

**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/08/22

1.2 Member State of notification: Spain

1.3 Date of consent and consent number: March 25th in Cataluña, April 10th 2008 in La Rioja

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* L.

3.2 Transformation event(s) (acronym(s) or vectors¹ used (if transformation event identity not available): 1507xNK603

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

3.4 Please provide the following information as well as the field(s) layout:

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.

| Geographical location(s) (administrative region and, where appropriate, grid reference) | Size of the release site(s) (²) (m ²) | Identity (³) and approximate 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) |
|--|--|---|---|
| Alcarrás [site 1] (Lleida) (Cataluña) | - Total surface of the release: 40800m ² - 1507xNK603 maize area: 90m ² | 1507xNK603 maize: ~ 8 plants/m ² | From: 10/06/2008 to: 30/09/2008 |
| Calahorra (La Rioja) (La Rioja) | - Total surface of the release: 5739m ² - 1507xNK603 maize area: 90 m ² | 1507xNK603 maize: ~ 6 plants/m ² | From: 19/06/2008 to: 02/12/2008 |

⁽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 layouts 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 ?

YES (notified by another juridical entity of the group) NO Unknown to date

If yes, indicate the country(ies) of notification: via EFSA (European Food Safety Authority)
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) : It will be used like any commercial maize

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) Efficiency and selectivity of pest protection trait, yield capacity, susceptibility to diseases.

- Altered agronomic properties (e.g. disease/pest/drought/frost-resistance, etc.) (specify) pest resistance

- Altered qualitative properties (prolonged shelf-life, enhanced nutritional value, modified composition, etc.) (specify)

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

- Stability of the expression
- Multiplication of lines
- Hybrid vigour study
- Molecular farming³
- 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
- 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) :

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.

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 (distinct from other seeds/tubers/etc.) (describe)
Transgenic seeds were in sealed bags or small paper bags, and boxes, labeled as "Contains genetically modified material". In addition, each bag or small paper bag was clearly labeled 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 clearly labeled and sealed bags, or small paper bags, and boxes.
- Destruction of superfluous seeds/planting material (describe the method involved).
The remaining genetically modified seeds, when any, were buried at the trial site.
- Temporal isolation (specify)
- Rotation (specify the previous crop)
- Other(s): (specify):
The isolation distance from GM trials to other maize crop was verified to be in accordance with the permit conditions (at least 200 m, and at least 250 m as required by the Autonomous Community of La Rioja).

6.1.2 During the sowing/planting activities :

- Method of sowing/planting (describe)
Seeds were planted with a precision sowing machine designed for micro-plot testing.
- Emptying and cleaning of the sowing machinery on the field of release.
After each individual plot sowing, the seeds remaining in the machine (if any) were collected in a specific container in the sowing machine. Then they were buried in the trial site. The machine was carefully inspected before leaving the site of release.
- Segregation during the sowing (provide example of containment to prevent spillage during the sowing/planting).
The seeds were in bags or small paper bags which were opened just as needed for the planting.
- 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 m, or at least 250 m as required by the Autonomous Community of La Rioja, was kept from GM trials to any other 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, or twelve in the Autonomous Community of La Rioja, border rows of non-genetically modified maize of a similar maturity surrounded the trials. At the end of the release, these border rows were destroyed like the rest of the plants in the trials.
- Cage/net/fence/signpost (specify):
- Pollen trap (specify):
The border rows planted around the trials created a pollen trap. At the end of the release, these non-GM 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)
At both locations (Alcarrás (Cataluña) and Calahorra (La Rioja)), the grain and remaining plant materials were destroyed by chopping and incorporated into the soil by deep ploughing.
- 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)
Waste plants were destroyed on the release site by chopping and were incorporated into the soil by ploughing.
- 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)
All the remaining plant material, including border rows, were chopped several times and then incorporated into the soil by deep ploughing.
- 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)
Any crop other than commercial maize crop.
- Crop rotation (specify)

Any crop other than commercial maize crop.

- Fallow/no crop (specify)
- Superficial soil work / no deep ploughing
- False-sowing beds
- Control of volunteers (specify intervals and duration).

The release sites will be visited during the following season to monitor the occurrence of potential volunteers. If any volunteers emerge, they will be destroyed prior to flowering. More particular attention will be given to the period between the months close to the maize sowing time in each area and the usual flowering period (i.e between February and June), as the main concerns are to do a proper control of the volunteers in the plot, and being sure that the farmer will not sow commercial maize on that site. If any volunteers emerged, they would be destroyed prior to flowering, by means of machines or by an appropriate herbicide treatment.

- 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 trials was made on September 30, 2008 in Alcarrás (Cataluña) and December 2, 2008 in Calahorra (La Rioja). The post-release monitoring plan has started since these dates.

The trial sites will be visited regularly in order to monitor the presence of volunteers. If they were any, they would be destroyed by means of machines or by an appropriate herbicide treatment. There were no volunteers in the trial sites so far. No commercial maize crop will be planted in these plots in 2009.

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, more frequent if some volunteers are detected and destroyed.
- ~~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 SNIF⁴ 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.

The observations were and will be done visually.

Moreover, to our knowledge, the release sites were visited by inspectors.

Indeed, a representative of the "Dirección General de Producción, Innovación e Industrias Agroalimentarias de la Generalitat de Cataluña" visited the trials in August, and checked the compliance with the requirements for the release of GM plants in the location of Alcarrás (Cataluña).

A representative of the "Gobierno de La Rioja" attended the planting of the trials in Calahorra (La Rioja), verifying that all operations were done 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.

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 potential reduction in the control of certain lepidopteran insects, such as the European corn borer (*Ostrinia nubilalis*), if the target insect pests develop resistance to the insecticidal protein as expressed in the genetically modified 1507xNK603 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 trials carried out, no loss of efficacy of 1507xNK603 maize plants on European corn borer was detected. Concretely, no damages caused by the European corn borer were observed on 1507xNK603 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 trials carried out, the likelihood of the occurrence of this potential identified adverse effect was negligible, taking into account the small surface occupied by the trials.

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.

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

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

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 these deliberate releases, 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.

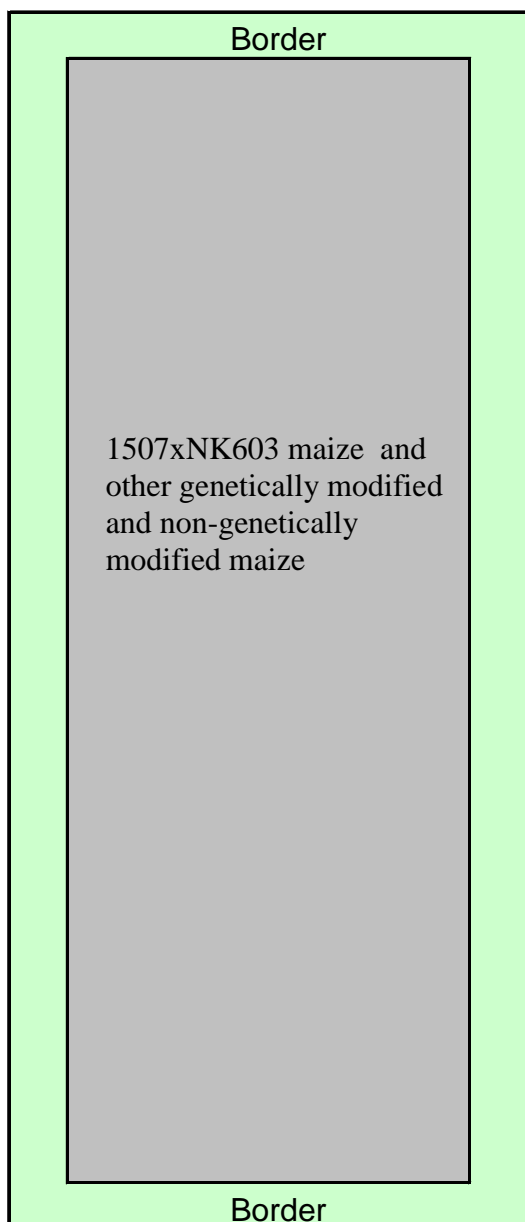
No risk for the human health or the environment has been identified as a result of the deliberate release of the genetically modified maize in these trials.

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

DATE : January 9, 2009

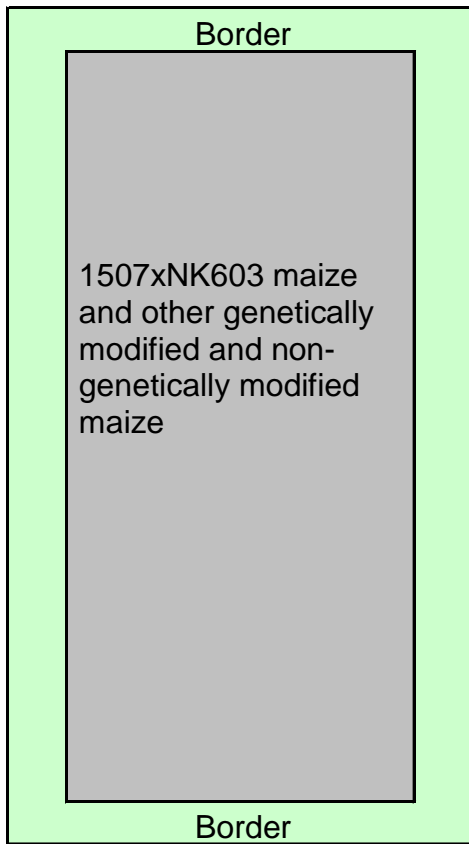
ANNEX 1 Field Layouts

- Location: Alcarrás [site 1] (Lleida, Cataluña)



border (at least 8 rows)

- Location: Calahorra (La Rioja, La Rioja)



border (at least 12 rows)