

**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/DE/07/190

1.2 Member State of notification: *Germany*

1.3 Date of consent and consent number: *Az. 6786-01-0190 of April 21, 2008*

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 vectors¹ 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) ⁽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)
Uebigau / Zabeltitz (Saxony)	- Total surface of the release: 5198 m ² - 98140 maize area: 3312 m ²	98140 maize: ~ 9.1 plants/m ²	From: 11.05.2009 to: 30.11.2009
Ausleben / Ausleben- Üplingen (Saxony-Anhalt)	- Total surface of the release: 5198 + 13500 m ² - 98140 maize area: 3312 + 210 m ²	98140 maize: ~ 9.1 plants/m ²	From: 11.05.2009 to : 30.11.2009
Neutrebbin / Neutrebbin (Brandenburg)	- Total surface of the release: 5198 m ² - 98140 maize area: 3312 m ²	98140 maize: ~ 9.1 plants/m ²	From: 9.05.2009 to: 17.09.2009

⁽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 ?

YES (by another juridical entity of the group) NO Unknown to date

If yes, indicate the country(ies) of notification: via EFSA (European Food Safety Authority)

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) : It will be used like any commercial maize

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

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

- 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 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)
Seeds were received packed in sealed double bags and boxes. Each bag containing transgenic seed was labeled as "Contains genetically modified material, not to be used for 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 on the planting day, in the original bags and boxes in which the seeds were received, clearly labeled and sealed. No processing of the seed was done before planting.
- Destruction of superfluous seeds/planting material (describe the method involved).
Superfluous seeds were destroyed by autoclaving.
- 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).

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.
After the sowing, the machine was emptied and cleaned on the site of release.
It 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 seed were in bags which were opened just as needed for planting. No spillage was observed.
- Other(s): (specify)

Inspectors attended the plantings at Ausleben (Saxony-Anhalt), Neutrebbin (Brandenburg) and Uebigau (Saxony), verifying that all operations were done correctly.

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.
 - 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 four 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.

At Neutrebbin (Brandenburg), a small portion of a border row has been resown and a small fine mesh net was added, before flowering of GM plants, in agreement with local Authorities.

At Uebigau (Saxony), some plants of the border rows were damaged by a herbicide drift, however, there were more border rows than the 4 required in the permit, some plants were resown and had grown prior to flowering of the GM plants.
- Cage/net/fence/signpost (specify)

As required in the permit, a signpost was placed at the trial sites indicating genetically modified maize not to be used as food or feed stuffs, and prohibiting any removal of plants or plant parts by unauthorized persons. Still the trials at Uebigau (Saxony) were the target of acts of vandalism.

A fence against wild pigs and other wild animals was installed around the trials at Uebigau (Saxony).
- 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.
- Removal of GM inflorescences before flowering (indicate the frequency of removal)
- Other(s): (specify)

Representatives of the local Authorities visited the trial sites several times during the release, checking 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)

In some trials, maize plant samples (forage, whole plant or ears) were collected in view of their analysis in a specialized laboratory.

Some trials, including border rows, have been harvested with a maize silage harvester.

All the remaining plant materials, including surrounding border rows, were destroyed by chopping using a mulcher and incorporated into the soil with a harrow at Uebigau (Saxony) and Neutrebbin (Brandenburg) or by ploughing at Ausleben (Saxony-Anhalt).
- Harvest / destruction before the ripeness of the seeds
The destruction occurred before the ripeness of the seeds at Neutrebbin (Brandenburg).

- 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 were hermetically packed at the site of release in a sealed double container, clearly labeled with the name of the genetically modified maize and the mention "not to be used as food or feed stuff".
- 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. In addition, unused kernels from ear samples collected for analysis at Ausleben (Saxony-Anhalt) and Uebigau (Saxony) were milled in a S1-room and then, the coarse grits were incorporated into the soil at Ausleben (Saxony-Anhalt) and Uebigau (Saxony) locations.
- 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 using a harrow or by ploughing.
- Other(s): (describe):

Inspectors visited the trials at Uebigau (Saxony) on 22 September 2009 after their partial destruction by vandalism.
Inspectors visited the trials at harvest/destruction at Uebigau (Saxony) and Neutrebbin (Brandenburg), verifying that all operations were done correctly.

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)

Sugar beets were planted at Neutrebbin (Brandenburg). New trials with genetically modified maize were planted at Ausleben (Saxony-Anhalt) in May 2010.
- Crop rotation (specify)

No commercial maize crop, see above and below.
- Fallow/no crop (specify) at Uebigau (Saxony)
- Superficial soil work / no deep ploughing
- False-sowing beds
- Control of volunteers (specify intervals and duration).

At Uebigau (Saxony) and Neutrebbin (Brandenburg), the release sites have been visited approximately every 2 months during a one year-period after the end of the release to control and manage the occurrence of potential maize volunteers, with special focus during the usual emergence and flowering periods. No volunteers were observed.
At Ausleben (Saxony-Anhalt), the release site was visited every month after the end of the release until May 2010 when other experiments of genetically modified maize were planted. No volunteers were observed. After the last year of trials, one year of monitoring will follow in accordance with the trial consents.
- 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 Ausleben (Saxony-Anhalt).
 - No (describe for which reason, e.g. vandalism, climatic conditions, etc)
Some trials at Uebigau (Saxony) were partially destroyed by vandalism.
Location Neutrebbin (Brandenburg) was harvested earlier than planned to avoid destruction as announced by vandals.
- 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 September 17, 2009 in Neutrebbin (Brandenburg), October 13, 2009 in Uebigau (Saxony), November 17 and 23, 2009 in Ausleben (Saxony-Anhalt). However, coarse grits of unused milled grain samples were incorporated into the soil at the Uebigau (Saxony) and Ausleben (Saxony-Anhalt) trial areas on November 30, 09. This date is considered as the end of the release at these two locations.

The post-release monitoring plan has been completed. It has started on these dates for a one year-period at Uebigau (Saxony) and Neutrebbin (Brandenburg), and until May 2010 at Ausleben (Saxony-Anhalt) since new genetically modified maize experiments were planted on the same areas.

As required in the permit, a ten meter-zone around the trial sites was included in the monitored area. No volunteers were found.

At Ausleben (Saxony-Anhalt), the new genetically modified maize experiments were the subject of regular monitoring. After the last year of trials, one year of post-release monitoring will follow in accordance with the trial consent.

Specify :

- Monitoring measures within site

Duration: At Uebigau (Saxony) and Neutrebbin (Brandenburg), one year after the end of the release. At Ausleben (Saxony-Anhalt) from the end of the release until other GM maize trials were planted

Frequency of visits (average): approximately every two months

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

At Uebigau (Saxony) and Neutrebbin (Brandenburg), the release sites have been visited approximately every 2 months during a one year-period after the end of the release to control and manage the occurrence of potential maize volunteers, with special focus during the usual emergence and flowering periods. No volunteers were observed.

At Ausleben (Saxony-Anhalt), the release site was visited every month after the end of the release until May 2010 when other experiments of genetically modified maize were planted. No volunteers were observed. After the last year of trials, one year of monitoring will follow in accordance with the trial consent.

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

- Monitoring measures of adjacent areas: a ten meter-zone around the trial site

Duration: same as the trial site (see above)

Frequency of visits (average) : same as the trial site (see above)

Area monitored : a ten meter-zone around the trial site

- ~~Observation of resistant relatives~~
- ~~Observation of resistant insects~~
- Control of volunteers ~~and/or monitoring of feral populations (specify intervals and duration)~~ same as the trial site (see above)
- ~~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.

Visual observations were made in accordance with the monitoring plan proposed in the notification.

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 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 environment were observed, during the release and post-release monitoring period.

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

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, during the release and post-release monitoring period.

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.

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

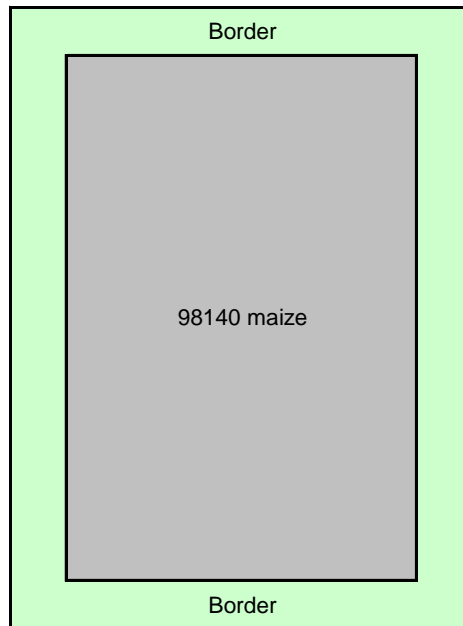
The measures proposed in the notification and the control measures taken seem to be consistent with the purpose of assuring the safety of the environment and of the human health.

The trials at Uebigau (Saxony) were partially destroyed by vandalism. A complaint was lodged for these acts of vandalism and only a complete judicial inquiry will allow identifying if there were uncontrolled releases from stolen plant material.

DATE : 28 January 2011

ANNEX 1: Field Layout

Locations: Uebigau (Saxony) and Neutrebbin (Brandenburg)



ANNEX 1: Field Layout

Location: Ausleben (Saxony-Anhalt)

