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/10/207

1.2 Member State of notification: Germany

1.3 Date of consent and consent number: Az. 6786-01-0207 of April 28, 2010

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

The current report is the annual end of campaign report for 2010.

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): 1507, 59122, NK603, 1507xNK603, 59122x1507xNK603

3.3 Unique identifier, if available : DAS-Ø15Ø7-1, DAS-59122-7, MON-ØØ6Ø3-6, DAS-Ø15Ø7-1xMON-ØØ6Ø3-6, DAS-59122-7xDAS-Ø15Ø7-1xMON-ØØ6Ø3-6

[1] In the case of small-scale field trials where several lines may be tested, the vectors used should be mentioned, which gives insight into the introduced traits and/or genetic elements. In the case of larger-scale trials, the number of events notified is limited to only one or a few events.

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

Geographical location(s) (administrative region and, where appropriate, grid reference)	Size of the release site(s) ([2]) (m2)	Identity ([3]) and approximate number of GM higher plants per event actually released (number of seeds/plants per m2)	Duration of the release(s) (from ... (day/month/year... until... (d/m/y)
Ausleben/Ausleben-Üplingen (Saxony-Anhalt)	- Total surface of the release: 12194 m^2 + 37244m^2 of which 720 m^2 + 20798 m^2 of genetically modified maize	7.4 to 10.2 genetically modified maize plants per m^2	From 09.05.10 (or 04.06.10) to 27.11.2010*

([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

* destruction by complete grain cracking and ensiling (27.10.10) followed by mulching and ploughing of plant residues (27.11.10). The final inactivation will be done by the ensiling process and use of the silage in a biogas facility.

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 1507 maize for import, processing and feed uses, and for food uses, in the European Union has been authorized by Commission decisions 2005/772/EC and 2006/197/EC, respectively. Placing on the market of 59122, 1507xNK603 and 59122x1507xNK603 for food and feed uses, import and processing in the European Union has been authorized, respectively, by Commission decisions 2007/702/EC, 2007/703/EC and 2010/428/EU.

Cultivation dossier for 1507 has been applied under # C/ES/01/01 by another juridical entity of the group. Applications for authorization of 59122 maize (reference EFSA-GMO-NL-2005-23), 1507xNK603 maize (reference EFSA-GMO-UK-2005-17) and 59122x1507xNK603 maize (reference EFSA-GMO-UK-2006-30), for import and processing including cultivation in the European Union have been submitted pursuant to Regulation (EC) n°1829/2003 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) : .....

[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.

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) : .....

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 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 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.

6.1.2 During the sowing/planting activities :

☑ - Method of sowing/planting (describe)
Seeds were planted with an experimental 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 release site. Remaining seeds, if any, were collected in plastic trays.

☑ - 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 300 m was kept from any maize crops used for food or feed stuff.
- 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.

☑ - Cage/net/fence/signpost (specify)
As required in the permit, a signpost was placed at the trial site 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.

☑ - Pollen trap (specify):
The non-genetically modified border rows planted around the trials created a pollen trap. At the end of the release, these non-genetically modified 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 site during the release, checking compliance with the requirements for the release of genetically modified 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)
The plant material, including border rows, was harvested with a silage harvester. Grain was completely cracked. The ensilaged material was compacted with a tractor and covered by an airtight awning at the field of release. Final inactivation will be done by the ensiling process and use of the silage in a biogas facility. The remaining maize plant stalks were mulched and incorporated into the soil by deep ploughing. In addition, in one trial, remaining ears after silage harvesting had been steamed at the site of release and incorporated into the soil.

☑ - Harvest / destruction before the ripeness of the seeds
Plant material was harvested at forage maturity, thus far away from grain maturity.

☐ - 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)
The plant material, including border rows, was chopped with a silage harvester for use of silage in a biogas facility. The remaining stalk residues were mulched and incorporated into the soil by deep ploughing. In addition, in one trial, remaining ears after silage harvesting had been steamed at the site of release and incorporated 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)

As indicated above, the remaining ears were steamed and incorporated into the soil, and remaining plant residues were mulched and incorporated into the soil by ploughing.

☑ - Other(s): (describe):

A representative of local Authorities attended the harvest checking kernel destruction, completely cracked before final inactivation by ensiling process and use of silage in biogas installations.

6.1.5 Post-harvest measures:

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

Frequency of visits (average): in average every two months.

☑ - Subsequent crop (specify)

No commercial maize crop will be planted in the same trial area during the year following the release.

☑ - Crop rotation (specify)

Any other crop, except commercial maize crop in the following year

☐ - Fallow/no crop (specify)

☐ - Superficial soil work / no deep ploughing

☐ - False-sowing beds

☑ - Control of volunteers (specify intervals and duration).

The release site will be visited at least every 2 months during a one year-period after the end of the release. Although probability of volunteer emergence is very low under Northern latitudes, they will be monitored and if any volunteers emerge, they will be destroyed prior to flowering, with an appropriate herbicide treatment or by any other appropriate measures. More frequent visits will be made to ensure proper control if volunteers are found.

☐ - 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 destruction of the trials in Ausleben (Saxony-Anhalt) was made by complete grain cracking and ensiling (27.10.10) followed by mulching and ploughing of plant residues (27.11.10). The post-release monitoring plan has started since this date.
As required in the permit, a ten meter-zone around the trial site is included in the monitored area. No volunteers were found so far.

Specify :

☑- Monitoring measures within site
Duration : one year from 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 (approximately every two months), 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: 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 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 and will be 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.

[4] Summary notification information format (=SNIF)

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 lepidopteran insects, such as the European corn borer (*Ostrinia nubilalis*) and/or target coleopteran insects, such as the Western corn rootworm (*Diabrotica virgifera virgifera*), to the insecticidal proteins expressed in the genetically modified 1507, 59122, 1507xNK603 and 59122x1507xNK603 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.

In the trials carried out, no loss of efficacy of 1507, 1507xNK603 or 59122x1507xNK603 maize plants on European corn borer was detected. Concretely, no damages caused by the European corn borer were observed on 1507, 1507xNK603 or 59122x1507xNK603 maize plants, which lead to the conclusion that there was no developed resistance in the target lepidopteran insects. This confirms that, in the case of the trials carried out, the likelihood of the occurrence of this potential identified adverse effect was negligible.
The presence of the target coleopteran insects, *Diabrotica*, has not been recorded to date, thus no development of resistance in the target insects was possible in the case of the trials carried out.

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.

[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.

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 case of this deliberate release, 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 these 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: 28 January 2011

ANNEX 1: Field Layout

Location: Ausleben-Üplingen (Saxony-Anhalt)