

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/12/03

1.2 Member State of notification: SPAIN

1.3 Date of consent and consent number: 23/12/11 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

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

Sugar beet H7-1 Round up Ready sugar beet

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.

3.2 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) (m2)	Identity (³) and approximate number of GM higher plants per event actually released (number of seeds/plants per m2)	Duration of the release(s) (from ... (day/month/year... until... (d/m/y)
Laguna de Negrillos León	1.000	H7-1 5040 plantas	Desde 22/03/12 Hasta 25/09/12
Dueñas Paalencia	1.000	H7-1 5040 plantas	Desde 17/04/12 Hasta 24/09/12
Tordesillas Valladolid	1.000	H7-1 5040 plantas	Desde 15/03/12 Hasta 25/09/12
Bercero Valladolid	1.000	H7-1 5040 plantas	Desde 15/03/12 Hasta 25/09/12

Plots 9 m².

- 3 varieties sugar beet GMO RR: SR-9001, SR-9002 y SR-9003

- 6 control varieties sugar beet no GMO: MICHELA, OSMA, ERESMA, SV1, SV2 Y SV3.

- 2 Borders: B (Variety no GMO) y B2 (Variety GMO)

Total 9 entries and 2 borders.

Entry Nr	Entry Name	Specifications	Spray
1	SR9001	Variedad RR	RR
2	SR9002	Variedad RR	RR
3	SR9003	Variedad RR	RR
4	OSMA	Variedad no GMO: Osma	Convencional
5	MICHELA	Variedad no GMO: Michela	Convencional
6	ERESMA	Variedad no GMO: Eresma	Convencional
7	SV1	Variedad no GMO: SV1	Convencional
8	SV2	Variedad no GMO: SV2	Convencional
9	SV3	Variedad no GMO: SV3	Convencional
10	B	Borde convencional: B	Convencional
11	B2	Borde RR: B2	Convencional

Scheme

Rep 1	B	6	8	4	9	7	B2	2	B2	5	B2	1	B2	B2	3	B2	B
Rep 2	B	B2	3	B2	4	8	9	5	B2	1	B2	7	B2	2	B2	6	B
Rep 3	B	5	9	6	4	B2	2	B2	B2	3	B2	8	B2	1	B2	7	B
Rep 4	B	5	B2	3	B2	7	8	B2	2	B2	B2	1	B2	6	4	9	B

Total Nr 68
Total Nr GMO 36
Total Nr no GMO 32

⁽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).
- Others : (specify)

5.3 Official testing

- Variety registration on a national variety catalogue
- 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

- Others: (describe)
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² For example, testing the new trait under environmental conditions.

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 (WI) of SESVANDERHAVE 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).

The WI.3. of SESVANDERHAVE establishes forms for the movement of the material to avoid an involuntary movement.

This instruction explains how to package GMO material properly, label and provide for the proper shipping 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).

By burnied 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 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

- 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:*

Manual harvest helped mechanically

Cleanliness in the place of the used machinery.

The sheets buried in the place plowing to 30cm

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

All the residues, after the analyses buried with quicklime.

- Other(s): (describe):

6.1.5 *Post-harvest measures:*

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

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

The beet cultivation will not be allowed in two years later to the liberation.

In the following cultivation after the liberation, lethal herbicides for de beet will be used.

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

- 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.

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 notiffier and Company responsible of the release, by 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 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 OGM 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

³ Summary notification information format (=SNIF)

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

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 plants of beet OGM have been always perfectly integrated in the field of essay together with the control no OGM varieties. Impossible to distinguish even for a technical specialist in the cultivation of sugar beet that did not know the scheme of the design.

All the remarks indicate 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 object of the communication B / ES / 12/03 was carried out without unexpected events.

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

The sowing, cultivation, treatments and harvest was made by the technical team of AIMCRA in accordance with the specified in the Notification / Authorization. All these specifications there joined to the ones of the Stewardship Plan of SESVANDERHAVE, written 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 stipulated for the practical achievement of these fields of essay.

The Authorities of the Ministerio de Agricultura y Medio Ambiente , across the technical staff of the OFFICE OF VEGETABLE VARIETIES, present in the works of sowing, harvest, buried of remains, ... etc. and accros the control visits have raised the corresponding Minutes.

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

The Company S.A. MARISA SESVANDERHAVE, pretends to present new later notifications in order to complete the corresponding evaluations for the varieties inscription in the Official Record.

DATE: October 2012