

**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/NL/07/09

**1.2 Member State of notification:** Netherlands

**1.3 Date of consent and consent number:** IM 07-009 March 27, 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<sup>1</sup> used (if transformation event identity not available):** 98140

**3.3 Unique identifier, if available :** DP-Ø9814Ø-6

**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)
Smilde (Drenthe)	- Total surface of the release: 4380 m <sup>2</sup> - 98140 maize area: 1374 m <sup>2</sup>	98140 maize: ~ 7.5 plants/m <sup>2</sup>	From: 04.06.2008 to: 26.08.2008

<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

See the trial layout 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 <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)
- 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):

**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**

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<sup>2</sup> For example, testing the new trait under environmental conditions.

<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.

**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) : .....

## 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 box which remained closed until planting. Each bag containing transgenic seed was labeled as "Contains genetically modified material", 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 box 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 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 400 m).

#### 6.1.2 During the sowing/planting activities :

- Method of sowing/planting (describe)  
Seeds were planted with a sowing machine.
- Emptying and cleaning of the sowing machinery on the field of release.  
Emptying and cleaning of the sowing machine was done by hand on the field of release. 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 seed were in bags which were opened just as needed for planting. Any spillage of seed at the emptying of the machine was prevented by catching the seeds in plastic bags.
- 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 400 m was kept from any other maize crops.
  - 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 four border rows of non-genetically modified maize of a similar maturity surrounded the trial. At the end of the release, these border rows were destroyed like the rest of the plants in the trial.
- Cage/net/fence/signpost (specify)
- Pollen trap (specify):  
The trial was destroyed by vandalism before plants reach the flowering stage. Otherwise, non-GM border rows planted around the trial would have created a pollen trap.
- Removal of GM inflorescences before flowering (indicate the frequency of removal)
- Other(s): (specify)  
The certified Environmental Safety Officer visited the trial at least every two weeks during the period of release. The field was also officially inspected during the period of release.  
As required in the permit, a sign was placed at the entrances of the field prohibiting access by unauthorized personnel to the trial area. Still the field was the target of acts of vandalism.

### 6.1.4 At the end of the release :

- Harvest/destruction methods (of crop or part of it) / other means (e.g.: sampling) (describe)  
The trials were destroyed by vandalism. Then, all the remaining plant materials, including surrounding border rows, were mowed, chopped and incorporated into the soil by a deep ploughing.
- Harvest / destruction before the ripeness of the seeds  
The trial was destroyed by vandalism before flowering, thus the plants never developed seeds. The crop residues were chopped and incorporated into the soil.
- 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)  
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.
- Other(s): (describe):  
The field was also officially inspected following the acts of vandalism.

### 6.1.5 Post-harvest measures:

Please indicate which measures were taken on the release site after harvest:

Frequency of visits (average):

Post-release monitoring was done during one year after the destruction of the transgenic plants.

- Subsequent crop (specify)

Potatoes

- Crop rotation (specify)

No commercial maize crop was planted in the same trial area during the year 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 site was visited every two months during the following season to control and manage the occurrence of potential volunteers. No volunteers were observed.

- 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.)

The trials were destroyed by vandalism. They were thus terminated prior to 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 post-release monitoring plan has been completed.

The trials were destroyed by vandalism 7 weeks and a half after planting, thus far away from flowering time for the late maturity varieties tested, and thus before any grain production can occur. Probability of volunteer emergence was therefore negligible. However, they were monitored every two months during a one-year period. No volunteers were found.

Specify :

- Monitoring measures within site

Duration : one year from the end of the release

Frequency of visits (average): every two months

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

Minimum inspections: at the end of the winter, at sowing time, prior to flowering and in August. Probability of volunteer emergence was negligible as the plants were destroyed before flowering and thus before any grain production can occur.

No volunteers were observed.

- ~~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.*

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>.*

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

#### 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.*

No environment problems were detected in these trials and during the post-release monitoring period. This confirms the environmental risk assessment which had not identified any risk for the human health or the environment as a result of the deliberate release of the genetically modified 98140 maize.

#### 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 during the release and the post-release monitoring.

#### 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 case of this deliberate release, all the control measures were taken by the notifier to avoid the spreading of pollen and seed 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.

The measures proposed in the notification and practical application of the control measures have been consistent with the purpose of guarantying the safety of the environment and of the human health.

The trials were destroyed by acts of vandalism. A complaint was lodged for these acts of vandalism and only a complete judicial inquiry will allow to identify if there were uncontrolled releases from stolen plant material.

DATE : 21 December, 2009

ANNEX 1...Field Layout

Location: Smilde (Drenthe)

