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/CZ/08/01

1.2 Member State of notification: Czech Republic

1.3 Date of consent and consent number: June 6, 2008; 42355/ENV/08

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[1] used (if transformation event identity not available): 98140

3.3 Unique identifier, if available : DP-Ø9814Ø-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) ([1]) (m^2)	Identity ([2]) 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)
Čáslav (Kutná Hora)	- Total surface of the release*: 3635.5 m² - 98140 maize area: 1358 m²	98140 maize: ~ 8.2 plants/m²	From: 13.06.2008 to: 27.11.2008
Ivanovice na Hané (Vyškov)	- Total surface of the release*: 6930 m² - 98140 maize area: 1568 m²	98140 maize: ~ 8.2 plants/m²	From: 12.06.2008 to: 19.11.2008
Ivanovice na Hané (Vyškov)	- Total surface of the release*: 6776 m² - 98140 maize area: 2257 m²	98140 maize: ~ 8.2 plants/m²	From: 12.05.2009 to: 15.11.2009
Čáslav (Kutná Hora)	- Total surface of the release*: 4732 m² - 98140 maize area: 2224 m²	98140 maize: ~ 8.2 plants/m²	From: 13.05.2009 to: 23.11.2009
Jarohněvice (Kroměříž)	- Total surface of the release*: 2223 m² - 98140 maize area: 300 m²	98140 maize: ~ 7.6 plants/m²	From: 14.05.2009 to: 30.10.2009
Praha (Praha)	- Total surface of the release*: 3397 m² - 98140 maize area: 2077 m²	98140 maize: ~ 8.2 plants/m²	From: 14.05.2009 to: 02.11.2009

([1]) Specify the size of the GM area and, where appropriate, the size of the non-GM area (e.g. non-GM border)
([2]) Vectors used

* Note: The total surface of the release includes border rows, alleys, and as appropriate, other genetically modified maize trials subject of other notifications within the surrounding borders.

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 ?

An application for the placing on the market of 98140 maize for food, feed, import and industrial processing in the European Union has been submitted to EFSA under Regulation (EC) n°1829/2003 (reference EFSA-GMO-UK-2008-53) 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 [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 ☐

- 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

[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-synthesized pharmaceuticals, plant-made pharmaceuticals, plant-based proteins production, etc.

- 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 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)
Genetically modified (GM) seeds were received packed in sealed double containers labeled as "Contains genetically modified material, not to be used for commercial cultivation, food or feed", with mention of the name of the genetically modified maize.

☑ - 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 in the original clearly labeled and sealed containers in which the seeds were received, separately from conventional seed. No processing of the seed was done before planting.

☑ - Destruction of superfluous seeds/planting material (describe the method involved)
Superfluous seeds were crushed and buried at the release site.

☐ - Temporal isolation (specify)

☐ - Rotation (specify the previous crop)

☑ - Other(s): (specify)
The isolation distance to other maize crop was verified to be in accordance with the permit conditions (at least 200 m from any conventional maize crop and 600 m from any organic maize crop).

6.1.2 During the sowing/planting activities :

☑ - Method of sowing/planting (describe)
Seeds were planted with a precision sowing machine.

☑ - Emptying and cleaning of the sowing machinery on the field of release.
Emptying and cleaning of the sowing machine was done on the site of release. The machine was carefully inspected before leaving the site of release. Remaining seeds were crushed and buried at the release site.

☑ - Segregation during the sowing (provide example of containment to prevent spillage during the sowing/planting).
The seed were in bags which were opened just as needed for planting. No spillage was observed.

☐ - 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 was kept from any commercial maize crops and 600 m from any organic maize crop.
- From sexually compatible wild relatives
  Not applicable, spontaneously maize has not any sexually compatible wild 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 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)
A signpost was placed at all corners of the trial site to forbid entry to the GMO site.

☑ - Pollen trap (specify):
The non-GM 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 trials.
In addition, at Jarohněvice sunflower was planted as a bee attractive plant in the surroundings.

☐ - 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)
Inspectors visited the trial sites during the release and checked the compliance with the requirements for the release of GM plants.

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 was done manually at Cáslav and Ivanovice na Hané in 2008. In 2009, harvest was done manually at Praha and Cáslav, or with a microplot combine at Ivanovice na Hané. Some plant tissue samples were taken for the purpose of the experiment at Jarohněvice in 2009. At all the 2008 and 2009 trial locations, the remaining plant materials, including surrounding border rows, and harvested material if any, were destroyed by chopping, crushing and incorporation into the soil by a deep ploughing after application of nitrogen fertilizer. In addition, disk tillage was used at Jarohněvice.

☑ - Harvest / destruction before the ripeness of the seeds
Destruction occurred before the ripeness of the seeds at Cáslav in 2008.

☑ - Effective removal of plant parts
In 2009, for the purpose of the experiment, some plant tissue samples were collected at Jarohněvice.

☑ - Segregated storage and transport of crop/waste (provide examples of containment to prevent spillage of collected seeds/crops/wastes)
The samples collected for analysis at Jarohněvice in 2009 were hermetically packed at the site of the release in a clearly labeled double container.

☑ - 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)

Waste plants were destroyed on the release site by chopping and were incorporated into the soil by deep 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 and then incorporated into the soil by deep ploughing. Then, soil preparation was done in accordance with the cultural practices in the area.

☐ - 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): Every month during the vegetative period
Post-release monitoring was done during a one-year period after the destruction of the trial.

☑ - Subsequent crop (specify)

No commercial maize crop was planted in the same trial area during the year following the release. After the 2008 trials, spring barley and spring wheat were planted at Cáslav and Ivanovice na Hané, respectively. After the 2009 trials, spring barley was drilled at Cáslav, Ivanovice na Hané and Jarohněvice. The next crop planted at Praha was safflower.

☑ - Crop rotation (specify)

No commercial maize crop was planted in the same trial area during the one-year period following the release (see subsequent crop above).

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

The release sites were visited regularly during a one-year period after the end of the release. At Praha and Ivanovice na Hané 2009 trial sites, some volunteers were observed at a very early stage of development and were mechanically removed. No more volunteers were observed. No maize volunteers were observed at the other sites.

☐ - 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 post-release monitoring plan has been completed.

The destruction of the 2008 trials was made on 19 and 27 November 2008 at Ivanovice na Hané and Cáslav, respectively. The post-release monitoring plan started on these dates and was done over a one-year period in order to check the absence of volunteers. No volunteers were observed on these sites.
The destruction of the 2009 trials was made on 30 October 2009 at Jarohněvice and 2, 15 and 23 November 2009 at Praha, Ivanovice na Hané and Cáslav, respectively. The post-release monitoring plan started on these dates and was done over a one-year period. The trial sites were visited regularly. No maize volunteers were observed at Jarohněvice and Cáslav. Some maize volunteers, transgenic or not, were found and destroyed at Praha and Ivanovice na Hané. However, they were at an early stage of development thus far away from flowering stage. They were mechanically removed and destroyed on the site of release. No more volunteers were then observed at these sites.

Specify :

☑- Monitoring measures within site
Duration : A one-year period after the end of the release
Frequency of visits (average): every month during the vegetative period

- ~~Observation of resistant relatives~~
- ~~Observation of resistant insects~~
- Control of volunteers (specify intervals and duration)
  The trial sites were visited regularly during a one-year period in order to monitor any potential maize volunteers. No maize volunteers were observed at the 2008 trial sites. Some volunteers were found and destroyed at the 2009 Ivanovice na Hané and Praha trial sites. No more volunteers were observed. No volunteers were observed at the other 2009 sites.

- ~~Monitoring of gene flow (specify)~~
- ~~Appropriate chemical treatment(s) and/or soil treatment(s)~~
- ~~Others (specify)~~

☑- Monitoring measures of adjacent areas:
Duration: same as for the trial area
Frequency of visits (average) : same as for the trial area
Area monitored : adjacent fields

- ~~Observation of resistant relatives~~
- ~~Observation of resistant insects~~
- Control of volunteers and/or monitoring of feral populations (specify intervals and duration) No volunteers were found.
- ~~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[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.

Visual observations were made in accordance with the monitoring plan.

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)*

[4] Summary notification information format (=SNIF)

- *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 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 98140 maize.
No environment problems were detected in these trials.

No effects were expected and observed during the post-release monitoring period.

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 during the release and the post-release monitoring period.

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

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.

As required in the permit, a special attention was given to the weed sensitivity to glyphosate-based preparations during the course of the experiments.
No weed resistance to glyphosate was observed in the trials.

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 seed of the genetically modified maize plants.
No negative effect of any kind that has or could have effects on the human health or the environment has been observed.

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.

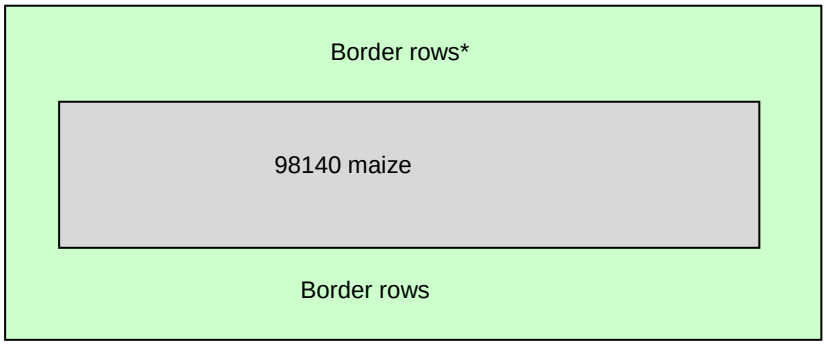
The safety and control measures applied to these trials provided optimum protection of the environment and human health.

DATE : 14 February 2013

ANNEX 1: Field Layouts

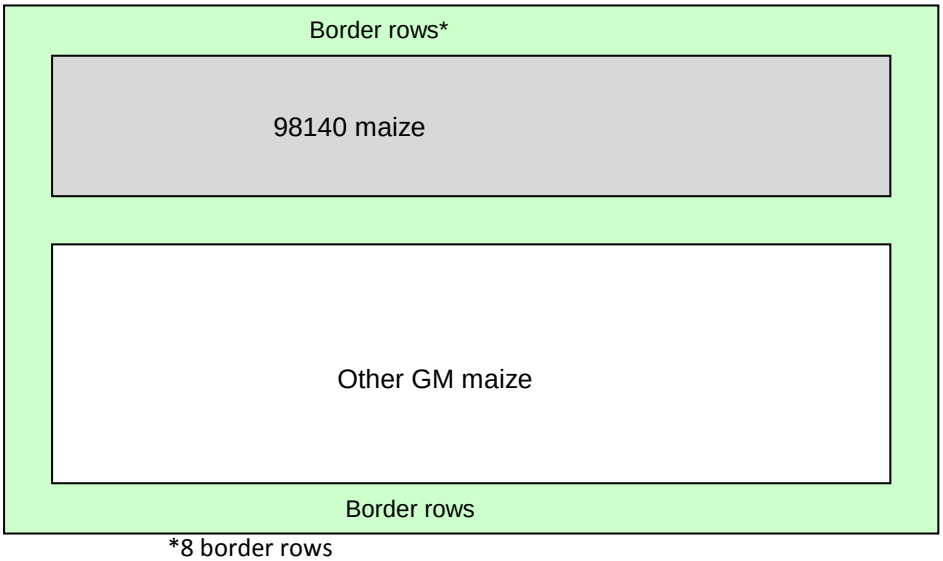
2008 trial sites

Location: Cáslav



*at least 8 border rows

Location: Ivanovice na Hané

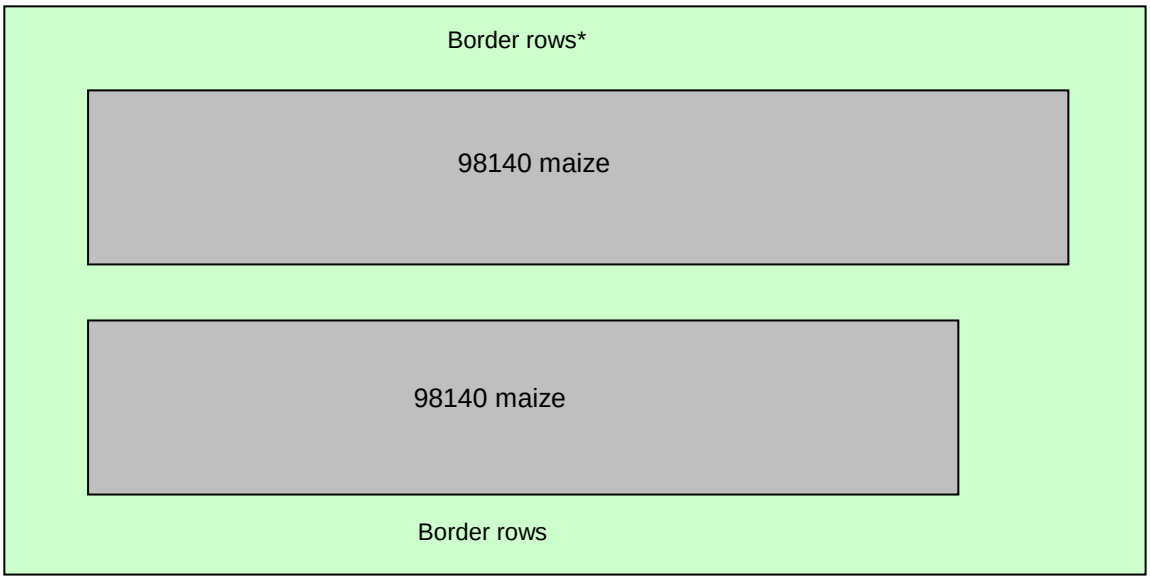


*8 border rows

ANNEX 1: Field Layouts

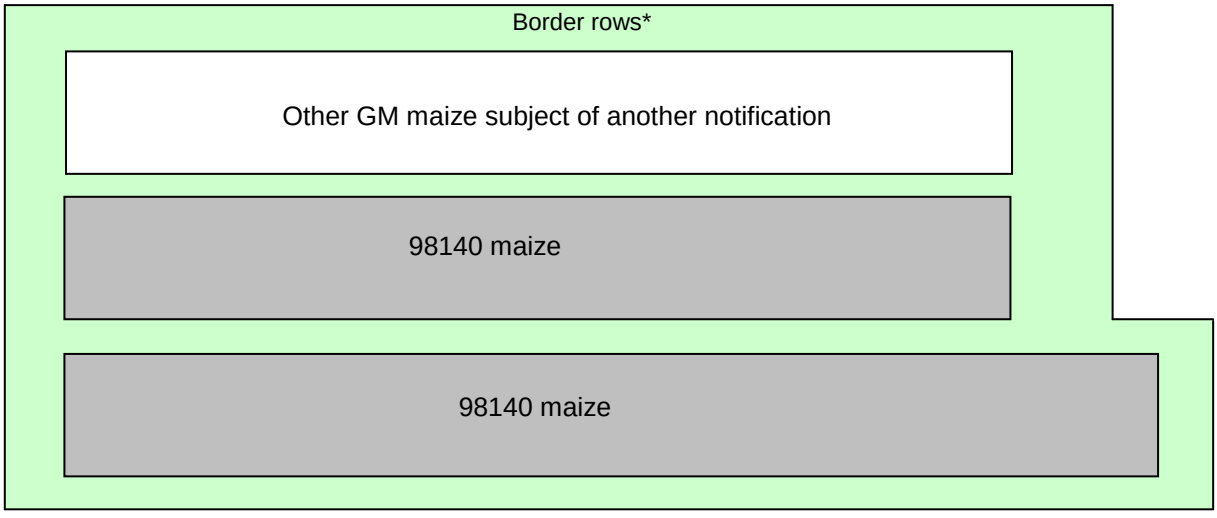
2009 trial sites

Location: Čáslav



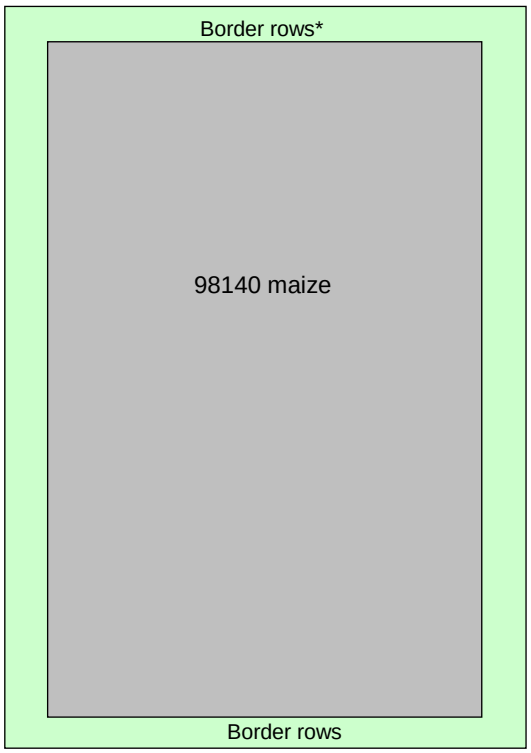
*8 border rows

Location: Ivanovice na Hané



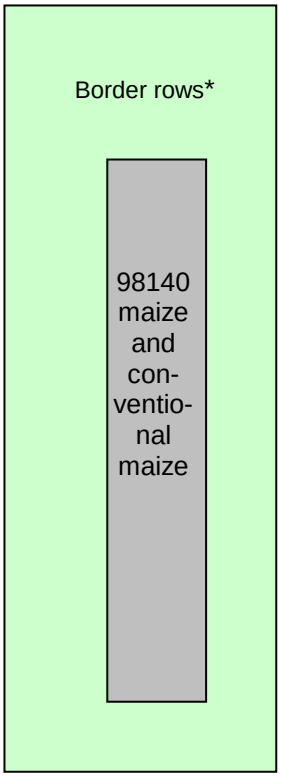
*8 border rows

Location: Praha



*8 border rows

Location: Jarohněvice



*at least 8 border rows