REPORT TO PRESENT THE RESULTS OF THE DELIBERATE RELEASE OF GENETICALLY MODIFIED HIGHER PLANTS INTO THE ENVIRONMENT ACCORDING TO ARTICLE 10 OF DIRECTIVE 2001/18/EC

FINAL REPORT OF THE EXPERIMENTAL RELEASE INTO THE ENVIRONMENT OF GENETICALLY MODIFIED MAIZE EVENT NK603

NOTIFICATION B/ES/13/06
FIELD TRIALS OF GENETICALLY MODIFIED MAIZE EVENT NK603
Testing year: 2013

FORMAT FOR THE PRESENTATION OF THE RESULT OF DELIBERATE RELEASE INTO THE ENVIRONMENT OF GENETICALLY MODIFIED HIGHER PLANTS IN ACCORDANCE WITH ANNEX XI OF ROYAL DECREE 178/2004

1 General information

1.1 European notification number: B/ES/13/06

1.2 Member State of notification: ESPAÑA

1.3 Date of consent and consent number: Orden de 17 de mayo de 2013 de la Consejería de Fomento y Medio Ambiente de Castilla y Leon

2 Report status

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

X the final report

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): NK603

3.3 Unique identifier, if available: MON-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 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]) (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)
Benavente (Zamora)	**3000 m2**	**Lines NK603 8pl/m2**	**Sowing : 24/05/2013 Destruction : 21/10/2013**

([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?

X Yes (by another juridical entity of the group) ☐ No ☐ Unknown to date

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

If yes, specify for which use(s):

X Import.

X Cultivation (e ;g ; seed/planting material production).

- Food.

X Feed.

- Pharmaceutical use (or processing for pharmaceutical use).

- Processing for pour.

  - Food use
  - **X** Feed use
  - Industrial use.

- Others (specify):

The import, processing and feed use in the NK603 are authorized in accordance with Directive 2011/18/CE (Commission Decision 2004/643/EC). The uses of NK603 and its fractions in feed uses were approved in accordance with Regulation CE/258/97 (Commission Decision 2005/448/EC). The cultivation of NK603 maize was requested in accordance with Directive 2001/18/EC (C/ES/03/01) and later by Regulation

1829/2003/EC (EFSA-GMO-NL-2005-22), which has favorable report of EFSA (29 May 2009).

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 ☒

The observation, selfing and crossing and data collection of NK603 lines

- 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 ☐

Not applicable

- Variety registration on a national variety catalogue

[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 pharceuticals, plant-based proteins production, etc.

- DUS (=Distinctness, Uniformity and Stability)
- VCU (=Value of Cultivation and Use)

- Others: (specify): …….

5.4 Herbicide authorization ☐

Not applicable

5.5 Deliberate release(s) for demonstration purposes ☐

Not applicable

5.6 Seeds multiplication ☐

Not applicable

5.7 Deliberate release(s) for biosafety/risk assessment research ☐

Not applicable

- 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) : .....

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).
  Before planting it was checked the isolation distance over the meters required with others maize commercial fields.
  The NK603 maize seed was packaged in paper envelopes.
  Each paper bag corresponding to each elementary plot has been labeled with the corresponding identification code according to the planting protocol.
  The envelopes containing the seeds were packaged, labeled and sealed in unbreakable containers in accordance with the protocol (cardboard boxes placed in rigid plastic containers with screw cap)

- 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).
  Each unbreakable container was wrapped in plastic and sent in cardboard boxes.
  The transport of the seeds to the field was performed the same day of planting. At all times, the seed handling has been performed by trained staff and knowledgeable about the preventive measures to avoid any seed dissemination.
- Destruction of superfluous seeds/planting material (describe the method involved).
  The remaining seed, together with the envelopes containing the seed was burned and buried inside the trial perimeter
- Temporal isolation (specify).

- Rotation (specify the previous crop).
  Previously there was no crop
  Other(s): (specify)

6.1.2 During the sowing/planting activities:

- Method of sowing/planting.
  The planting date was notified in advance to the authorities.
  The planting was carried out with a self-cleaning air seeder adapted for planting microplot trials.
- Emptying and cleaning of the sowing machinery on the field of release.
  The sowing machine was checked and cleaned before and after planting within the release site.
- Segregation during the sowing (provide example of containment to prevent spillage during the sowing/planting).
  The envelopes containing the seeds were opened only within the area occupied by the trial at the time of planting. All seed handling was performed by trained staff and knowledgeable about the preventive measures to avoid seed dissemination.
- Other(s): (specify)

6.1.3 During the period of release:

- Isolation distance (x meters)
  Before planting it was verified the isolation distance of at least 200m with other maize commercial fields
    - From sexually compatible commercial plant species.
    - From sexually compatible wild relatives.

- Border rows (with the same crop or a different one, with a non-transgenic crop, x meters, etc).
  It has been planted 8 rows of non gmo corn around the entire trial perimeter
- 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 frecuency of the removal, x metres around the GM field, etc).
  The release area was monitored throughout the whole growth season. Any weediness tendency or major susceptibility to pests or diseases than conventional corn has been observed.
- 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 dates of harvest and destruction of the trial have been reported in advance to the competent authority.

The collection of selected ears was made by hand. All the collected material has been packaged, using the third packaging mentioned in the notification, within the field for its shipment to the lab.
The harvest has been performed in 3 different dates, the last harvest coinciding with the destruction of the trial. The harvest and packaging was performed under the supervision of an officer of the competent authority.
The rest of the trial, including borders was harvested with a combine and the plants were debris. The harvested grain was buried in a hole within the perimeters of the trial, being covered by at least 0,5m of soil.
The plants remains have been buried by tillage to a depth of at least 30cm.
The destruction of the field has been performed under the supervision of an officer of the competent authority.

- 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).
  The collected material was packaged for shipment at the time of collection. Transport was performed according to the protocol in a triple packaging avoiding any risk of seed dispersal
- Clean up of machinery on the release site.
  After the destruction of the trial the harvest equipment and the machinery was cleaned before leaving the release site
- Destination of the waste, treatment of waste/ surplus yield/plant residues (describe).
  The harvested grain was buried in a hole within the perimeter of the trial and covered by at least 0,5 m of soil.
  The plants remaining in the field has been buried by tillage to a depth of at least 30cm.
  The destruction of the trial has been performed under supervision of an officer of the competent authority.
- 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).
  In the release site will follow the traditional work of preparation for the subsequent crop.
- 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)
The release site will be monitored frequently throughout the growing season following the release in order to destroy any eventual maize volunteers that may appear.

- Subsequent crop (specify).
  The subsequent crop cannot be commercial maize.
- Crop rotation (specify).

- Fallow/no crop (specify).

- Superficial soil work / no deep ploughing.

- False-sowing beds.

- Control of volunteers (specify intervals and duration).
  During the following crop the release site will monitored
- 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:
   The release has proceeded as planned
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:
   There was no need of taking any action

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

X **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.

Specify:

- Monitoring measures within site

  Duration: **monitoring will be performed during one year after the release**

  Frequency of visits (average): **During the following crop the release site will monitored**

  - Observation of resistant relatives.
  - Observation of resistant insects.
  - Control of volunteers (specify intervals and duration).

    On the visits to the release site will be monitored for the appearance of potential volunteers for destruction
  - Monitoring of gene flow (specify).
  - Appropriate chemical treatment(s) and/or soil treatment(s).
  - Others (specify).

- Monitoring measures of adjacent areas:

Not applicable

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.

General observations on plant health, disease susceptibility and development of plants

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:

[4] Summary notification information format (=SNIF)

- 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.

NK603 maize plants have developed normally and presented a crop cycle and behavior similar to that of the corresponding conventional isogenic.
It has been verified glyphosate tolerance of plants NK603

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.
Not observed any unexpected effect

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.

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.
Field trial was carried out according to the conditions proposed in the notification and laid down in the order of May 17, 2013 of the Consejería de Fomento y Medio Ambiente de Castilla y Leon, ensuring the safety and respect for the environment and human health.
The trial proceeded as planned and NK603 maize plants behaved normally, similar to the conventional maize.
There has been no adverse effect on human or animal health or the environment.
There has been no different effect of genetically modified plants from conventional maize in relation to crop development.

DATE: **13/02/2014**