

**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/11/18

1.2 Member State of notification: Spain

1.3 Date of consent and consent number: March 15th 2011

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): NK603

3.3 Unique identifier, if available : MON-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) (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)
Marchena Sevilla (Andalucía)	- Total surface of the release: 1632 m ² - NK603 maize area : 72 m ²	NK603 maize: ~ 9 plants/m ²	From: 11/04/11 To: 14/09/11
Dos Hermanas Sevilla (Andalucía)	Total surface of the release: 1632 m ² - NK603 maize area: 72 m ²	NK603 maize: ~ 9 plants/m ²	From: 07/04/11 To: 15/09/11
Tauste Zaragoza (Aragón)	Total surface of the release: 1560 m ² - NK603 maize area: 72 m ²	NK603 maize: ~ 8,5 plants/m ²	From 13/04/11 To: 05/10/11
Ejea de los Caballeros Zaragoza (Aragón)	Total surface of the release: 1560 m ² - NK603 maize area: 72 m ²	NK603 maize: ~ 8,5 plants/m ²	From: 14/04/11 To: 04/10/11
Nuez de Ebro Zaragoza (Aragón)	Total surface of the release: 1560 m ² - NK603 maize area: 72 m ²	NK603 maize: ~ 8,5 plants/m ²	From: 13/04/11 To: 04/07/11
Villar de Rena Badajoz (Extremadura)	Total surface of the release: 1560 m ² - NK603 maize area: 72 m ²	NK603 maize: ~ 8,5 plants/m ²	From: 08/04/11 To: 16/09/11
La Gineta Albacete (Castilla la Mancha)	Total surface of the release: 3240 m ² - NK603 maize area: 72 m ²	NK603 maize: ~ 8,5 plants/m ²	From: 17/05/11 To: 29/11/11

(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 ?

Placing on the market of NK603 maize for import, processing and feed uses has been authorized by Commission decision 2004/643/EC. The use of food and food ingredients derived from NK603 was authorized by Commission decision 2005/448/EC. An application for authorization of NK603 maize for import and industrial processing and derived food and feed including cultivation in the European Union has been submitted pursuant to Regulation (EC) n°1829/2003 (reference #EFSA-GMO-NL-2005-22) by another company.

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)

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

- 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 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 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):
Each lot of genetically modified seed was prepared in small paper envelopes, clearly labeled as containing genetically modified material. Each envelope was identified with the entry code according to the experimental protocol and contained the amount of seed needed for one experimental plot.
- 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)
Envelopes containing the seed remained closed until planting. Transport of the seed to the field was done on the planting day, in the envelopes in which the seed was prepared, ordered according to the trial design and placed inside conveniently labeled and closed boxes.
- Destruction of superfluous seeds/planting material (describe the method involved).
All the GM seeds were planted. However, as described hereafter in point 6.1.2. (2nd item), at the end of each individual plot sowing, the seeds remaining in the machine (if any) were aspirated to a specific container in the planter and were then buried in the soil at the site of the release.
- Temporal isolation (specify)
- Rotation (specify the previous crop)
- Other(s): (specify):
The isolation distance to any other non-experimental maize crop was verified to be in accordance with the permit conditions (at least 200m).

6.1.2 During the sowing/planting activities :

- Method of sowing/planting (describe)
Seeds were planted with a special sowing machine designed for micro-plot testing which allows an easy cleaning of the remaining seeds and avoids any mixture of seeds.
- Emptying and cleaning of the sowing machinery on the field of release.
At the end of each individual plot sowing, the remaining seeds in the machine (if any) were aspirated to a specific container in the planter. Once the sowing was finished at each

location the planting equipment was carefully inspected and cleaned before leaving the trial plot and all the remaining seeds were buried in the soil.

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

Seeds were transported to the field in individual small paper envelopes per each micro-plot and each envelope was opened only once the previous plot was planted and the remaining seed (if any) was captured in the container on the planter.

- Other(s) : (specify):

A representative of the Ministry of Environment attended the planting at Nuez de Ebro (Zaragoza), Ejea de los Caballeros (Zaragoza), Tauste (Zaragoza), La Gineta (Albacete) and Villar de Rena (Badajoz).

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 GM trial 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 seeded around the whole trial. At the end of the release, these non-genetically modified maize rows were destroyed like the rest of the plants in the trial.

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

In the location of La Gineta (Albacete) in Castilla la Mancha, the whole plot where the trial was carried out had a fence that protected the trial against predators damage. In the locations of Ejea de los Caballeros (Zaragoza) and Tauste (Zaragoza) in Aragon, the trial was surrounded by a fence to protect the trial against predator's damage.

- Pollen trap (specify):

The conventional maize hybrid of similar maturity planted around the trial 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)

- Removal of bolters/relatives/hybrid partners (indicate the frequency of the removal, x meters around the GM field, etc)

- Other(s): (specify):

Representative of the Ministry of Environment visited all the trial sites during the release, verifying that all operations were done correctly.

6.1.4 At the end of the release :

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

In all the locations except at Nuez de Ebro (Zaragoza), the harvest of the border rows sown around the trials as pollen traps and the harvest of each micro-plot in the trials were done using a combine designed to harvest micro-plots trials for agronomic value, which provided the yield in kilograms and the percentage of moisture of the grain for

each individual micro-plot. Once these evaluations were completed, the grain harvested was destroyed using a milling equipment installed in the combine, except at the location of Nuez de Ebro (Zaragoza) in Aragon, where the trial was destroyed before flowering. At all the locations, the remaining plant materials were destroyed with a chopper equipment installed in the combine and by several disk ploughing. Finally, in all locations, the grain milled (except at Nuez de Ebro (Zaragoza)) and all the plant material destroyed were incorporated into the soil by deep ploughing.

- Harvest / destruction before the ripeness of the seeds
At the location of Nuez de Ebro (Zaragoza), the trial suffered mechanical damages due to vandalism actions during the night from 13 to 14 June 2011, thus the trial was terminated earlier. The trial was destroyed on 04 July 2011, prior to flowering, thus far away from the ripeness of the seeds. The plant material was destroyed by several chopping and incorporation into the soil by deep ploughing.
- 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.
All the machinery used was carefully cleaned on the release site.
- Destination of the waste, treatment of waste/ surplus yield/plant residues (describe)
In all locations, all the plant residues generated during the release were incorporated into the soil by deep ploughing, once the grain was previously milled (except at Nuez de Ebro (Zaragoza)), and the remaining plant material destroyed by chopping as described above.
- 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)
Trial area has been chopped several times to destroy the plant material and then deep ploughed to incorporate all the plant waste into the soil.
- Other(s): (describe):
A representative of the Ministry of Environment attended the trial destruction at all the locations, checking compliance with the requirements for the release of genetically modified plants.

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 except commercial maize
 - Crop rotation (specify)
The following year there 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).
A proper monitoring of volunteers will be implemented during a one year-period following the end of the release. If volunteers are observed they will be destroyed before flowering. Special attention will be paid during the period from soil preparation for sowing to pre-flowering stage. If needed, any undesired emerged plant would be destroyed mechanically or by an appropriate herbicide treatment.

A few volunteers were observed at Ejea de los Caballeros (Zaragoza), Tauste (Zaragoza) and Villar de Rena (Badajoz), they were immediately destroyed at a very early stage of development. No more volunteers were observed to date. No maize volunteers were observed in the trial sites of Nuez de Ebro (Zaragoza), Marchena (Sevilla), Dos Hermanas (Sevilla) and La Gineta (Albacete) to date.

- 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, except at Nuez de Ebro (Zaragoza)
 - No (describe for which reason, e.g. vandalism, climatic conditions, etc.)
At Nuez de Ebro (Zaragoza), the trial was damaged by a vandalism action during the night from 13 to 14 June 2011 and was destroyed before flowering.
- 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 was made on July 4th 2011 in Nuez de Ebro (Zaragoza), September 14th in Marchena (Sevilla), September 15th in Dos Hermanas (Sevilla), September 16th in Villar de

Rena (Badajoz), October 4th in Ejea de los Caballeros (Zaragoza), October 5th in Tauste (Zaragoza), November 29th in La Gineta (Albacete). The post-release monitoring plan has started since these dates. The trial sites will be visited regularly for a one-year period in order to check the absence of volunteers. If there were any, they would be controlled by means of machines or by an appropriate herbicide treatment.

A few volunteers were observed at Ejea de los Caballeros (Zaragoza), Tauste (Zaragoza) and Villar de Rena (Badajoz), they were immediately destroyed at a very early stage of development. No more volunteers were observed to date. No maize volunteers were observed in the trial sites of Nuez de Ebro (Zaragoza), Marchena (Sevilla), Dos Hermanas (Sevilla) and La Gineta (Albacete) to date. No commercial maize will be sown in those sites in 2012.

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, with particular attention during usual maize emergence and flowering periods.
- ~~• 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.

A representative of the Spanish "Ministerio de Medio Ambiente y Medio Rural y Marino", visited all the locations during the summer, once the crop was established, to check compliance with the requirements for the release of GMO and he attended the harvest and destruction of the trials in all locations, verifying that these 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.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 environment risk assessment has not identified any risk for the human health or the environment as a result of the deliberate release of the genetically modified NK603 maize.

No environment problems were detected in these trials.

No effects are expected during the post-release monitoring period. None were observed so far.

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 the 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 the 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.

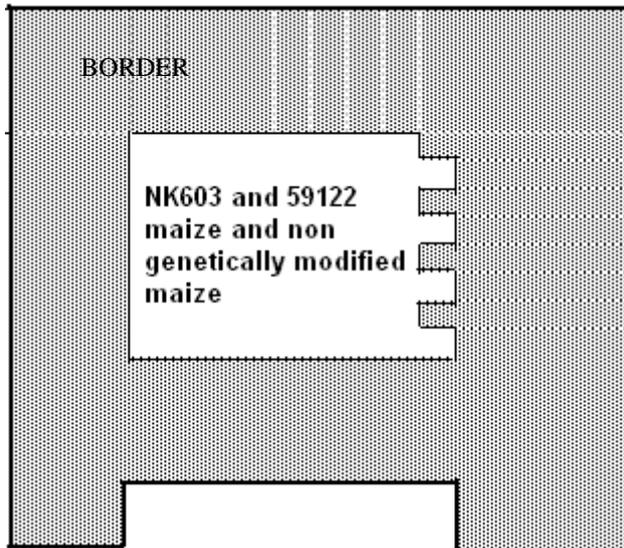
The measures proposed in the notification and the control measures taken seem to be consistent with the aim of respecting the environment and human health safety.

However, we deplore the vandalism actions committed toward one of these experimental trial sites and the loss of the corresponding trial.

DATE : 17 February 2012

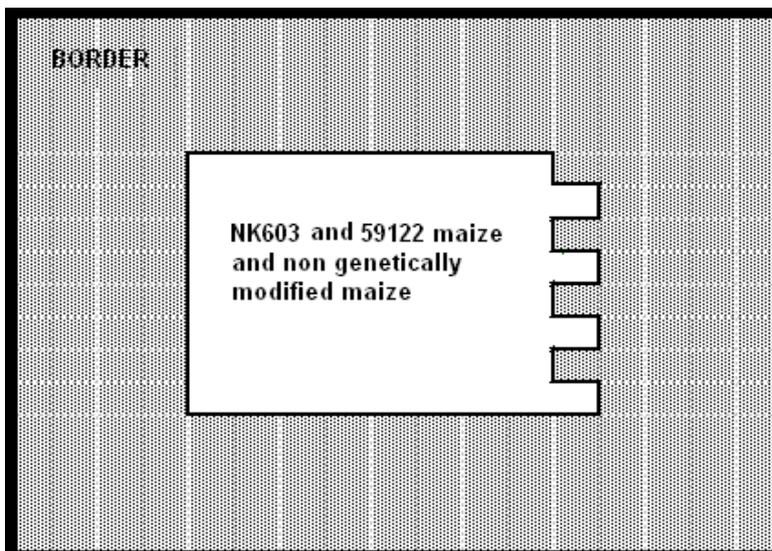
ANNEX 1: Field Layouts

Locations: Marchena (Sevilla, Andalucía), Dos Hermanas (Sevilla, Andalucía)



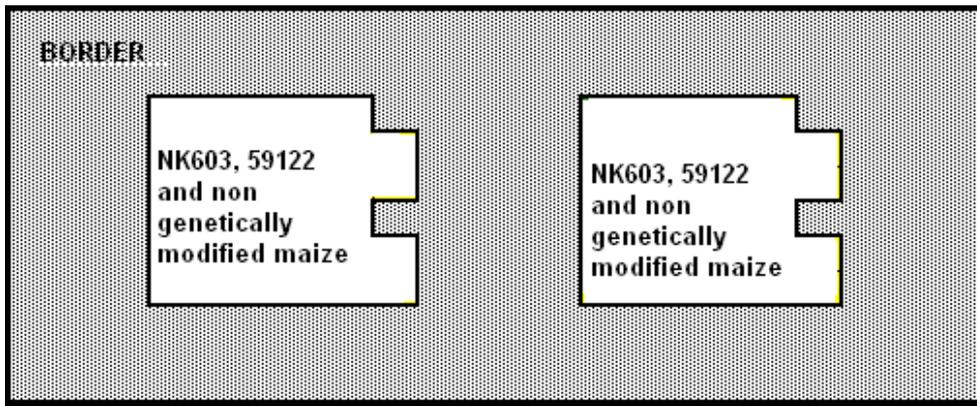
*Border: at least 8 rows

Locations: Ejea de los Caballeros (Zaragoza, Aragón), Tauste (Zaragoza, Aragón), Nuez de Ebro (Zaragoza, Aragón) y Villar de Rena (Badajoz, Extremadura)



*Border: at least 8 rows

Location: La Gineta (Albacete, Castilla la Mancha)



*Border: at least 8 rows