FINAL REPORT OF THE RESULT OF DELIBERATE RELEASE INTO THE ENVIRONMENT OF GENETICALLY MODIFIED WHEAT IN ACCORDANCE WITH ARTICLE 10 OF DIRECTIVE 2001/18/EC NOTIFICATION B/ES/04/08

1. General information

1.1. **European notification number:** B/ES/04/08

1.2. **Member State of notification:** Spain

1.3. **Date of consent and consent number:** March 5th ,2004 (B/ES/04/08)

2. *Report status*

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

[X] the final report

[ ] a post-release monitoring report
o final o intermediary

3. Characteristics of the release

3.1. **Scientific name of the recipient organism:** *Triticum aestivum*

3.2. **Transformation event(s) (acronym(s)) or vectors[1] used (if transformation event identity not available):**

- Event FR3177
- Event FR3173

3.3. **Unique identifier, if available:** Not available

[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(r)-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] (m^2)**	**Identity[3] and aproximate number of GM higher plants per event actually released (number of seeds/plants per m^2)**	**Duration of the release(s) (from *(day/month/year)*... until...*(d/m/y)*)**
Finca Alameda del Obispo (Municipal Term of Córdoba 14004) (Experimental state of IAS-CSIC)	55 m^2 approximately (about 325 m^2 including the edges barrier non-GM)	Wheat; 350 seeds per m^2. The total number of seeds genetically modified does not exceed the 3.500	From: (09/03/2004) until (07/07/2004) Sowing- destruction of the field

4. *Any kind of product that the notifier intends to notify at a later stage*

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 ☐ No ☒ Unknown to date

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

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

-Food use
-Feed use
-Industrial use

[2] Specify the size of the GM area and, where apropiate, the size of the non-GM area (e.g. non-GM border)
3 Vectors used

-Others (specify)

5. *Type(s) of deliberate release(s)*

Please select the main type(s) (in boxes) as well as subtype(s) of the releases. In the case of multi-sites, multi-events and/or multi-annual release(s), please provide a general overview of the types 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

[X]

Obtaining material for efficacy analysis

5.2. Deliberate release(s) for development purposes

[ ]

-Event screening

-Proof of concept[4]

-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/droght/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[5]

-Phyto-remediation

-

Others:.....(describe).....
.....

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

[5] *"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-synthesized pharmaceuticals, plant-made pharmaceuticals, plant-based proteins production, etc.

5.3. **Official testing**

☐

-Variety registration on a national variety catalogue

-DUS (=**D**istinctness, **U**niformity and **S**tability)
-VCU (=**V**alue of **C**ultivation and **U**se)

-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**

☐

-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 effects on non-target organisms

-Observation of resistant relatives

-Observations of resistant insects

-Others (describe).....

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)

Please report the risk-management measures, which have been used to avoid or minimize 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 labeling of the GM seeds/planting material lots (distinct from other seeds/ tubers/ etc.) (describe).....X

All the seeds of the trail have been packed in an exclusive box for this trail, (with a triple container for security) sealed and identified by an specific labeling at external and internal package.

-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) X

Seeds were contained at a triple layer package
The transport to the experimental field has been done personally by the technician responsible for the sowing, just in the moment of that.

-Destruction of superfluous seeds/planting material (describe the method involved) X

-Others (specify): No other cereal field trials were in the proximity of this field trial

6.1.2. During the sowing/ planting activities:

-Method of sowing/ planting:

Sowing was performed by hand as scheduled in the field trial protocol following a randomized block design with four repetitions

-Others (specify): The field trial was covered with a net to avoid the access of birds and rodents.

6.1.3. During the period of release:

-Isolation distance(s)

-from sexually compatible commercial plan species: major of 10 meters
-from sexually compatible wild relatives: major of 10 meters

-Border row(s) (with the same crop or a different one, with a non-transgenic crop, x meters, etc.):

The trail is surrounded with 5 meters of conventional wheat.

-Pollen trap (specify):

These 5 meters of conventional wheat around the trail act as a pollen trap.

6.1.4. At the end of the release:

-Harvest/ destruction methods (of crop or parts of it)/ other means (describe):

Each plot was separately harvested by hand.

According to the protocol, 200 ears from the border were taken for *Fusarium* species determination. Fifty ears were harvested from each border of the field trial. These spikes will serve for *Fusarium* species identification.

Spikes were thrilled without blowing to avoid damaged grain losses. As the result of this process grain was mixed with other spike products such as glumes. All this material was packed in the cotton bags provided with a red label inside indicating the genotype and the corresponding repetition. Besides, bags were identified with an extra label (outside) to allow easier bag manipulation. A total of 33 bags were obtained divided as follows:

- 4 bags for the spikes harvested from the border and
- 29 from the field trial (two bags were needed for one plot).

The bags were preliminary packed for delivery the 7th of July. A final package with a triple layer security for delivery was prepared.
Remaining ears in the field trial were harvested by hand and package in a plastic box. Besides, the non-GM border was mechanically harvested. It was packed in a different plastic box. Both packages were burned according to the technical protocol.

Field trial residues were incorporated to the soil using the adequate machinery.

All these operations were performed the 17th of July of 2004.

6.1.5. Post- harvest measures:

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

-Frequency of visits (average): 2 times per month

-Subsequent crop (specify): Non- cereal

-Control of volunteers (specify intervals and duration) During the year following the trial, to allow the identification of possible volunteers of wheat that arise, and to proceed to its elimination.

2 controls per month during the period (July 04 – July 05).

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) 8Article 6(2)(a)(vi) and Annex III.B of Directive 2001/18/EC) had to be taken:

-No

6.2. Post-release monitoring measures

Please indicate:

-the post-release monitoring plan will begin (in the case of the final post-release monitoring report) **in July, 04, until July 05.**

-monitoring measures within site

-Duration: from July, 04, to July 05

-Frequency of the visits (average): twice a month

-Control of volunteers (specify intervals and duration): At each vitis to the release site: 2 times per month during the period (July 04 – July 05).

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

During the visits to the field of trail by the responsible technician (15/month during the experimentation) has been observed that no anomaly has existed in the development of the plants or any unexpected event that could indicate a risk.

6.4. Observed effect(s)

6.4.1. Explanatory note

No adverse effect has been observed for the human health or the environment.

6.4.2. Expected effect(s)

G.M. plants has shown higher protection from *Fusarium* infestation than conventional

6.4.3. Unexpected effect(s)[6]

No unexpected effect has been observed.

6.4.4. Other information

The taken samples have been sent to:

Syngenta Seeds
Jealott's Hill Research Station
Bracknell, RG42 6EY, UK

7. *Conclusion*

No negative effect has been observed for the human health or the environment.
G.M. plants have shown protection against *Fusarium* infestation.

The information provided in this report is not considered confidential in accordance with Article 25 of Directive 2001/18/EC.

This does not prevent the competent authority from requiring additional information from the notifier, both confidential and non-confidential.

In the case of confidential data, it should be provided in an Annex to the report format, with a non-confidential summary or general description of these data, which will be made available to the public

Date: October 8th 2004

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