

**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/06/01

1.2 Member State of notification

Spain.

1.3 Date of consent and consent number

APRIL 18th, 2006 by Order of the Environmental Counselor of Junta de Castilla y León.

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 vector(s) used (if transformation event identity not available)

H7-1

3.3 Unique identifier, if available

KM-ØØØH71-4

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	Duration of the release (days)
Valladolid (E-47100 Tordesillas)	60 m²	1000 plants	63
Valladolid (E-47133 Bercero)	99 m²	1250 plants	154
Valladolid (E-47113 Villabarba)	99 m²	1250 plants	154
Zamora (E-49870 Villavendimio)	60 m²	780 plants	152
Valladolid (E-47529 Villafranca de Duero)	35 m²	460 plants	62

Trials layout:

4. ANY KIND OF PRODUCT 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.

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

Not applicable.

5.5 Deliberate releases for demonstration purposes

Not applicable to this field.

5.6 Seeds multiplication

Not applicable.

5.7 Deliberate releases for biosafety/risk assessment research (Please, specify)

The release objective was to measure the residue levels in sugarbeet plants treated with the glyphosate formulation MON78044 (360 g/L active ingredient).

5.8 Other types of deliberate releases

Not applicable.

6. METHODS, RESULTS OF THE RELEASE, MANAGEMENT AND MONITORING MEASURES IN RESPECT OF ANY RISK TO HUMAN HEALTH OR THE ENVIRONMENT

6.1 Risk management measures

6.1.1 Before the sowing

- Seeds have been packed and clearly labelled to avoid confusion or a potential mixing with conventional seeds.
- Seeds (1 package with 6000 seeds) were transported by a MONSANTO AGRICULTURA ESPAÑA S.L. company's representative.

6.1.2 During the sowing / planting activities

- Competent authorities were informed of the sowing dates and other key operations. After the sowing, the planting machinery was cleaned up before leaving the plot. Measures implemented are listed below.
- Transgenic seeds sown were packed and clearly labelled. Therefore, only the sowing cones and the pneumatic planter were exposed to those seeds
- All the 6000 seeds were planted (no leftover remains).
- Seeds were separated in single packages, so they were never mixed. A package was open only when the previous one was sown and the machine cleaned.

6.1.3 During the period of release

- Trials have been monitored on several dates during the growing season, and have been visited by some experts and competent authorities:

The only incidences worthy of mention are:

Due to the delay for sowing (because the authorization was delayed)

- 1) plants suffered due to heat and the lack of water in May, 2 trials
- 2) 2 trials had to be destroyed (poor emergence)

Dates of visit:

May 10th-11th, 2006 (sowing)

June 08th, 2006

June 26th, 2006

July 12th, 2006 (early destruction of 2 trials)

July 13th, 2006

August 02nd, 2006

August 30th, 2006

September 19th, 2006

October 10th-11th, 2006 (harvest and removal of sugar beets not used in the study)

6.1.4 At the end of the release

The actions undertaken are listed below:

- Authorities were informed on the intended harvesting and plants removal dates. See Annexes 4 and 5 which include photos of the destruction of trials and reports on them.
- All the removed material has been kept apart, and clearly identified. All the material which was not meant for further analysis was destroyed in the plot.

6.1.5 Post harvest measures

TRIAL DESTRUCTION METHODS:

- After the last sampling and before the farmers harvested the field, plants were pulled up by hand (the same day as the trials were harvested).
- Plants were cut out (with a knife) in 4 pieces minimum. Then they were buried in the plot with a disk tool.

6.1.6 Other(s) measure(s) (Describe)

Not applicable.

6.1.7 Emergency plans

Not applicable

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 IIIb of Directive 2001/18/CE]

They were not necessary.

6.2 Post-release monitoring measures

The monitoring results confirmed that sugar beets were as safe as their nearly isogenic conventional counterpart for human and animal health, and for the environment.

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

Please specify:

Monitoring measures within the release site

Field trials will be visited in 2008, during the following growing season, to:

- 1) Make sure the trial plot (5 sites) is not sown with sugar beets in 2007.
- 2) Destroy any volunteers.

Monitoring measures in adjacent areas

Surrounding fields to the trials will be visited during the following growing season to destroy any sugar beet volunteers.

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

General observations on plants health, illness sensitivity, plants development; no unusual or unexpected characteristic observed.

6.4 Observed effects

No unexpected effects were 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.

Sugar beets presented the same risk to human or animal health or the environment as conventional sugarbeet varieties.

6.4.2 Expected effects

Sugar beets grew normally and presented a crop cycle similar to their isogenic conventional counterparts; they also were similar regarding illness or pest sensitivity.

6.4.3 Unexpected effects

No unexpected effects were observed

6.4.4 Other information

Not applicable

7. CONCLUSION

Field trials were carried out as planned. No unexpected effects were observed, therefore these varieties are considered to be as safe as conventional ones, but it is worth mentioning that, since they allow a new tool for postemergence weed control, they are an alternative which is more compatible with biodiversity, as they allow weeds control using a herbicide without risk sentences.

Date: December 03rd, 2006

Fco. Serge Lagrasse