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/RO/09/20

1.2 Member State of notification: Romania

1.3 Date of consent and consent number: n°20/02.06.2009

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~~

No trials were conducted in 2012 and 2013 under this permit.
The last trials under this permit were carried out in 2011

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

3.3 Unique identifier, if available : DAS-Ø15Ø7-1

[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)
SCDA – Lovrin (Timiş county)	- Total surface of the release: ~ 1100 m^2 - 1507 maize area: 210 m^2	1507 maize: 5 plants/m^2	From: 20.05.2011 to: 26.09.2011 *

([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
* Due to poor emergence, 1507 maize plots were destroyed on 22.06.2011; the plots were re-planted with conventional maize on 10.07.2011. The destruction of the total trial area was done on 26.09.2011.

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 ?

Placing on the market of 1507 maize for import, processing and feed uses, and for food uses, in the European Union has been authorised by Commission decisions 2005/772/EC and 2006/197/EC, respectively.
A notification for the placing on the market of 1507 maize including cultivation in the EU (Reference # C/ES/01/01) has been submitted 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,) (specify)
☐- Altered agronomic properties (e.g. disease/pest/drought/frost-resistance,) (specify)
☐- Altered qualitative properties (prolonged shelf-life, enhanced nutritional value, modified composition,) (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
  - 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

[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,

☐- 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/) (describe)

- Transgenic seed for each plot were packed in sealed and separate bags, clearly labeled as containing GMO.
- The transgenic seed bags were accompanied by a document indicating the name of the transgenic maize, the unique identifier code and the mention "contains genetically modified organism".

☑ - 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)

- The seed bags were transported to the field in sealed plastic bags and solid cardboard boxes.
- The bags were opened just as needed for the planting.

☑ - Destruction of superfluous seeds/planting material (describe the method involved).

- The remaining seeds were packed in accordance with the permit requirements and returned to the notifier.

☐ - 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) and the field was permanently guarded in order to prevent the access of unauthorized persons.

6.1.2 During the sowing/planting activities:

☑ - Method of sowing/planting (describe)

- Seeds were planted with an experimental planter.

☑ - Emptying and cleaning of the sowing machinery on the field of release.

- The experimental planter was carefully examined after planting and cleaned at the site of the 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 the planting. The remaining seeds were carefully collected and returned to the notifier. No seed mixture or spillage was observed.

☑ - Other(s): (specify)

- Inspectors of Timis Directions for Agriculture and Rural Development attended the planting in SCDA Lovrin (Environmental Guard) and wrote a report certifying that appropriate procedures have been used for correct field planting.

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 other non-experimental maize crops.
- From sexually compatible wild relatives
  - Not applicable, 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)

- At least 12 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):

- At least 12 border rows of non-genetically modified maize were planted around the trial to create a pollen trap. At the end of the release, these non-GM rows were destroyed like the rest of the trial.

☐ - 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)

☐ - Other(s): (specify)

6.1.4 At the end of the release :

☑ - Harvest/destruction methods (of crop or part of it) / other means (e.g.: sampling) (describe)

- Due to poor emergence in the plots, 1507 maize plants were manually destroyed, collected and buried into the soil on 22.06.2011, prior to flowering. The plots were re-planted with conventional maize on 10.07.2011.
- On 26.09.2011, all the plant material (GM maize subject of other notifications, conventional checks and border rows) was destroyed by chopping and incorporation into the soil at the release site by a deep ploughing.

☑ - Harvest / destruction before the ripeness of the seeds

- Due to poor emergence in the plots, 1507 maize plants were destroyed one month after the planting, thus prior to flowering and ripeness of the seeds.

☐ - 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

- The choppers and other tools used for destruction of the site were carefully cleaned on the release site after utilization.

☑ - 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 with a chopping machine and then incorporated into the soil by a deep ploughing.

☑ - Other(s): (describe):

- Inspectors from Environmental Guard attended the destruction of genetically modified plants on 22.06.2011 and then the final destruction of the trial and wrote reports certifying that appropriate procedures have been used for correct destruction.

6.1.5 Post-harvest measures:

Please indicate which measures were taken on the release site after harvest:
Frequency of visits (average):

- The site has been visited regularly over a two-year period following the end of the release, as required in the permit.

☑ - Subsequent crop (specify)

- No commercial maize crop was planted in the same trial area during the two years following the release. During the first year of post-release monitoring, winter wheat was planted at SCDA Lovrin whereas common vetch was planted during the second year of post-release monitoring.

☑ - Crop rotation (specify)

- No commercial maize crop was planted in the same trial area during the two-year period following the end of 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 has been visited over a two-year period after trial destruction. It has been visited every month during the whole vegetation period over the first year of post-release monitoring, to control and manage the occurrence of potential volunteers, if any, with particular attention during the usual maize emergence and flowering periods. No volunteers were observed. Although probability of volunteer emergence was very low, the monitoring has continued for an additional one-year period, as required in the permit. The site was visited every two months during the whole vegetation period over the second year of post-release monitoring. 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)

None

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,)
As the emergence of the plants was poor in the plots, it was decided to proceed with the destruction of the GM plants, prior to flowering. The plots were re-planted with conventional maize.

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 on going** (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 trial was made on 26.09.2011.
The post-release monitoring plan started on this date. Although no volunteers were found during the first year of post-release monitoring, it was continued over an additional one-year period, as required in the permit. No volunteers were observed.

Specify :

☑- Monitoring measures within site
Duration: 24 months from 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)
  During the two-year post-release monitoring period, the release site has been visited every month or every two months during the vegetation periods, with particular attention during the usual maize emergence and flowering periods, to control and manage the occurrence of potential volunteers, if any. 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[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 proposed in the notification.

[4] Summary notification information format (=SNIF)

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 potential reduction in the control of certain lepidopteron insect pests, such as the European corn borer (*Ostrinia nubilalis*), if the target insect pests develop resistance to the insecticidal protein as expressed in 1507 maize, has been identified in the environmental risk assessment of the notification, as the only potential risk resulting from the interaction between the genetically modified maize and the target organisms. However, the likelihood of the occurrence of this potential identified adverse effect was negligible, taking into account the small surface occupied by the trial.
- The likelihood of the occurrence of this potential adverse effect was all the more negligible that in the trial carried out, due to poor emergence of the plants in the plots,

the release of 1507 maize plots was prematurely interrupted one month after the planting thus prior to flowering.

- No adverse effect was observed.

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 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 case of this deliberate release, all the control measures were taken to avoid the spreading of pollen and grains of the genetically modified 1507 maize plants.

- No risk for the human health or the environment has been identified as a result of the deliberate release of the genetically modified 1507 maize in this trial.

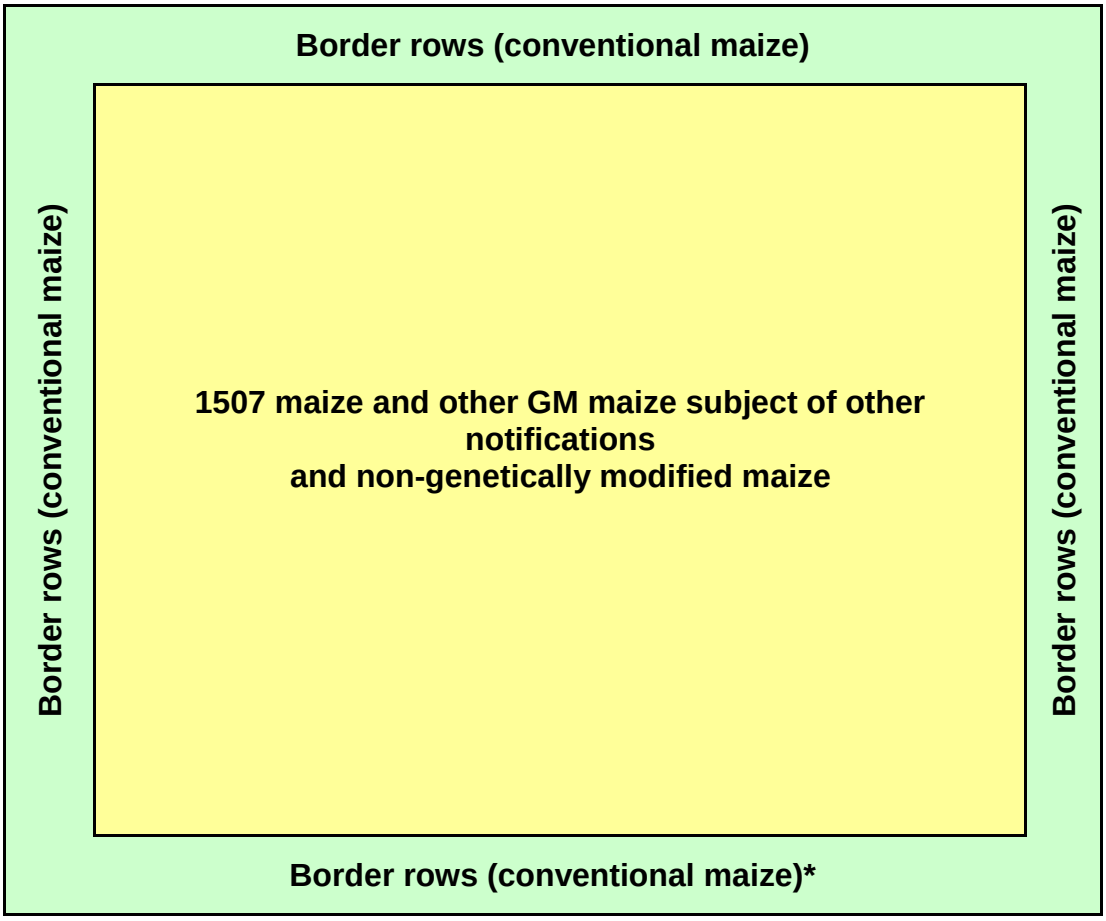
- The safety and control measures applied to these trials provided optimum protection of the environment and human health.

DATE : 13 December, 2013

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

ANNEX 1: Field Layout

Location: SCDA Lovrin (Timis county)



* at least 12 rows