

**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/11/04

1.2 Member State of notification

Spain

1.3 Date of consent and consent number

Order of March 17, 2011 by the Council of the Environment of the Autonomous of Region of Castilla y Leon.

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) (m ²) | Identity and approximate number of GM higher plants per event actually released (number of seeds/plants per m ²) | Duration of the release(s): |
|---|---|--|--|
| Tordesillas-Villanueva de Duero (Valladolid) | 1.518 m² | H7-1 sugarbeet 10,6 plants/m² | Sowing: 6 April, 2011 Destruction of efficacy trials: 20 June, 2011 Destruction other trials 26 September, 2011 |
| Tordesillas-Villavieja (Valladolid) | 1.518 m² | H7-1 sugarbeet 8,9 plants/m² | Sowing: 6 April, 2011 Destruction of efficacy trials: 20 June, 2011 Destruction other trials: 27 September, 2011 |
| Laguna Dalga (León) | 1.518 m² | H7-1 sugarbeet 5,6 plants/m² | Sowing: 15 April, 2011 Destruction of efficacy trials: 13 July, 2011 Destruction other trials: 29 September, 2011 |

Other potential sites were not used for trials execution: Valdefuentes del Páramo (LE), Urdiales del Páramo (LE) and Cabezón de Pisuerga (VA), because the three above selected sites better met criteria to enable agronomic and compliance requirements.

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 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 in the Commission Decision of 24 October 2007 (2007/692/EC). 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

Not applicable.

5.3 Official testing

Not applicable.

5.4 Herbicide authorization

Efficacy, selectivity and residue trials intended for Registration of glyphosate herbicide formulations on H7-1 sugarbeet, genetically modified for tolerance to glyphosate.

Efficacy and selectivity trials were carried out with the technical assistance of AIMCRA (Asociación de Investigación para la Mejora del Cultivo de la Remolacha Azucarera), accredited to undertake officially recognized trials for crop protection (EOR 3/96).

Residue trials were carried out in collaboration with the company Eurofins Agroscience Service S.L., authorised to undertake GLP trials (10/3/BPL03).

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

- Before the sowing, it was confirmed that each of the selected sites did show guarantees for an appropriate trial execution, including a minimum isolation of 5 m from other commercial sugarbeet fields.
- Seeds of H7-1 sugarbeet were triple packed and clearly labelled in KWS SAAT AG installations located in Germany. Delivery to Spain was appropriately communicated to the Competent Authorities in the Ministry of Environment, Rural and Marine Affairs and in the Council of Environment from Castilla y Leon.
- Seed transport to the field was made the same day of the sowing, in the pre-prepared bags, labelled and closed in the laboratory, which were undamaged when they arrived at the release site.

6.1.2 During the sowing/planting activities

- Sowing dates were notified with anticipation to Competent Authorities and conducted under their supervision.
- Seeds were manipulated by qualified staff, warned about preventive measures to avoid any dissemination.
- Sowing was made with clean sowing machinery, the planter was a special piece of equipment adapted for microplot sowing in trials, which self-cleans itself and keeps the ducts empty in order to avoid the seeds being mixed.
- Before removing the machinery out of the field, it was checked that all the sowing cones and ducts had been cleaned and there were no remaining seeds either inside or outside of the sowing machine.
- To avoid involuntary dispersion of the seeds, once the sowing was completed the remaining seeds and their packages were buried within the trial site.
- Experimental plots were sown according to the experimental layout, appropriately selected for the intended studies and ensuring that a perimeter of at least 5 m uncultivated land was isolating the testing area.
- Trials placed in Laguna Dalga had to be re-sown on May 12 due to heavy rains during the seed germination period, which impacted on plant density and would have limited the quality of the data generated. The procedure followed was the same as described before and the small plants from the first planting were destroyed by tilling within the trial site.

6.1.3 During the period of release

- Trials have been monitored during the growing season, including fortnightly visits during the period of June-August to ensure an early detection and destruction of inflorescences, if any, thus avoiding any pollen dispersion.
- During the performed visits there was no observation of a different effect of the genetically modified plants than the conventional sugarbeet on crop development, susceptibility to diseases or other pests, bees or other insects presence, birds or mammals occurrence. Therefore, it is suggested that the effect of the release on “non target” organisms”, on arthropofauna, or on the biodiversity in general has been similar to those caused by conventional sugarbeet cultivation.
- No incidences have been observed related to safety for human health and environment.

6.1.4 At the end of the release:

- Authorities have been informed in advance on the harvesting and destruction dates, which have been conducted under their supervision.
- Crop residues from the plots for the efficacy study were destroyed and buried early in the season within the trial site with a moldboard, once the study was completed (see 3.4). During the visits performed later, intended to supervise the selectivity and residue trials, the fallow area, where efficacy trials were previously set, was monitored. If a plant regrowth was detected it was appropriately destroyed within the trial site.
- Trials were harvested by hand. Plants were sequentially harvested and chopped in three sections: leaves, crowns and roots. Crowns and roots were bagged and labeled for full traceability, and transported with a custody register until they reach the AIMCRA laboratory, in Valladolid. Leaves were destroyed and buried within the trial site by moldboard tillage.

- Roots were conveniently processed and analyzed in AIMCRA facilities. Subsequently, the exceeding samples and residues after analysis, together with the crowns were appropriately buried by a soil layer of at least 30 cm depth.
- The processing and laboratory analysis were performed before starting the season with conventional sugarbeet, then highlighting the precautions to guarantee that they could not end up in the human or animal food chain.
- All the equipment, tools and means of transport were carefully cleaned and the plant residues buried either within the trial site or in AIMCRA facilities.
- Sugarbeet samples for residue analysis were conveniently collected, labeled and transported linked to a custody chain until reaching the Eurofins laboratories, accredited for such analysis (the custody register has been provided to the Competent Authority). All the activities were conducted following standard and GLP certified procedures.

6.1.5 Post-harvest measures

A field visit program and monitoring has been initiated in the areas where trials were established, which will continue until July 2012 in order to eliminate sugarbeet regrowth, if any. The subsequent commercial crop will be different from marketable sugarbeet.

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

Not applicable.

6.1.7 Emergency plan(s)

All the biosafety measures planned to avoid accidental releases have been applied

Please indicate:

a) if the release proceeded as planned

The release proceeded as planned.

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]

They were not necessary.

6.2 Post-release monitoring measures

The monitoring results confirmed that H7-1 sugarbeet plants are as safe as any conventional sugarbeet variety for human and animal health, or the environment.

According to the cases mentioned, please indicate the monitoring measures adopted

Please specify:

Monitoring measures within site

Trial plots will be visited during the following growing season to destroy the regrowth of sugarbeet plants, if any.

Monitoring measures of adjacent areas

No specific measures are planned as none of the tested plants had inflorescences. However, the isolation perimeter with fallow land and surrounding area have been included in the ongoing monitoring.

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

Specific observations on weeds control and on tested plants have been recorded according to the protocol for efficacy and selectivity studies. Also, general observations on plant development and health have been performed as well as a general surveillance to record unusual or different abundance of insects, birds or mammals than in conventional fields.

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 sugarbeet 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 that expected for conventional sugar beet counterparts cultivated in the testing areas and under same agronomic practises.

In these trials, tolerance to glyphosate herbicide of H7-1 sugarbeet plants has been confirmed.

6.4.3 Unexpected effects

Unexpected effects were not observed

6.4.4 Other information

None

7 CONCLUSION

The deliberate release was carried out in agreement with the measures proposed in the notification and established by the Competent Authority in the Order of March 17, 2011 by the Council of the Environment of the Autonomous of Region of Castilla y Leon, guaranteeing safety to human and animal health, and to the environment.

Field trials and studies 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. Sugarbeet varieties with genetic modification H7-1 behave similarly to the conventional sugar beet. Furthermore, no negative effect on the human or animal health, or on the environment have been detected during the trials execution.

Efficacy, selectivity and residue results are being analyzed and will be later presented to Competent Authorities to support the authorisation of the tested formulations with the a.i. glyphosate.