. No extra measures should be taken for further releases. SESVanderHave SOPs are fully relevant and up to date with present requirements

The Company S.A. MARISA SESVANDERHAVE, does not intend to present new notifications in order to complete the corresponding evaluations for the varieties inscription in the Official Record.

DATE: 27 November 2013