

**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/08/01

1.2 Member State of notification:

Spain

1.3 Date of consent and consent number:

- Autonomous Region of Castilla y Leon: Order of March 28th, 2008 by the Regional Counselor of the Environment.

2 REPORT STATUS

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

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 vectors used (if transformation event identity not available):

H7-1

3.3 Unique identifier, if available.

KM-000H71-4

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) (m²)	Identity and approximate number of GM higher plants per event actually released (number of seeds)	Duration of the release(s): (from...(day/month/year)...to...(day/month/year))
Valdefuentes del Paramo (León)	Area with GM plants*: 189 m ²	H7-1 sugar beet (8100 seeds)	From 25/04/2008 to 06/10/2008
Tordesillas (Valladolid)	Area with GM plants*: 1629 m ²	H7-1 sugar beet (65700 seeds)	From 26/04/2008 to 17/11/2008
Pampliega (Burgos)	Area with GM plants*: 189 m ²	H7-1 sugar beet (8100 seeds)	From 28/04/2008 to 07/10/2008
Melgar de Fernamental (Burgos)	Area with GM plants*: 279 m ²	H7-1 sugar beet (11700 seeds)	From 28/04/2008 to 07/10/2008
San Cristóbal de la Polantera (León)	Area with GM plants*: 279 m ²	H7-1 sugar beet (11700 seeds)	From 25/04/2008 to 06/10/2008
Miranda de Ebro (Burgos)	Area with GM plants*: 189 m ²	H7-1 sugar beet (8100 seeds)	From 24/04/2008 to 22/09/2008

*GM: genetically modified

The trials initially foreseen in Villaquirán (Burgos) were not carried out.

4 ANY KIND OF PRODUCTS THAT THE NOTIFIER INTENDS TO NOTIFY AT A 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 at a later stage?

Yes. Placing on the market of food and feed produced from genetically modified sugar beet H7-1 has been authorized in the EU in accordance with Regulation (EC) No 1829/2003 (Commission Decision of 24 October 2007, published in OJEU on 27/10/2007). Application for authorisation of H7-1 sugar beet cultivation has been submitted in accordance with Regulation 1829/2003 (EFSA-GMO-DE-2008-63).

5 TYPE(S) OF DELIBERATE RELEASES

5.1 Deliberate releases for research purposes

Not applicable.

5.2 Deliberate releases for development purposes

- Evaluation of agronomic performances, yield capacity, germination capacity, plant vigour, plant height.
- Determination of the expression of proteins and the composition in different plant tissues, at different growing stages.
- Determination of the level of residues in different plant tissues, after application of herbicides.
- Others (Describe): Additional data and observations on genetically modified sugar beet, including its comparative development with non-genetically modified varieties.

Trials were carried out in collaboration with Agrisearch Ibérica S.L., authorised to undertake GLP trials (3/BPL003) and officially accredited plant protection products (EOR 35/98).

5.3 Official testing

Not applicable.

5.4 Herbicide authorization

Trials with different herbicides were carried out in two locations (San Cristobal de la Polantera and Melgar de Fernamental), which were reported to the correspondent competent authority with the following codes: S08-00285-01 and S08-00285-02

These trials were carried out in collaboration with the company Agrisearch Ibérica S.L., authorised to undertake GLP trials (3/BPL003) and officially accredited trials with plant protection products (EOR 35/98).

5.5 Deliberate release(s) for demonstration purposes

Not applicable.

5.6 Seeds multiplication

Not applicable.

5.7 Deliberate releases for biosafety/risk assessment research

Not applicable.

5.8 Other types of deliberate releases

Not applicable.

6 METHOD(S), RESULT(S) OF THE RELEASE, MANAGEMENT AND MONITORING MEASURE(S) IN RESPECT OF ANY RISK TO HUMAN HEALTH AND THE ENVIRONMENT

6.1 Risk management measure(s)

6.1.1 Before the sowing/planting

- Clear labelling of the GM seeds batches/planting material. Seed for each GM variety was stored in a closed paper bag, and labelled with its correspondent identification. Each paper bag corresponded to a row from the elemental plot.
- Segregation during the processing and transport of the seeds/planting material (description of the method used, one or more examples of isolation mechanisms to avoid spills during processing and transporting). Seeds were transported to the field the same day of the sowing, in the pre-prepared paper bags, labelled and closed in the laboratory, and classified according to the trial layout. To avoid confusion or seeds mixing, the bags were opened sequentially, so that one paper bag was opened when the previous one had been placed in the sowing machine.
- Destruction of surplus seeds/planting material: All seeds prepared for the trial were sowed.
- The trials were surrounded by 6 furrows of conventional sugar beet, to separate conventional sugar beet from MG sugar beet. They were destructed together with the sugar beet plants from the trial.

6.1.2 During the sowing/planting activities

- Method of sowing/planting: trials were sown with a special planter for trials sowing and microplots; this machine self-cleans itself from one plot to another, keeping the ducts empty and avoiding seeds to be mixed.
- Emptying and cleaning of the sowing/planting machinery on the field of release. At the end of each plot, the seeds deposits and the ducts were emptied; the potential seed mixing was therefore avoided.
- Segregation during sowing/planting: All seeds were kept in individual paper bags, adequately identified. As explained above, a paper bag was not open until the previous seed was placed in the machine: it was not possible to mix seeds from two different paper bags.
- Others: Only Monsanto and co-operator company staff had access to the the trial seeds. The planter's ducts and deposits were cleaned after sowing the trial, to avoid any remaining seed could be released out of the trial area.

6.1.3 During the period of release

- Isolation distance(s) (meters): was not necessary.
- Border(s) rows: at least 6 rows of non-genetically modified sugar beet, of the same maturity, were sown surrounding each trial. At the end of the release, these non-GM sugar beet rows were chopped like the rest of the trial.
- Cage/net/fence/signpost was not necessary.
- Pollen trap was not necessary .
- Removal of GM inflorescences before flowering. The trials were visited weekly to remove any developing inflorescences, an then avoiding pollen production.
- Removal of volunteers/wild relatives/hybrids collaborators

Others:

6.1.4 *At the end of the release:*

- Destruction/harvest methods (of crop or part of it)/other means (sample harvesting and analysis of sugar beet pulp). At harvest time, the yield of the tested varieties was evaluated, and root samples were prepared for analytic purposes. This process were done in the laboratory of the Spanish Association for Sugar Beet Crop Investigation and Improvement (AIMCRA), located in Valladolid. The rest of the crop was destroyed.
- Harvest/destruction before seeds maturity: Different tissues samples were collected during the testing period. The samples were double packed in closed paper bags, labelled with its correspondent identification and frozen before sending them to the analytic laboratories. The samples collection and their manipulation were carried out carefully guaranteeing that they could not end up into the human or animal food chain. Their custody chain has been sent to the Competent Authority.
- Effective removal of plant parts
- Segregated storage and transport of crops/debris: Samples for analytical purposes were hermetically packed at the trial site. Every action was done following standard and GLP certified procedures.
- Clean up of machinery on the release site. Every machinery used at any stage from harvest to destruction was carefully cleaned at each trial site.
- Destination of the debris, treatment of waste/surplus yield/crop debris: crop debris were destroyed, chopped and incorporated into the soil at the end of the study.
- Post-harvest treatment and cultivation measures on the release site: at the end of the study, crop waste was chopped and incorporated into the soil.
- Other(s):

6.1.5 *Post-harvest measures*

The trial field will be visited during the following growing season to check marketable sugar beet has not been planted, and to destroy volunteers, if any.

- Subsequent crop: any crop different from marketable sugar beet
- Crop rotation: the following year any crop (except marketable sugar beet) will be grown.
- Fallow/no crop
- Superficial soil work/no deep ploughing
- False-sowing beds
- Control of volunteers: field trials will be visited during the following growing season to destroy the volunteer sugar beet plants, if any.
- Appropriate chemical treatment(s) (specify)
- Appropriate soil treatment(s) (specify)
- Others:

6.1.6 *Other(s) measure(s) (specify)*

6.1.7 *Emergency plan(s)*

Indicate:

- a) If the release proceeded as planned:
 - Yes
 - No

b) If measures according to the emergency plan(s) [article 23.2.a) 6° of Regulation and Annex V B] should be adopted:

- No
- Yes

6.2 Post-release monitoring measures

The trials were destructed on October –November 2008 (See 3.4)

Specify:

- Monitoring measures within the release site
 - Duration: trial fields will be visited during the following growing season to destroy sugar beet volunteers, if any.
- Monitoring measures in adjacent areas:

6.3 Plan for observation(s)/method(s) involved(s)

General observations on plant health, disease sensitivity and plant development; Furthermore any unexpected or unusual characteristic has been recorded.

6.4 Observed effect(s)

No unexpected effects have been observed.

6.4.1 All results of the deliberate releases 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.

H7-1 sugar beet plants did not pose any risk of adverse effects to human or animal health or to the environment different from those of conventional varieties.

6.4.2 Expected effects

H7-1 sugar beet plants developed normally and presented a crop cycle and yield similar to their isogenic conventional sugar beet counterparts.

6.4.3 Unexpected effects

Neither damage nor any kind of negative effects that could impact or have an effect on human health or the environment were observed.

6.4.4 Other information

None

7 CONCLUSION

The voluntary release was carried out in agreement with the measures proposed in the notification and established by the Competent Authority in the Authorization Order of March 28th, 2008 by the Regional Counselor of the Environment, guaranteeing safety to human and animal health, and to the environment.

Field trials were carried out as planned. During the release, all the measures to avoid the pollen spread of the genetically modified plants outside the trial fields were taken and appropriate management was applied to the samples collected for analytic purposes. Sugar beet varieties with genetic modification H7-1 behave similarly to the conventional sugar beet and it has not been observed any negative effect on the human or animal health, or on the environment.