

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/09/48**

1.2 Member State of notification: **Spain**

1.3 Date of consent and consent number: **30/03/2009**

2 Report status

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

- the final report
- **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 vectors¹ used (if transformation event identity not available): **NK603XMON810**

3.3 Unique identifier, if available: **NK603XMON810**

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 large-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)
ÉCIJA, SEVILLA	9000 asked, used less	3000 seeds maximum, 4 rows, 3 replications, 1 variety NK603XMON810. 4000 m ² with border rows and filler non GMO	23/04/2009 sowing 24/09/2009 harvest
ALNAZCÁZAR, SEVILLA	9000 asked, used less	3000 seeds maximum, 4 rows, 3 replications, 1 variety NK603XMON810. 4000 m ² with border rows and filler non GMO	22/04/2009 sowing 21/09/2009 harvest
LA LUISIANA, SEVILLA	9000 asked, used less	3000 seeds maximum, 4 rows, 3 replications, 1 variety NK603XMON810. 4000 m ² with border rows and filler non GMO	22/04/2009 sowing 23/09/2009 harvest
MURUZÁBAL DE ANDIÓN, NAVARRA	9000 asked, used less	3000 seeds maximum, 4 rows, 3 replications, 1 variety NK603XMON810. 4000 m ² with border rows and filler non GMO	29/04/2009 sowing 14/10/2009 harvest
MURILLO EL CUENDE, NAVARRA	9000 asked, used less	3000 seeds maximum, 4 rows, 3 replications, 1 variety NK603XMON810. 4000 m ² with border rows and filler non GMO	29//04/2009 sowing 13/10/2009 harvest

(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:.....

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):

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).

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).

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.

- 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) :

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).
The GMO seed were placed in individual envelops of 100 seeds, each envelop labeled, this was done in the premises of Limagrain Ibérica. The rests of seeds not used were given back to the seed suppliers Limagrain France.

- 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).

The envelops were transported in owned vehicles by Limagrain Ibérica personal instructed about the nature of the material in closed boxes and labeled.

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

The superfluous material (occasionally 2-4 seeds) is recollected and destroyed by burning in the sowing site, it is checked no re-grown exists.

- Temporal isolation (specify).

- Rotation (specify the previous crop).

Écija: Cereal, wheat

Álanzcácar: fallow, not sown

La Luisiana; Cereal, wheat

Ejea: sunflower

Murillo: Cereal, barley

- Other(s): (specify)

6.1.2 During the sowing/planting activities:

- Method of sowing/planting.

Trial sowing machine, auto cleaning, the excess of seed not sowed goes to a close container were the seed can be recovered.

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

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

- Other(s): (specify)

6.1.3 During the period of release:

- Isolation distance (x meters)

- From sexually compatible commercial plant species. **200 meters**
- From sexually compatible wild relatives.

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

- Cage/net/fence/signpost (specify).

- Pollen trap (specify).
- Removal of GM inflorescences before flowering (indicate the frequency of removal).
- Removal of bolters/relatives/hybrid partners (indicate the frequency of the removal, x metres around the GM field, etc).
- 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).
- Harvest / destruction before the ripeness of the seeds.

Grain harvest by a combine having weight meter unit and water content measurement unit. Later the grain is recovered from the machine and buried in the liberation site in presence of technicians from the Agriculture Minister.

- Effective removal of plant parts.
Chopping of the plant parts and bury in the liberation site.
- 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 combine is cleaned of rests of grain and other plant material in the liberation site, the residues are buried in place.
- Destination of the waste, treatment of waste/ surplus yield/plant residues (describe).
- 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).

Soil preparation for next crop that is not maize.

- 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) **Monthly.**

- Subsequent crop (specify).
Écija: wheat
Alnazcázar: wheat
La Luisiana: wheat

Murillo: alfalfa
Ejea: sunflower

- Crop rotation (specify).
- Fallow/no crop (specify).
- Superficial soil work / no deep ploughing.
- False-sowing beds.
- Control of volunteers (specify intervals and duration).
- Appropriate chemical treatment(s) (specify).
- Appropriate soil treatment(s) (specify).
- Other(s) (specify)

6.1.6 Other(s) measure(s): (describe) **The monthly visits make sure there is no re-grown of maize. Not found till now.**

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.) **No incidence to report**

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 monitoring plan post-release goes on. The monthly visits have nothing to report till now.**
- **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: **one year**

Frequency of visits (average): **monthly**

- Observation of resistant relatives.
- Observation of resistant insects.
- Control of volunteers (specify intervals and duration). **Control of volunteers for one year monthly, nothing to report till now.**
- Monitoring of gene flow (specify).
- Appropriate chemical treatment(s) and/or soil treatment(s).
- Others (specify).

- Monitoring measures of adjacent areas:

Duration: **One year at the same time of the visits to the release site, before sowing 2009 no incidence or re-growth to report in the adjacent plots.**

Frequency of visits (average): **monthly**

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.

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.

Apart of the normal observations relative to the evaluation of maize varieties, it has been checked that this varieties are resistant to the herbicide glyphosate, and specially in the location of Ejea were there was a corn borer attack, it could be confirmed that this plants were resistant to corn borer.

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).

Nothing has been detected in effects over the human health or environment, different to the effects related to a normal maize cultivation in the relative to agriculture land preparation, etc.

⁴ Summary notification information format (=SNIF)

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 GMO plants shown tolerance to corn borer, not the non GMO plants or the plants with only the GMO event NK603 sown in the same trial.

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.

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.

Nothing could be detected in relation to biodiversity in general different to what can happen with a normal non GMO maize cultivation, or a “BT” maize tolerant to corn borer, this plants are tolerant to corn borer. No effect could be observed over non-target organism.

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

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

appropriate, make reference to any kind of product the notifier intends to notify at a later stage.

To our understanding, any new liberation that could be proposed with this event, could have a similar protocol to the one used in this liberation.

DATE: 15-january 2009