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/10/41

1.2 Member State of notification: Spain

1.3 Date of consent and consent number: 23rd of March and 26th of May, 2010

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: *Zea mays*

3.2 Transformation event(s) (acronym(s) or vectors[1] used (if transformation event identity not available): 59122x1507xNK603

3.3 Unique identifier, if available : DAS-59122-7xDAS-Ø15Ø7-1xMON-ØØ6Ø3-6

[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 larger-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)
Alcarrás (Lleida) (Cataluña)	- Total surface of the release: 51972 m² - 59122x1507xNK603 maize are: 6413 m²	59122x1507xNK603 maize: ~ 8 plants/m²	From: 23/06/10 To: 21/10/10

([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

See the trial layout in Annex 1.

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?

Placing on the market of 59122x1507xNK603 for food and feed uses, import and processing in the European Union has been authorized by Commission decision 2010/428/EU.
An application for authorization of 59122x1507xNK603 maize for food and feed uses, import and processing, including cultivation in the European Union has been submitted pursuant to Regulation (EC) n°1829/2003 by another juridical entity of the group (reference EFSA-GMO-UK-2006-30).

☐ YES ☑ NO ☐ Unknown to date

If yes, indicate the country(ies) of notification:
If yes, specify for which use(s):

- ☐ Import
- ☐ Cultivation (eg ; seed/planting material production)
- ☐ Food
- ☐ Feed
- ☐ Pharmaceutical use (or processing for pharmaceutical use)
- ☐ Processing for
    - 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):

5.1 Deliberate release(s) for research purposes ☐

5.2 Deliberate release(s) for development purposes ☐

☐- 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)

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 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

[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-synthesized pharmaceuticals, plant-made pharmaceuticals, plant-based proteins production, etc.

☐- 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) :

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 labeling of the GM seeds (distinct from other seeds/tubers/etc.) (describe)
The genetically modified seed lots were contained in sealed bags and boxes, clearly labeled as containing genetically modified material. In addition, each bag was clearly identified with the test entry code comparable to the code in the experimental protocol.

☑ - 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)
Transport of the seed to the field was done on the planting day, in the original sealed and clearly identified bags and boxes in which the seeds were received. No processing of the seed was done before planting.

☑ - Destruction of superfluous seeds/planting material (describe the method involved).
The remaining seeds were buried in the soil at the site of the release.

☐ - Temporal isolation (specify)

☐ - Rotation (specify the previous crop)

☑ - Other(s): (specify)
It was checked that the plot was isolated as required in the authorization (at least 200m to any other non-experimental maize crop).

6.1.2 During the sowing/planting activities:

☑ - Method of sowing/planting (describe)

Seeds were planted with two conventional sowing machines.

☑ - Emptying and cleaning of the sowing machinery on the field of release

The planting units of the planting machines were cleaned on the release site before and after proceeding to the planting of each seed lot in order to avoid any seed mixture. At the end of the planting, the remaining seeds were buried into the soil on the release site. The planting machines were carefully inspected and cleaned before leaving the trial site.

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

Seeds were in separate bags which were opened only once the previous plot was planted and remaining seed collected.

☐- Other(s): (specify)

6.1.3 During the period of release:

☑ - Isolation distance (x meters)

- From sexually compatible commercial plant species

An isolation distance of at least 200 meters was kept from the genetically modified trials to any other non experimental maize crops.

- From sexually compatible wild relatives

Not applicable, spontaneously maize has not any sexually compatible relatives in Europe.

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

At least eight border rows of non-genetically modified maize of a similar maturity were planted around the trial.

☐ - Cage/net/fence/signpost (specify)

☑ - Pollen trap (specify)

The conventional maize rows of similar maturity planted around the trial created a pollen trap. At the end of the release, these non-genetically modified rows were destroyed like the rest of the trial.

☐ - 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 maize plants, including border rows, were destroyed using a chopper, addition of urea to facilitate the decomposition of the plant material and incorporation into the soil by ploughing. In addition, the remaining plant materials which were still on the trial surface were destroyed using a rotavator and compacted. The remaining plant residues were also recovered by hand and incorporated into the soil at the release site. All the trial plant materials were incorporated into the soil.

☐ - 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)

☑ - Clean up of machinery on the release site.

The machinery used was cleaned on the release site.

☑ - Destination of the waste, treatment of waste/ surplus yield/plant residues (describe)
All the plant residues were destroyed through the use of a chopper and a rotavator and were incorporated into the soil by ploughing or manually.

☑ - 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 remaining plant materials were destroyed using a chopper and a rotavator and then incorporated into the soil by ploughing. They were also recovered by hand and incorporated into the soil on the release site, as described in point 6.1.4 (1st item).

☐ - 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): approximately every two months

☑ - Subsequent crop (specify)
Wheat was planted.

☑ - Crop rotation (specify)
Wheat

☐ - Fallow/no crop (specify)

☐ - Superficial soil work / no deep ploughing

☐ - False-sowing beds

☑ - Control of volunteers (specify intervals and duration).
A proper monitoring of volunteers will be implemented during a one-year period after the end of the release. If any volunteers emerge, they will be destroyed prior to flowering, mechanically or manually. Special attention will be paid during the period from usual soil preparation for maize sowing to pre-flowering stage.
Maize volunteers were observed after the trial destruction and were destroyed during the preparation of the field for wheat planting in November 2010. No more maize volunteers were observed in the trial site so far.

☐ - 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

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.

The destruction of the trial in Alcarrás (Cataluña) was completed on 21 October 2010. The post-release monitoring plan has started since this date. Some maize volunteers were observed on the site after the trial destruction but they were destroyed during the preparation of the field for the planting of wheat on 30 November, 2010. Subsequently and to date, no more maize volunteers were observed on the site. The trial site will be visited regularly in order to monitor potential maize volunteers. If there were any, they would be controlled mechanically or manually, in any case before flowering.

Specify:

☑- Monitoring measures within site
Duration: one year after the end of the release.
Frequency of visits (average): approximately every two months

- ~~Observation of resistant relatives~~
- ~~Observation of resistant insects~~
- Control of volunteers (specify intervals and duration)
  Regular visits, in particular during usual maize emergence and flowering periods. If there were any maize volunteers, they would be controlled by means of machines and/or manually. As described above, some maize volunteers were observed after the trial destruction but they were destroyed during the preparation of the field for the subsequent crop. No more maize volunteers were observed to date.
- ~~Monitoring of gene flow (specify)~~
- ~~Appropriate chemical treatment(s) and/or soil treatment(s)~~
- ~~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.

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.

The observations were and will be done visually.
In addition, the trial plot was visited by inspectors.
A representative of the Departament d'Agricultura, Alimentació i Acció Rural (Servei de Producció Agricola, Control del Material Vegetal) from Catalunya Generalitat attended the planting of the trial at Alcarrás (Catalunya), verifying that all the operations were done correctly. Also, it was checked that the trial destruction was made correctly.

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.

[4] Summary notification information format (=SNIF)

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.ec.europa.eu/.

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 potential reduction in the control of certain lepidopteran insects, such as the European corn borer (*Ostrinia nubilalis*) and certain coleopteran insects, such as the Western corn rootworm (*Diabrotica virgifera virgifera*), if the target insect pests develop resistance to the insecticidal proteins as expressed in the genetically modified 59122x1507xNK603 maize, has been identified in the environmental risk assessment of the notification as the only potential risk resulting from the interaction between the genetically modified maize and the target organisms.
In the trial carried out, no loss of efficacy of 59122x1507xNK603 maize plants on European corn borer was detected. Concretely, no damages caused by the European corn borer were observed on 59122x1507xNK603 maize plants, which lead to the conclusion that there was no developed resistance in the target lepidopteran insects. This confirms that, in the case of the trial carried out, the likelihood of the occurrence of this potential identified adverse effect was negligible, taking into account the small surface occupied by the trial. The presence of the target coleopteran insects, *Diabrotica*, has not been recorded to date, thus no development of resistance in the target insects could be detected in the case of the trial carried out.

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

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

effects or observations, this section should be as detailed as possible to allow a proper interpretation of the data.

No damage or any kind of negative effects on human health or 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.

None

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.

In the frame of the release, all the control measures were taken to avoid the spreading of pollen and grains of the genetically modified maize plants.

No negative effect of any kind has been observed that has or could have effects on the human health or the environment.

No risk for the human health or the environment has been identified as a result of the deliberate release of the genetically modified maize in this trial.

The proposed measures in the notification and the control measures taken seem to be consistent with the aim of respecting the environment and human health safety.

DATE: 7 February 2011

ANNEX 1: Field Layout

Location: Alcarrás (Lleida, Cataluña)