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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

Presentation to

Federal Office of Consumer Protection and Food Safety

Department 4 Genetical Engineering

Mauerstr. 39-42

D-10117 Berlin, Germany

Reference **6789-01-0198**

Final Report for Release **2009-2010**

Date: 31 January 2012

1.	**General information**

1.1	European notification number: **B/DE/ 08/198**

1.2	Member State of notification: …**Germany**

1.3	Date of consent and consent number: **15 May 2009, 6789-01-0198**

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) ……. **GA21 herbicide tolerant maize** ……..

3.3	Unique identifier, if available: **MON-00021-9**……..

[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 large(r) 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) lay-out:

Year	Geographical local location or places (administrative region and coordinates of reference when it proceeds)	Local surface or places (m²)	*Identity and approximate number of top plants MG liberated really by every event (N º of seeds / plants for m²)*	*Duration of her or the liberations: (Of … (day / month / year)up to (day / month / year*
2009	D-39167 Eichenbarleben Field Part 8, Section 75-78	4200 m^2 GA21 maize + 2000 m^2 conventional maize	9 plants/m2	20.05.2009 – 29.09.2009*
	D-04916 Herzberg Field Part 2, Section 322	1930 m^2 GA21 maize + 1370 m^2 conventional maize	9 plants/m2	04.06.2009- 19.08.2009*
2010	D-39167 Eichenbarleben Field Part 8, Section 75-78	4200 m^2 GA21 maize + 2000 m^2 conventional maize	9 plants/m2	In 2010 only post-harvest monitoring; Release only in 2009: 20.05.2009 – 29.09.2009*
	D-39167 Eichenbarleben Field Part 7, Section 33/10	2300 m^2 GA21 maize + 1700 m^2 conventional maize	8 plants/m2	18.5.2010 – 15.10.2010
	D-04916 Herzberg Field Part 2, Section 322	2100 m^2 GA21 maize + 2100 m^2 conventional maize	8 plants/m2	30.04.2010 – 03.10.2010*, **

Comment by applicant :

** Vandalism in 2009 and 2010 in summer. No additional observation to report. Following the vandalism the plant material from the field site was chopped and mulched earlier at some locations. Destruction of the border rows in the same way at the same time or later.*

Duration of the release period covers the day of sowing until the destruction and mulching of the all plant material, including the border rows.

*** Harvest took place on 3. Oct 2010 according to field logbook and not on 3 Nov 2010 as mentioned in the interim report.*

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 ☐ No ☐ Unknown to date

If yes, indicate the country(-ies) of notification : **U.K**……
If yes, specify for which use(s):

- ☒ Import
- ☒ Cultivation (e.g. Seed/planting material production)
- ☒ Food
- ☒ Feed
- Pharmaceutical use (or processing for pharmaceutical use)
- ☒ Processing for :
  - ☒ Food use
  - ☒ Feed use
  - ☒ Industrial use
- – Others (specify):

The GA21 maize application (Reference EFSA-GMO-UK-2008-60) under Regulation (EC) No 1829/2003 from Syngenta Seeds, for food and feed uses, import, processing and cultivation received the positive Scientific Opinion of EFSA on December 9th, 2011.

5. Type(s) of deliberate release(s)

Please select the main type(s) (in boxes) as well as sub-type(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
- ☒ 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)
- – Improved agronomic properties (e.g. disease/pest/drought/frost resistance, etc) (Specify)
- – Improved qualitative properties (prolonged shelf-life, enhanced nutritional value, modified composition, etc) (Specify)
- – Stability of the expression
- – Multiplication of lines
- – Hybrid vigour study
- – Molecular farming
- – Phyto-remediation
- – Others: ……..

5.3	Official testing	☐

- Variety registration on a national variety catalogue
  - DUS (= Distinctness Uniformity Stability)
  - VCU (= Value of Cultivation and Use)
- Others: (Specify)…….

5.4	Herbicide authorisation	☒

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
- Observations 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

Without prejudice to the specific environmental risk assessment as well as to the consent conditions, the notifier shall provide the following information **in respect of any effect for human health or the environment.** 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.

6.1 Risk management measure(s)

Please report the risk management measures, which have been used to avoid or minimise 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 labelling of the GM seeds/planting material lots (distinct from other seeds/tubers/etc)
  Each bag was clearly labelled: "Contains genetically modified organism: MON-ØØØ21-9".

- ☒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)
  Seed were transported in closed and triple package in separate containers and were managed by qualified staff. Transport of the seeds to the field was done on the day of planting.

- ☒ Destruction of superfluous seeds/planting material (Describe the method involved).
  2009 and 2010:
  Eichenbarleben: Remaining seed storage in S1 room until sowing at Herzberg. Herzberg/Elster: Remaining seed was collected and later analysed by the supervising authority (Landesamt für Verbraucherschutz, Landwirtschaft und Flurneuordnung (LVFL) Brandenburg).

- Temporal isolation (Specify) – **not used**

- Rotation (Specify the previous crop(s))
  No special crop rotation requested in the permit. No maize cultivation after harvest after the last year of field trial to comply with monitoring requirements of the permit.

- Other(s): (Specify)
  Generally, a minimum isolation distance of 200 m from other commercial maize fields was confirmed to comply with the permit.

6.1.2 During the sowing/planting activities:

- ☒Method of sowing/planting
  Sowing was carried out with a microplot field trial machine .

- ☒Emptying and cleaning of the sowing/planting machinery on the field of release
  All equipment used to seed was free of plant material before entering the trial site. After sowing, all the equipment used for planting was cleaned on the trial site to eliminate unintended transport of any seed or plant material from the trial site. The residual seed recovered during the process of cleaning was buried in the field trial site.

- ☒Segregation during the sowing/planting (Provide example(s) of containment to prevent spillage during the sowing/planting)
  After sowing, the sowing machine was cleaned recovering all the seeds eventually not planted.

- Other(s): (Specify)……

6.1.3 During the period of release:

- ☒Isolation distance(s) (x metres) from sexually compatible plant species, both wild relatives and crops
  Isolation distance at least 200m following permit conditions.

- ☒ Border row(s) (with the same crop or a different one, with a non-transgenic crop, x metres, etc)
  At least four border rows of conventional maize of similar maturity.

- ☒ Cage/net/fence/signpost (Specify)
  Identification of the test site by labelling. Following permit condition II.13.: "Trial using genetically modified maize. Unauthorized removal is not permitted."

- ☒ Pollen trap (Specify)
  The border rows of conventional maize are also a pollen trap. At the end of the release, these border rows were destroyed like the rest of the trials.

- Removal of GM inflorescences before flowering (Indicate the frequency of the removal)
  N/A

- Removal of bolters/relatives/hybrid partners (Indicate the frequency of the removal, x metres around the GM field, etc) – **N/A**

- Other(s): (Specify)
  Regular monitoring of all field sites on plant development following the condition of the permit.

6.1.4 At the end of the release:

- ☒ Harvest/destruction methods (of crop or parts of it)/other means (e.g., sampling and analysis of sugar beet pulp). (Describe)
  2010 Eichenbarleben (Field part 7, section 33/10): Harvest by plot maize chopper. All harvested plant material was chopped and mulched into the soil.

- ☒ Harvest/destruction before the ripeness of the seeds
  2009 (Herzberg und Eichenbarleben) and 2010 Herzberg: Following vandalism no material available to harvest. Destruction of all remaining plant material (border rows and rest of GM plants) by chopping and mulching into the soil.

- Effective removal of plant parts

- ☒ Segregated storage and transport of crop/waste (Provide example(s) of containment to prevent spillage of collected seeds/crops/wastes)
  Plant samples transported in closed and labelled containers. Each sample packed separately and was labelled with details to track back each sample to the respective field trial.

  No transport of bigger amount of plant material.

6.1.4 At the end of the release: (cont`d)

– ☒ Clean up of machinery on the release site
All machinery and equipment used for harvesting and plant material destruction were cleaned at the field trial area.

– ☒ Destination of the waste, treatment of waste/surplus yield/plant residues (Describe)
No waste disposal from the field site. All the remaining plant material after harvest was chopped and incorporated into the soil.

– ☒ Post-harvest treatment and cultivation measures on the release site (Describe the method(s) for preparing and managing the release site at the end of the release, including cultivation practices)
Mulching and flat soil cultivation. Conventional soil cultural practices in the whole area were followed after the trial termination.

– Other(s): (Describe)……..

6.1.5 Post-harvest measures

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

– ☒ Frequency of visits (average): **At least one time per month after the finalisation of the release**

– ☒ Subsequent crop (Specify) :
No crop rotation requested in the permit. Commercial maize was not grown on the trial sites the following year to monitor the field sites unimpeded and to comply with the permit.

– ☒ Crop rotation (Specify) - **No crop rotation requested in the permit**

– Fallow / no crop (Specify) – **N/A**

– ☒ Superficial soil work/no deep ploughing - **Superficial soil work**

– ☒ False-sowing beds
Eichenbarleben: cross the sowing bed; Herzberg: in the sowing bed

– ☒ Removal of volunteers (Specify intervals and duration)
Specific monitoring at least once per month has been implemented along the following year after the last harvest to track any volunteer. No monitoring during dormant season. No volunteer from 2009 – 2011.

– Appropriate chemical treatment(s) (Specify) – **No volunteers, no chemical treatment.**

– Appropriate soil treatment(s) (Specify) – **No volunteers, no soil treatment.**

– Others (Please specify) - **None**

– *6.1.6 Other(s) measure(s): (Describe)*

No other measures

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) :…….
Vandalism at both locations in 2009 and at Herzberg 2010 finalised 3 of 4 trials early.

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):
Supervising and competent authority were informed immediately on the destruction of the field trials following vandalism in 2009 and 2010. No other measures were requested following the emergency plan. For destruction of vandalised plants see section 6.1.4 of this report.

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.**

6.2 Post-release monitoring measures (cont`d)

Post release monitoring 2010 and 2011 for field trial locations 2009 – 2010:

Year	Geographical local location or places (administrative region and coordinates of reference when it proceeds)	Local surface or places (m²)	*Identity and approximate number of top plants MG liberated really by every event (N º of seeds / plants for m²)*	*Duration of her or the liberations: (Of … (day / month / year)up to (day / month / year*	*Monthly Post release monitoring until*
2009	D-39167 Eichenbarleben Field Part 8, Section 75-78	4200 m^2 GA21 maize + 2000 m^2 conventional maize	9 plants/m2	20.05.2009 – 29.09.2009*	*See 2010*
	D-04916 Herzberg Field Part 2, Section 322	1930 m^2 GA21 maize + 1370 m^2 conventional maize	9 plants/m2	04.06.2009- 19.08.2009*	*See 2010*
2010	D-39167 Eichenbarleben Field Part 8, Section 75-78	4200 m^2 GA21 maize + 2000 m^2 conventional maize	9 plants/m2	In 2010 only monitoring; Release only in 2009: 20.05.2009 – 9.09.2009*	18 Aug 2011
	D-39167 Eichenbarleben Field Part 7, Section 33/10	2300 m^2 GA21 maize + 1700 m^2 conventional maize	8 plants/m2	18.5.2010 – 15.10.2010	1 Dec 2011
	D-04916 Herzberg Field Part 2, Section 322	2100 m^2 GA21 maize + 2100 m^2 conventional maize	8 plants/m2	30.04.2010 – 03.10.2010*	5 Dec 2011

Comment by applicant :

** Vandalism in 2009 and 2010 in summer. No additional observation to report. Following the vandalism the plant material from the field site was chopped and mulched earlier at some locations. Destruction of the border rows in the same way at the same time or later.*

Duration of the release period covers the day of sowing until the destruction and mulching of the all plant material, including the border rows.

6.2 Post-release monitoring measures (cont`d)

The results of this monitoring are meant to confirm or invalidate earlier assumptions in the risk assessment. According to the afore-mentioned 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.
Specify :

– ☒ Monitoring measures within site
Following the permit the monitoring included the trial site, the border rows and the additional 10 m surrounding the field site.

Duration: **At least 1 year since field trial harvest**

Frequency of visits (average): **at least one visit per month during the vegetation period**

Observation of resistant relatives **Not relevant as no wild relatives of maize in Germany**

– Observation of resistant insects **N/A as crop is herbicide tolerant**

– Removal of volunteers (specify intervals and duration)
At regular visits during the vegetation period at least once per month all field trials sites were monitored for volunteers. Results have been recorded in the field logbook. No volunteers were found over the whole field trial period.

– Monitoring of gene flow (specify)
Not relevant as isolation measure minimised potential gene flow.

– Appropriate chemical treatment(s) and/or soil treatment(s) **Not requested**

– Others (Specify) **N/A**

– Monitoring measures of adjacent areas **Not requested**

Duration:
Frequency of visits (average):
Area monitored:
– Observation of resistant relatives
– Observation of resistant insects
– Removal of volunteers (specify intervals and duration)
– Monitoring of gene flow (specify)
– Appropriate chemical treatment(s) and/or soil treatment(s)
– Others (please specify)

6.3 Plan for observation(s)/Method(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[2] 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.

Comment by applicant:
No amendment was requested for the application and SNIF of Part B. Until today no additional scientific insights or methods have been developed to change the methods and processes used in these investigations.

6.4 Observed effect(s)

6.4.1 Explanatory note

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 an 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

[2] Summary Notification Information Format (= SNIF)

6.4.2 Expected effect(s)

The potential effects, which were already identified in the environmental risk assessment of the notification and could therefore be anticipated shall be addressed under this section.

Notifiers should supply data from the deliberate release(s) which validate the assumptions made in the environmental risk assessment.

The GA21 maize, approved as indicated above in this report for environmental release, differs only for its tolerance to the herbicide active ingredient glyphosate compared to conventional maize. Non-trangenic, near isogenic control maize with the same genetic background was grown for comparison. No phenotypic difference was observed between GM and non-GM maize.

6.4.3 Unexpected effect(s)[3]

'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 unexpected effects have been detected during the field trials. Therefore the outcome of the risk assessment remains unchanged as a result of these trials.

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.

Following the destruction of 3 of the 4 field trials by vandalism, limited opportunity was given for observations. No further information in addition to all above can be provided here.

[3] 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.

Following the destruction of 3 of the 4 field trials by vandalism, limited opportunity was given for observations. During the field trials and thereafter no observation were made to conclude on negative or unexpected impact on humans, animals or environment. The conditions of the permit 6789-01-0198 to conduct and monitor this release were followed. The conditions were adequate to conduct these trials.

DATE: