REPORT TO PRESENT THE RESULTS OF THE DELIBERATE RELEASE OF GENETICALLY MODIFIED HIGHER PLANTS INTO THE ENVIRONMENT ACCORDING TO THE ANEX XI OF RD 178/2004, FROM 30TH JANUARY

FINAL REPORT OF THE EXPERIMENTAL RELEASE INTO THE ENVIRONMENT OF GENETICALLY MODIFIED SUGARBEET EVENT H7-1

NOTIFICATION B/ES/13/02
FIELD TRIALS OF GENETICALLY MODIFIED SUGARBEET EVENT H7-1
Release year: 2013

FORMAT FOR THE PRESENTATION OF THE RESULT OF DELIBERATE RELEASE INTO THE ENVIRONMENT OF GENETICALLY MODIFIED HIGHER PLANTS IN ACCORDANCE WITH THE ANEX XI OF RD 178/2004, FROM 30TH JANUARY

KWS

1 General information

1.1 European notification number: B/ES/13/02

1.2 Member State of notification: Spain

1.3 Date of consent and consent number: 22.02.2013

2 Report status

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

☒ the final report

- a post-release monitoring report

- final - intermediary

3 Characteristics of the release

3.1 Scientific name of the recipient organism: *Beta vulgaris* ssp. *vulgaris*

3.2 Transformation event(s) (acronym(s) or vectors[1] used (if transformation event identity not available): H7-1 sugar beet

3.3 Unique identifier, if available: KM-ØØØH71-4

[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]) (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)
Villamediana (Palencia)	**3000 m^2**	**10 plantas / m^2**	**19/03/2013 –10/10/2013**
Olmos de Esgueva (Valladolid)	**3000 m^2**	**10 plantas / m^2**	**19/03/2013 – 14/10/2013**
Nava de Arevalo (Ávila)	**3000 m^2**	**10 plantas / m^2**	**19/03/2013 –09/10/2013**

([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

If yes, indicate the country (ies) of notification: **EU**

If yes, specify for which use(s):

- Import. ☒
- Cultivation (e ;g ; seed/planting material production). ☒
- Food. ☒
- Feed. ☒
- Pharmaceutical use (or processing for pharmaceutical use).
- Processing for pour.
  - Food use ☒
  - Feed use ☒
  - Industrial use.
- Others (specify):

Placing on the market of food and feed produced from genetically modified sugar beet H7-1 has been authorized in the EU according to Regulation (EC) No 1829/2003 (Commission Decision 2007/692/EC of 24 October 2007).

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 ☐

Not applicable

5.2 Deliberate release(s) for development purposes ☐

Not applicable

- 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).
- Altered agronomic properties (e.g. disease/pest/drought/frost-resistance, etc.) (specify).
- Altered qualitative properties (prolonged shelf-life, enhanced nutritional value, modified composition, etc.) (specify).
- Stability of the expression.
- Multiplication of lines.
- Hybrid vigour study.
- Molecular farming[3].
- Phyto-remediation.
- Others : (specify) .....

[2] For example, testing the new trait under environmental conditions.

[3] « Molecular farming » means the production of substances (for instance, proteins, pharmaceuticals) by plants, which have been genetically modified for a particular trait. “Molecular farming” could be defined as well as the production of plant-synthesised pharmaceuticals, plant-made pharceuticals, plant-based proteins production, etc.

5.3 Official testing ☐

- Variety registration on a national variety catalogue
    - DUS (=Distinctness, Uniformity and Stability)
    - VCU (=Value of Cultivation and Use)
- Others: (specify): …….

5.4 Herbicide authorization ☐

Not applicable

5.5 Deliberate release(s) for demonstration purposes ☒

Resistance against total herbicide Glyphosate

5.6 Seeds multiplication ☐

Not applicable

5.7 Deliberate release(s) for biosafety/risk assessment research ☐

Not applicable

- Vertical gene transfer studies.
    - Out-crossing with conventional crops
    - Out-crossing with wild relatives
- Horizontal gene transfer studies (gene transfer to micro-organisms).
- Management of volunteers.
- Potential changes in persistence or dispersal.
- Potential invasiveness.
- Potential effects on target organisms.
- Potential effects on non-target organisms.
- Observation of resistant relatives.
- Observation of resistant insects.
- Others: (describe) .....

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

(describe) : .....

Not applicable

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)

Please report the risk-management measures, which have been used to avoid or minimise the spread of the GMO(s) outside the site(s) of release, and in particular those measures:

- Which were not originally notified in the application,
- Which were applied in addition to the conditions in the consent,
- Which the consent required only under certain conditions (e.g. dry periods, flooding),
- For which the consent allowed the notifier a choice among different measures.

Tick the examples where appropriate:

6.1.1 Before the sowing/planting:

- Clear labelling of the GM seeds (distinct from other seeds/tubers/etc.) (describe).
  Seeds for each field were packed into fabric bags that have been closed until they were used for sowing.
  All bags with trial seeds for each trial site were packed into labeled and unbreakable containers according to the protocol. All labels for GMO were in blue color to distinguish easier between GM and conventional seed lots.

- 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).
  Seeds were transported in labeled and unbreakable containers. Transport of the seeds to the field trial site was done at the day of sowing.

- Destruction of superfluous seeds/planting material (describe the method involved).
  The seeds remaining after sowing were burned and remaining ashes and residues were buried deeply on the trial site.

- Temporal isolation (specify).
  Not applicable

- Rotation (specify the previous crop).

  The previous crops were the following ones:

- **Olmos de Esgueva (Valladolid): Barley**
- **Villamediana (Palencia): Wheat**
- **Nava de Arevalo (Ávila): Maize**

- Other(s): (specify) .....

6.1.2 During the sowing/planting activities:

- Method of sowing/planting.
  Sowing the trials was conducted with a pneumatic self-cleaning sowing machine specifically adapted for sowing field trials.
  ACOR and KWS responsible people were present during sowing to follow the trial protocol.

- Emptying and cleaning of the sowing machinery on the field of release.
  The machinery used for sowing was cleaned from possibly remaining seeds before sowing at the site of the release. After finalization of the sowing process the machinery was further cleaned at the trial site to avoid potential spread of genetically modified seeds outside the trial site.
  The remaining seeds recovered during the cleaning process were burned. Remaining ashes and residues were buried deeply at the site of the release.
  The sowing machine was further equipped with a self-cleaning system to avoid seed mixture. The machine separates and collects seeds which have not been sown in the corresponding plot. Remaining seeds were treated as described above.

- Segregation during the sowing (provide example of containment to prevent spillage during the sowing/planting).
  The seeds for each field were packed into clearly labeled individual fabric bags (see 6.1.1). These bags were only opened on the sowing machine at the appropriate position of the sowing machine during the sowing process.

- Other(s): (specify)

6.1.3 During the period of release:

- Isolation distance (x meters)
  Not applicable
  - From sexually compatible commercial plant species.
  - From sexually compatible wild relatives.

- Border rows (with the same crop or a different one, with a non-genetically modified crop, x meters, etc).
  Not applicable

- Cage/net/fence/signpost (specify).
  Not applicable

- Pollen trap (specify).
  Not applicable

- Removal of GM inflorescences before flowering (indicate the frequency of removal).
  The trial site was controlled every 2 weeks during the vegetation period with specific attention to the finding and removal of possibly appearing bolters to avoid pollen production by genetically modified plants.

- Removal of bolters/relatives/hybrid partners (indicate the frequency of the removal, x metres around the GM field, etc).
  No bolters were detected during the whole vegetation period.

- Other(s): (specify)…….
  Not applicable

6.1.4 At the end of the release:

- Harvest/destruction methods (of crop or part of it) / other means (e.g.: sampling) (describe).
  Harvest was conducted according to the relevant protocol which was authorized previously by the competent authorities.

  The roots were harvested mechanically, being the material processed in the same field with the harvester. After the harvest the rests (in particular all the crowns) and the frozen brie samples were transported to the ACOR facilities were all the GMO material was destroyed.

  After harvest operations were finished, the trial plots were controlled and plant residues that were not delivered to ACOR facilities and that remain at the field site were buried and incorporated into the soil and covered by a soil layer of at least 30 cm. This was done in order to push the natural biodegradation process and to make sure that no emerging beet plants will appear on following years.

  According to legal requirements, the Quality laboratory was cleaned both before and after processing the samples to avoid any mixture with other material.

- Harvest / destruction before the ripeness of the seeds.
  Not applicable

- Effective removal of plant parts.
  Not applicable

- Segregated storage and transport of crop/waste (provide examples of containment to prevent spillage of collected seeds/crops/wastes).
  Not applicable

- Clean up of machinery on the release site.
  The machinery used for sowing, soil tillage, plant protection measures and other activities was carefully cleaned at the site of the release.

- Destination of the waste, treatment of waste/ surplus yield/plant residues (describe).

The rest (all the crowns in particular) and the frozen brei samples were transported and destroyed through deep burial with quicklime close the ACOR facilities.

The plant residues that were not delivered to ACOR facilities and that remain at the field site were buried and incorporated into the soil and covered by a soil layer of at least 30 cm. This was done in order to push the natural biodegradation process and to make sure that no emerging beet plants will appear on following years.

- Post-harvest treatment and cultivation measures on the release site (describe the method for preparing and managing the release site at the end of the release, including cultivation practices).
  The preparation of the release site for the subsequent crop will be conducted with measures typical for common agricultural practice.

- Other(s): (describe):

6.1.5 Post-harvest measures:

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

Frequency of visits (average):
The experimental site will be controlled regularly once a month during the growing season following the release with specific regard to the removal of possibly emerging beet plants.

- Subsequent crop (specify).
  In the year following the release any crop, except sugar beet, can be cultivated on the release site.

- Crop rotation (specify).
  See above

- Fallow/no crop (specify).
  Not applicable

- Superficial soil work / no deep ploughing.
  Not applicable

- False-sowing beds.
  Not applicable

- Control of volunteers (specify intervals and duration).
  Post harvest monitoring for possibly emerging beets from crop residues will be carried out during the growing season following the release.
  The experimental site will be controlled regularly once a month (see above) during the vegetation period following the release.

Potential emerging beet plants will be removed by mechanical, manual or chemical measures.

- Appropriate chemical treatment(s) (specify).
  Not applicable

- Appropriate soil treatment(s) (specify).
  Not applicable

- 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**
- No (describe for which reason, e.g. vandalism, climatic conditions, etc.)

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**
- Yes (describe)

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: **During the year after the trial harvest**

  Frequency of visits (average):
  During the growing season following the release the trial site will be controlled regularly once a month.

  - Observation of resistant relatives. **Not applicable**
  - Observation of resistant insects. **Not applicable**
  - Control of volunteers (specify intervals and duration).
    During the regular controls (see above), special attention will be directed to the appearance of possibly emerging beet plants.
  - Monitoring of gene flow (specify). **Not applicable**
  - Appropriate chemical treatment(s) and/or soil treatment(s). **Not applicable**
  - Others (specify).

- Monitoring measures of adjacent areas: **Not applicable**

  Duration:
  Frequency of visits (average):
  Area monitored:
  - Observation of resistant relatives.
  - Observation of resistant insects.
  - Control of volunteers and/or monitoring of feral populations (specify intervals and duration).
  - Monitoring of gene flow (specify).
  - Appropriate chemical treatment(s) and/or soil treatment(s).
  - 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 SNIF[4] part B need to be specified in detail.

[4] Summary notification information format (=SNIF)

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.

KWS/ACOR responsible technicians made visual observations about any unexpected event that could happen at the site of the release during all visits of the trials (once every 2 weeks during the growing season, see 6.1.3). In addition, two inspections were conducted by the competent authorities (Consejería de Fomento y Medio Ambiente) in the sowing and harvesting date.

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.

The main objectives of the information given in this section are:

- to confirm or invalidate any assumption regarding the occurrence and impact of potential effect(s) of the GMO(s) which was/were identified in the environmental risk assessment,

- to identify effect(s) of the GMO(s) which was/were not anticipated in the environmental risk assessment.

The observed **effect(s)/interaction(s)** of the GMO(s)

- with respect to any risk to human health,
- with respect to any risk to the environment

shall be reported under this section.

Particular attention shall be drawn to unexpected and unintended effect(s).

Indications as regards the effects, that the notifier may have to report, are provided hereunder. The effects have obviously to be considered in the light of the crop, the new trait, the receiving environment as well as the conclusions of the environmental risk assessment, which is carried out on a case-by-case basis.

In order to structure the information and to facilitate and efficient search within the given information, the notifier shall use, as far as possible, specific keywords to fill in the text fields under Chapter 6, especially sections 6.4.2, 6.4.3 and 6.4.4. A most updated list of those specific keywords is available on the Internet at: http://gmoinfo.jrc.it.

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.

The H7-1 sugar beet plants developed normally and demonstrated performance in the field similar to conventional sugar beet plants.

6.4.3 Unexpected effect(s) [5]

"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.

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

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.

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.

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

The field trials were conducted as planned and the plants developed as expected and demonstrated field performance similar to conventional sugar beet. No unexpected or adverse effects were observed.
Accordingly the conclusions of the risk assessment of the application that H7-1 sugar beet poses no risk on human and animal health and the environment are confirmed.

DATE: **January 8th, 2014**