

**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/09/53

**1.2 Member State of notification:** Spain

**1.3 Date of consent and consent number:** March 25<sup>th</sup> 2009 in Castilla-La Mancha, March 31<sup>st</sup> 2009 in Aragon, April 20<sup>th</sup> 2009 in La Rioja, May 29<sup>th</sup> and modification on July 30<sup>th</sup>, 2009 in Cataluña.

## **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 vectors<sup>1</sup> used (if transformation event identity not available):** 59122

**3.3 Unique identifier, if available :** DAS-59122-7

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

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<sup>1</sup> 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) ( <sup>2</sup> ) (m <sup>2</sup> )	Identity ( <sup>3</sup> ) and approximate number of GM higher plants per event actually released (number of seeds/plants per m <sup>2</sup> )	Duration of the release(s) (from ... (day/month/year... until... (d/m/y)
Alpera (Albacete) (Castilla-La Mancha)	- Total surface of the release: 5888m <sup>2</sup> - 59122 maize area: 22.5 m <sup>2</sup>	59122 maize: ~ 6 plants/m <sup>2</sup>	From: 09/06/2009 to: 24/11/2009
La Gineta (Albacete) (Castilla-La Mancha)	- Total surface of the release: 4647m <sup>2</sup> - 59122 maize area: 22.5 m <sup>2</sup>	59122 maize: ~ 6 plants/m <sup>2</sup>	From: 10/06/2009 to: 03/12/2009
Gimenells i El Pla de la Fonts (Lleida) (Cataluña)	- Total surface of the release: 4389m <sup>2</sup> - 59122 maize area: 22.5 m <sup>2</sup>	59122 maize: ~ 6 plants/m <sup>2</sup>	From: 22/06/2009 to: 12/08/2009
Calahorra (La Rioja) (La Rioja)	- Total surface of the release: 4602m <sup>2</sup> - 59122 maize area: 22.5 m <sup>2</sup>	59122 maize: ~ 6 plants/m <sup>2</sup>	From: 15/06/2009 to: 19/01/2010 *

(<sup>2</sup>) Specify the size of the GM area and, where appropriate, the size of the non-GM area (e.g. non-GM border)

(<sup>3</sup>) Vectors used

\* checking of efficiency of the deep ploughing made on 27 november and of the burying of superficial residues made on 2 december 2009

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 59122 maize for food and feed uses, import and processing in the European Union has been authorized by Commission decision 2007/702/EC.

Cultivation dossier has been applied under # EFSA-GMO-NL-2005-23 by another juridical entity of the group.

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 <sup>2</sup>

- 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)

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<sup>2</sup> 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 farming<sup>3</sup>
- Phyto-remediation
- Others : (specify) Collect additional data

**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) : .....

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<sup>3</sup> « 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 small paper envelopes, and boxes, labeled as "Contains genetically modified material". In addition, each small paper envelope 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 paper envelopes 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 Communities of La Rioja and Castilla-La Mancha).

#### 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 small paper envelopes 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 Communities of La Rioja and Castilla-La Mancha, 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 Communities of La Rioja and Castilla-La Mancha, 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):  
As requested by the autonomous community of Castilla-La Mancha, the trial site in La Gineta and Alpera was protected from predators by a fence.
- 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)  
According to the trial needs, plant tissues were sampled at different stages of maize development at the location of Calahorra (La Rioja), Alpera and La Gineta (Castilla-La Mancha) and exported in view of their analysis in a specialized laboratory outside Spain.  
At the location of Calahorra (La Rioja), the grain and remaining plant materials were destroyed by chopping and incorporated into the soil by deep ploughing. Ears or ear parts and individual kernels which could have remained on the field surface after ploughing were collected manually and buried in the field.  
At the location of La Gineta (Castilla-La Mancha), the grain was harvested with a plot harvester and milled at the same time. It was incorporated into the soil by deep ploughing, with all the remaining plant materials which were destroyed by chopping using a rotovator.  
At the location of Alpera (Castilla-La Mancha), the grain was harvested with a conventional harvesting machine and buried in a deep hole dugged at the site of release. The remaining plant materials were chopped with a rotovator and incorporated into the soil by deep ploughing.
- Harvest / destruction before the ripeness of the seeds  
At the location of Gimeneles i El Pla de la Font (Cataluña), the trials were destroyed prior to flowering, thus far away from the ripeness of the seeds. This anticipated destruction was due to a heavy hail storm which considerably damaged the plants, thus for agronomic reasons the trial was terminated early. The plant material was destroyed by chopping and incorporation in the soil by deep ploughing.

At the locations of Calahorra (La Rioja), Alpera (Castilla-La Mancha) and La Gineta (Castilla-La Mancha), for the trial sampling needs, some maize plants were destroyed before the ripeness of the seeds (or even before flowering). At the end of the release, all the plant material was destroyed by chopping and incorporation in 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)  
The samples collected for analysis in some of the trials were hermetically packed at the site of release in a clearly labeled double container and frozen on the site.
- 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. In addition, at La Gineta (Castilla La Mancha), the grain (when any) was milled before being buried in the soil.
- 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 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 a one-year period after the end of the release to monitor the occurrence of potential volunteers. More particular attention will be given during the period from soil preparation for maize sowing in each area to the usual flowering period. 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, at Calahorra (La Rioja), Alpera and La Gineta (Castilla-La Mancha)
  - No (describe for which reason, e.g. vandalism, climatic conditions, etc.)  
At Gimennells i El Pla de la Font (Cataluña), the trial was damaged by a heavy hail storm on 1st August, 2009. For agronomic reasons, it was thus terminated earlier. The plants had not reached the flowering stage.
- 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 August 12, 2009 at Gimennells i El Pla de la Font (Cataluña), November 24, 2009 at Alpera (Castilla-La Mancha), , December 3, 2009 at La Gineta Castilla-La Mancha), November 27, 2009 at Calahorra (La Rioja) with two additional visits for verification of efficiency of the deep ploughing on December 2 and January 19, 2010, date which is considered as the final destruction.

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. However, at Gimennells i El Pla de la Font, probability of volunteer emergence is negligible since the trial was destroyed prior to flowering (and thus prior any grain production).

There were no volunteers in the trial sites so far. No commercial maize crop will be planted in these plots in 2010.



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 SNIF<sup>4</sup> 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.

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

A representative of the "Departament d'Agriculture, Alimentació I Acció Rural de la Generalidad de Catalunya" visited the trials at planting and destruction, and checked the compliance with the requirements for the release of GM plants in the location of Gimenells i El Pla de la Font (Cataluña).

A representative of the Consejería de Agricultura de la Junta de Comunidades de Castilla-La Mancha visited the trials several times during the release period in both La Gineta and Alpera (Castilla-La Mancha), checking compliance with the requirements for the release of

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<sup>4</sup> Summary notification information format (=SNIF)

GM plants, and attended trial destruction at these locations with a representative of the Ministry of Environment, verifying the correct destruction of the plant material. 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 and then made subsequent inspections.

## 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 only potential risk resulting from the interaction between the genetically modified maize and the target organisms identified in the environmental risk assessment of the notification was the development of resistance of the target coleopteran insects, such as the Western corn rootworm (*Diabrotica virgifera virgifera*), to the insecticidal proteins expressed in the genetically modified 59122 maize. However, the likelihood of the occurrence of this potential identified adverse effect was negligible, taking into account the small surface occupied by the trials.

The presence of the target coleopteran insects, *Diabrotica*, has not been recorded to date, thus no development of resistance in the target insects was detected in the case of the trials carried out.

#### 6.4.3 *Unexpected effect(s)*<sup>5</sup>

*“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

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<sup>5</sup> 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.

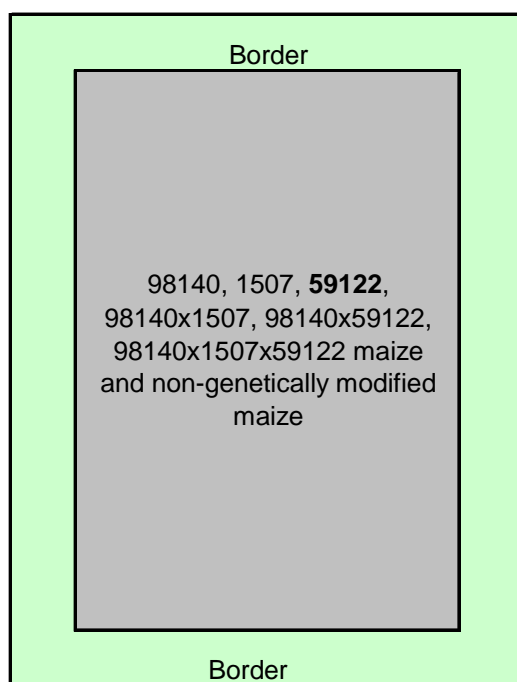
No risk for the human health or the environment has been identified as a result of the deliberate release of the genetically modified maize in these trials.

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

DATE : 20 January 2010

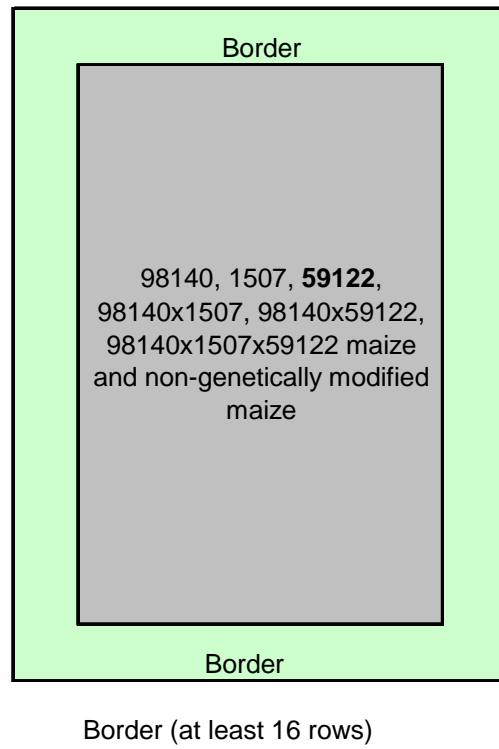
ANNEX 1 Field Layouts

- Location: Alpera (Albacete, Castilla-La Mancha)

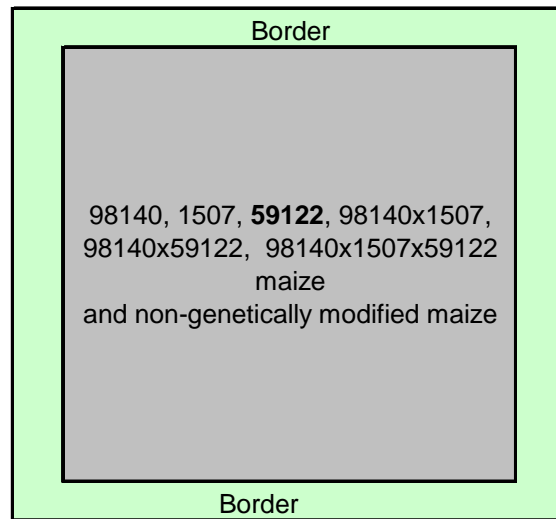


Border (at least 16 rows)

- Location: La Gineta (Albacete, Castilla-La Mancha)



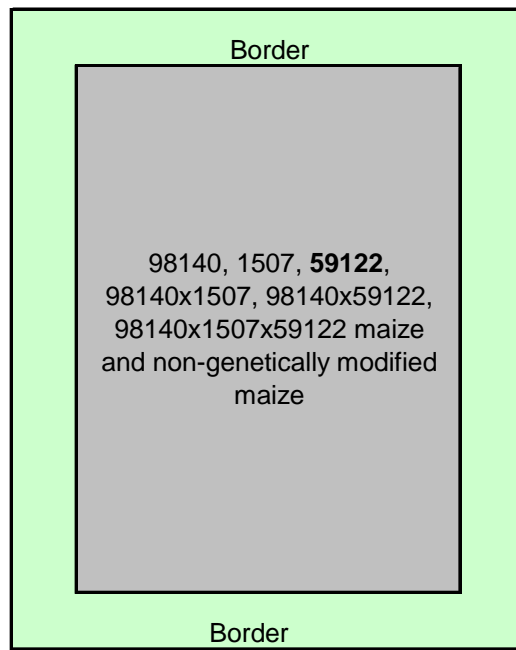
- Location: Gimenells i El Pla de la Font (Lleida, Catalunya)



Border (at least 8 rows)

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- Location: Calahorra (La Rioja, La Rioja)



Border (at least 16 rows)