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/07/07

1.2 Member State of notification: Romania

1.3 Date of consent and consent number: no.7/April 23, 2007

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): 59122x1507xNK603

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

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

[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.

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)
CTS Mircea Vodă (Brăila county)	- Total surface of the release (including other companies' trials and non-GM maize): ~ 13,000 m² - 59122x1507xNK603 maize area: 770 m²	59122x1507xNK603 maize: ~ 6 plants/m²	From: 14.05.2010 to: 22.11.2010
CTS Tecuci (Galați county)	- Total surface of the release (including other companies' trials and non-GM maize): ~ 8,000 m² - 59122x1507xNK603 maize area: 925 m²	59122x1507xNK603 maize: ~ 6 plants/m²	From: 05.05.2010 to: 01.11.2010
CTS Dâlga (Călăraşi county)	- Total surface of the release (including other companies' trials and non-GM maize): ~ 40.000 m² - 59122x1507xNK603 maize area: 925 m²	59122x1507xNK603 maize: ~ 6 plants/m²	From: 19.05.2010 to:01.10.2010
CTS Râmnicu Sărat (Buzău county)	- Total surface of the release (including other companies' trials and non-GM maize): ~ 15,000 m² - 59122x1507xNK603 maize area: 770 m²	59122x1507xNK603 maize: ~ 6 plants/m²	From: 17.05.2010 to:15.10.2010
CTS Troianu, (Teleorman county)	- Total surface of the release(including other companies' trials and non-GM maize): ~ 10000 m² - 59122x1507xNK603 maize area: 770 m²	59122x1507xNK603 maize: ~ 6 plants/m²	From: 21.05.2010 to:18.11.2010

([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

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 59122x1507xNK603 for food and feed uses, import and processing in the European Union has been authorized by Commission decision 2010/428/EU.
An application for authorization of 59122x1507xNK603 maize for import and processing including cultivation in the European Union has been submitted pursuant to Regulation (EC) n°1829/2003 by another juridical entity of the group (reference EFSA-GMO-UK-2006-30).

☐ 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)

[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.

5.3 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) : .....

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)

- Seed for each plot were packed in sealed and separate packets, 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 packets were transported to the Testing center and to the field in double package, sealed plastic bags and solid cardboard boxes.
- The small paper packets were opened just as needed for the planting.

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

- In all Testing centers, remaining seeds and empty packets were carefully collected and destroyed by burying them deeply into the soil at the site of release, following recommendation of inspectors of local competent authorities.

☐ - 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 manually in all official testing sites.

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

- The manual planters were 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).

- No seed mixture or spillage occurred. The seed were in small paper bags which were opened just once as needed for each plot planting. The remaining seeds and

empty packets were carefully collected and destroyed by burying them deeply into the soil at the release site.

☐ - 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 200 m was kept from any other 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, etc)

- At least 8 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):

☑ - Pollen trap (specify):

- At least 8 border rows of non-genetically modified maize were planted around the trials 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)

☑ - Other(s): (specify)

- Inspectors from Directions for Agriculture and Rural development visited the trials in the official testing center M.Voda during the release.

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 all Testing centers, excepting M. Voda where harvest was done manually, the experimental plots as well as border rows were harvested with an experimental combine. After weighting and moisture determinations, the harvested grains were spread on the site of release and incorporated into the soil by energic disking and deep plough, as recommended by the local inspectors of the Environmental Guard or other local competent authority.
- All the remaining plant material, including border rows, was incorporated into the soil by energic disking and deep plough.

☐ - Harvest / destruction before the 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 equipment used for harvest and destruction was 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 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 active disking and deep plough.

☑ - Other(s): (describe):

- Inspectors from Directions for Agriculture and Rural Development and/or local agencies for Environmental Protection and/or Environmental Guard attended the harvest and/or the trial destruction and wrote a report certifying that appropriate procedures have been used for correct field destruction.

6.1.5 *Post-harvest measures:*

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

- The sites will be visited regularly during the 2 year-period following the end of the release.

☑ - 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 sites will be visited every 2 months during the whole vegetation period to control and manage the occurrence of potential volunteers, if any.
- Although probability of volunteer emergence is very low, they will be monitored and if any volunteer emerges, they will be destroyed prior to flowering, with an herbicide treatment other than glyphosate and glufosinate or by any other appropriate measures.

☐ - 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, in all testing locations.

- ~~**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 was made on:

- 01.10.2010 in Dâlga,
- 15.10.2010 in Râmnicu Sărat
- 01.11.2010 in Tecuci
- 18.11.2010 in Troianu.
- 22.11.2010 in Mircea Vodă

The post-release monitoring plan has started since those dates. No volunteers were observed to date.

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)
  The release sites will be visited every 2 months during the whole vegetation period in order to control and manage the occurrence of potential volunteers, if any, with particular attention during usual maize emergence and flowering periods.
- ~~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 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.

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

[4] Summary notification information format (=SNIF)

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 lepidopteran insect pests, such as the European corn borer (*Ostrinia nubilalis*) and certain coleopteran insects, such as the Western corn rootworm (*Diabrotica virgifera virgifera*), if the target insect pests develop resistance to the insecticidal proteins as expressed in 59122x1507xNK603 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.
- In the trials carried out, no loss of efficacy of 59122x1507xNK603 maize plants on European corn borer was detected. Concretely, no damages caused by the European corn borer were observed on 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, taking into account the small surface occupied by the trials.
- The presence of the target coleopteran insects, *Diabrotica*, has not been recorded to date on the five experimental sites, 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.

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

[5] 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 these deliberate releases, all the control measures were taken to avoid the spreading of pollen and grains of the genetically modified 59122x1507xNK603 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 the genetically modified 59122x1507xNK603 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.

DATE: 14 December, 2010

ANNEX 1: Field Layout

Locations: *Official testing centers (Mircea Voda, Tecuci, Dalga, Ramnicu Sarat and Troianu)*