

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/11/15

1.2 Member State of notification: Spain

1.3 Date of consent and consent number: Consent 124/1026 May, 04, 2011 of the Consejo Interministerial for OGM of the “Ministerio de Medio Ambiente y Medio Rural y Marino”.

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

- a. Family name: Chenopodiaceae
- b. Genus: Beta
- c. Species: vulgaris
- d. Subspecies: vulgaris
- e. 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)
Laguna de Negrillos (León)	1.000 m ²	H7-1 event 2.160 plantas	From 12/05/2011 until 27/09/2011
Magaz (Palencia)	1.000 m ²	H7-1 event 2.160 plantas	From 06/05/2011 until 29/09/2011
Villalazán (Zamora)	1.000 m ²	H7-1 event 2.160 plantas	From 06/05/2011 until 28/09/2011

(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

Field layout :

The trial is composed of plots 9 m².

- 2 tolerant varieties to glyphosate of genetically modified sugar beet: SR 9001 and SR 9002

- 6 control varieties of conventional sugar beet, not genetically modified:
MICHELA, OSMA, ERESMA: Official varieties control
SV1, SV2, SV3: SESVANDERHAVE varieties control

- 2 Borders:

B (conventional, not modified Variety)

B2 (Variety genetically modified).

Total 8 entries in the trial and two borders

Entry Nr	Entry Name	Specifications	Spray
1	SR9001	RR hybrid	RR
2	SR9002	RR hybrid	RR
3	OSMA	non GMO hybrid: Osmá	Conv
4	MICHELA	non GMO hybrid: Michela	Conv
5	ERESMA	non GMO hybrid: Eresma	Conv
6	SV1	non GMO hybrid	Conv
7	SV2	non GMO hybrid	Conv
8	SV3	non GMO hybrid	Conv
9	B	Conv border	Conv
10	B2	RR border	Conv

Varieties layout

Repetición 1	B	8	B2	1	B2	7	5	4	B2	2	B2	3	6	B
Repetición 2	B	7	8	6	3	4	B2	2	B2	5	B2	1	B2	B
Repetición 3	B	3	5	8	B2	1	B2	7	4	B2	2	B2	6	B
Repetición 4	B	B2	2	B2	6	8	3	7	5	4	B2	1	B2	B

Total number of plots 56
 Number of GMO plots 24
 Number of non GMO plots 32

Spray layout

Repetición 1	B	8	B2	1	B2	7	5	4	B2	2	B2	3	6	B
Repetición 2	B	7	8	6	3	4	B2	2	B2	5	B2	1	B2	B
Repetición 3	B	3	5	8	B2	1	B2	7	4	B2	2	B2	6	B
Repetición 4	B	B2	2	B2	6	8	3	7	5	4	B2	1	B2	B

Total number of plots 56
 Number of RR spray 8
 Number of conventional spray 48

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

- Agronomic performances, **yield capacity**

5.3 Official testing

- Variety registration on a national variety catalogue

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

5.8 Other(s) type(s) of deliberate release(s):

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 SESVANDERHAVE Work Instructions (WI) have been applied.

WI.01. Coding and labelling GM sugar beet material, marking of facilities

Availability of SESVanderHave GMO label

Marking GMO material

Marking storage facilities for GMO material

- 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).

WI.03 Shipment/movement of GM sugar beet material and Traceability forms. To avoid an unintended movement

Packaging of GM sugar beet material for shipment/movement and documents: Packaging and labelling for external movements

Do not pack GMO material with different genes in the same final package.

Pack GMO material in a so-called triple packaging: double-walled inner packaging in a rigid outer container. Several events with the same gene can be packed together in the same outer container. The packaging as a whole should be leak or sift proof. The outer packaging should not break, disrupt or open when dropped.

- watertight or sift proof primary receptacle(s);
- a secondary packaging which is leak or sift proof;
- if multiple fragile primary receptacles are placed in a single secondary packaging they shall be individually wrapped or separated to prevent contact between them;
- an outer packaging shall be strong enough for its capacity, mass and intended use.

To prevent that the plant material becomes wet during transport, the outer packaging should contain a water-repellent layer.

Some examples:

- paper seed bags in a metal container in a cardboard box;
- plastic tubes with screw cap in closed plastic bag with cushioning material in a box;
- closed collection tubes in holder, in strengthened paper bag in a box.

Label and mark the inner receptacle(s) according to WI.01.TE-ES.

Check whether the seed or hybrid codes do exist in a database (JIT or LIMS), check sample codes with the field logbook (correctness of codes). In case of problems inform the PL.

Label the outer box with the black triangle on 2 sides on the outside and one on the inside: the 2 cm/side for small boxes and the 15 cm/side triangle for big boxes.

Add on the outside:

- name and address of consignee,
- name and address of the sender,
- **Documentation for external movements**
- The accompanying documentation (within the EU):
- consignment note or Airway Bill (shipper/courier to provide),
- Pro Forma invoice, if needed (logistic dept.),

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

Burned and buried

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 cleanliness of the seed drill.

- 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

6.1.3 During the period of release:

The conditions of the notification/consent have been applied to maintain 5 m of clean soil and to eliminate the bolting plants.

6.1.4 At the end of the release:

- Harvest/destruction methods (of crop or part of it) / other means (e.g.: sampling) (describe).
The treatment of the harvested beets, leaves and residues of harvest have been managed in accordance with the notification/consent

6.1.5 Post-harvest measures:

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

The monitoring post-harvest will be managed by AIMCRA technical staff in accordance with the notification / consent.
The beet growing will not be allowed in two years later to the liberation.
Lethal herbicides for the beet will be used in the crops following the release.
Periodic visits will be realized to avoid the appearance of any volunteer.

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

- **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): **monthly**

- Appropriate chemical treatment(s) and/or soil treatment(s).
The herbicides used in after release crops, have to be lethal for the sugar beet

- Monitoring measures of adjacent areas:

There were not bolting plants. The monitoring of adjacent areas is not foreseen

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 SNIF² 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.

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

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

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.

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 the possibility of dispersion of pollen from plant OGM. Never the flowering of plants was allowed

*6.4.3 Unexpected effect(s)*³

“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

² Summary notification information format (=SNIF)

³ Without prejudice to Article 8 OF Directive 2001/18/EC as regards handling of modifications or new information.

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 unexpected effects were observed.

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.

The OGM beet plants have been always perfectly integrated in the field of the trial together with the control and border non OGM varieties. It was impossible to distinguish even for a technical specialist in the cultivation of sugar beet if he did not know the field layout.

All the remarks indicate us that the presence of these plants of beet OGM in the environment is equivalent to the presence of plant of cultivated conventional 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 release of the communication B / ES / 11/15 was carried out without unexpected events.

The OGM seed came up to the plot, in safe conditions, in accordance with the Work Instructions of SESVANDERHAVE.

The drilling, cultivation, treatments and harvest have been realized by the technical staff of AIMCRA in accordance with the specified in the Notification / consent. All these specifications were joined the proper ones of the Stewardship plan of SESVANDERHAVE, and shown in a field book for every field of trial handled by the AIMCRA technical staff.

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

The Administration, across the technical personnel of the OFICINA DE VARIEDADES VEGETALES, with presence in the operations of drilling, harvest, buried of remains, ... etc. and with monitoring visits has raised the corresponding Minutes.

The release and the way in which it has been carried out by the experienced AIMCRA personnel in this kind of field trials with sugar beet, has been satisfactory and indicates that the way of acting must be continue.

S.A. MARISA SESVANDERHAVE, tries with new later notifications to complete the corresponding evaluations for varieties registration on the National Variety Catalogue

DATE: October 2011