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/09/27
1.2 Member State of notification: Spain
1.3 Date of consent and consent number: 31/03/2009

2. REPORT STATUS

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

3. CHARACTERISTICS OF THE RELEASE

3.1 Scientific name of the recipient organism: Zea maiz
3.2 Transformation event(s) (acronym(s) or vectors1 used (if transformation event identity not available): 1507 maize
3.3 Unique identifier, if available: DAS-01507-1
3.4 Please provide the following information as well as the field(s) layout:
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.

Destruction date Frescano: 13 July 2009
Destruction date Ejea de los Caballeros: 03 August 2009

Notification B/ES/09/27: Efficacy trials 1.- Location: Frescano Province 50 (Zaragoza); DAS03706HP DAS 1507 DAS04703HP DAS 1507 5.33 plants/m² Sowing date: 21/05/2009 Destruction date: 13/07/2009	Notification B/ES/09/27: Efficacy trials 2.- Localización: Ejea de los Caballeros Province 50 (Zaragoza); DAS03706HP DAS 1507 DAS04703HP DAS 1507 5.33 plantas/m² Sowing date: 11/06/2009 Destruction date: 03/08/2009

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(s) at a later stage?

☐ YES ☐ NO (it has already been done) ☒ Unknown to date

If yes, indicate the country (ies) of notification: It has already been notified
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):

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):

3

5.1 Deliberate release(s) for research purposes ☒

5.2 Deliberate release(s) for development purposes ☒

- Agronomic performances: efficacy against *Agrotis spp.*.

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 ☐

5.5 Deliberate release(s) for demonstration purposes ☐

5.6 Seeds multiplication ☐

5.7 Deliberate release(s) for bio-safety/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 invasiveness
- Potential effects on target organisms
- Potential effects on non-target organisms
- Observation of resistant relatives

[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 pharmaceuticals, plant-based proteins production, etc.

- Observation 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 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 were packed in triple bags which are closed until planting. Each bag was clearly labelled.

☒ - 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)
Seed were stored and transported separate from other seeds. Only seed needed for starting the trial were transported on that way to the field.

☒ - Destruction of superfluous seeds/planting material (describe the method involved).
Seeds from each bag were counted before seeding, remaining seeds were buried.

☐ - Temporal isolation (specify)

☐ - Rotation (specify the previous crop)

☐ - Other(s): (specify) .....

6.1.2 During the sowing/planting activities:

☒ - Method of sowing/planting (describe)

Seeds were planted with a standard sowing machine which allows an easy cleaning of the remaining seeds.

☒ - Emptying and cleaning of the sowing machinery on the field of release.

At the end of the individual plot sowing, the remaining seeds in the machine (if any) were buried at the end of the plot.

☒ - Segregation during the sowing (provide example of containment to prevent spillage during the sowing/planting).

The seed bags had the required seeds to avoid carrying loose seeds and reduce likelihood of accidental spillage.

☐ Other(s): (specify)

All personnel involved with the trials have been trained to prevent involuntary release/spillage.

6.1.3 During the period of release:

☒ - Isolation distance (x meters) from sexually compatible wild relatives

More than 200 m from commercial maize.

☒ - Border rows (with the same crop or a different one, with a non-transgenic crop, x meters, etc)

Four border rows were seeded around the whole trial with a non-transgenic commercially available hybrid of similar relative maturity as a pollen trap. At the end of the release, these rows were destroyed and treated as transgenic plants.

☐ - Cage/net/fence/signpost (specify)

☒ - Pollen trap (specify) see above.

☐ - Removal of GM inflorescences before flowering (indicate the frequency of removal)

☐ - Other(s): (specify)

6.1.4 At the end of the release:

☒ - Harvest/destruction methods (of crop or part of it) / other means (e.g.: sampling) (Describe)

The plants were chopped and ploughed.

☒ - Harvest / destruction before the ripeness of the seeds

☒ - Effective removal of plant parts

☐ - Segregated storage and transport of crop/waste (provide examples of containment to prevent spillage of collected seeds/crops/wastes)

☒ -None of the seeds or plant parts were moved outside the trial site.

☒ - Clean up of machinery on the release site.

All the machinery used was cleaned on the release site.

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

Waste plants were discarded at the trial area for naturally composting.

☐ - 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)

Trials area has been turned over in autumn and the plant material as chopped and buried.
☒ - Other(s): (describe) The trial destruction was carried out by mechanical farm works (Removing the plants, mincering and burying them .

6.1.5 Post-harvest measures:
Please indicate which measures were taken on the release site after harvest:
Frequency of visits (average) approximately every two months
☒ - Subsequent crop (specify)
The following crop will be any crop different from commercial maize.
☒ - Crop rotation (specify)
The following year will be any crop different from commercial maize.
☐ - Fallow/no crop (specify)
☐ - Superficial soil work / no deep ploughing
☐ - False-sowing beds
☐ - Control of volunteers (specify intervals and duration).
The release site will be visited several times after the trial destruction to confirm that the farmer will not sow commercial maize on that site and to control potential volunteer plants. If needed, any undesired plant emerged would be mechanically destroyed or by using herbicides (other than gluphosinate-ammonium).

☐ - Appropriate chemical treatment(s) (specify)
☐ - Appropriate soil treatment(s) (specify)
☐ - 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

Monitoring results confirm that 1507 maize plants do no present a risk for the human, animal health and the environment.

Specify:
☒ Monitoring measures within site
Duration: from May 2009 to December 2009.
Frequency of visits (average): approximately every two weeks
Observation of resistant relatives and of resistant insects.
Control of volunteers (specify intervals and duration) Regular visits will be more frequent if some volunteers are detected.

 Monitoring measures of adjacent areas:
Not applicable
Duration
Frequency of visits (average):
Area monitored:
Observation of resistant relatives and 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
General observations on plant health, susceptibility to diseases, on development of the plants will be carried out.

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.

1507 maize plants didn't show any risk to human, animal health and the environment.

6.4.2 Expected effect(s)
The environmental risk assessment has not identified any risk for the human health or the environment as a result of the release into the environment of 1507 maize. 1507 maize plants have developed normally, in a comparable way with the non GM near isogenic line. No environment problems were detected in the trial

6.4.3 Unexpected effect(s) [5]
Not relevant

6.4.4 Other information
Not relevant

7. CONCLUSION
The trials have been carried out in the predicted manner. No negative effects to human health or the environment have been observed. 1507 maize plants have grown as expected.