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/09/16

1.2 Member State of notification: Romania

1.3 Date of consent and consent number: NO 16 /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 (x)
- a post-release monitoring report

No trials were conducted in 2010 and 2013 under this permit.
The last trials under this permit were carried out in 2009.

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): MON 89034

3.3 Unique identifier, if available: MON 89Ø34-3

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]) (m^2)**	**Identity ([3]) 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)**
CARPINIS (Timis)	50 **m^2**	7 plants/ **m^2**	09.06-24.11.2009

([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

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 ?

The European Commission approved MON 89034 maize for food, feed, import and processing in accordance with Regulation (EC) No 1829/2003 on GM food and feed.

☐ 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)
MON 89034– resistance to Ostrinia nubilalis
☐- 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) : …….

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

[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.

☐- 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)

- Monsanto Romania is responsible for labeling, packing, special storage of the genetically modified seeds and also has the responsibility of training the personal which is manipulating and using the seed according to the applicable regulations .

☑ - 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 small paper bags in which the seeds were received, ordered according to the trial design, and placed inside appropriate closed, sealed and labeled boxes.
- No processing of the seed was done before planting.

☐ - Destruction of superfluous seeds/planting material (describe the method involved).
☐ - Temporal isolation (specify)
☑ - Rotation (specify the previous crop)

☑ - Other(s): (specify):

6.1.2 During the sowing/planting activities :

☑ - Method of sowing/planting (describe)
☐ - Emptying and cleaning of the sowing machinery on the field of release.
☑ - Segregation during the sowing (provide example of containment to prevent spillage during the sowing/planting).
☐ - Other(s): (specify)

6.1.3 During the period of release:

☑ - Isolation distance (x meters)

- The isolation distance to other maize crop was verified to be in accordance with the permit conditions (at least 200 m) .

☑ - Border rows (with the same crop or a different one, with a non-transgenic crop, x meters, etc)

☐ - Cage/net/fence/signpost (specify):

☑ - Pollen trap (specify):

- 6 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)

☐ - 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)

☐ - 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.

- Equipments (threshers, choppers) and other tools used for sampling and harvest were carefully cleaned on the release sites after utilization.

☑ - Destination of the waste, treatment of waste/ surplus yield/plant residues (describe)

- Waste plants were destroyed on the release sites by chopping and were incorporated into the soil by deep plough.

☑ - 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)

☐ - Other(s): (describe):

6.1.5 Post-harvest measures:

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

☑ - Subsequent crop (specify)

- cereal

☑ - Crop rotation (specify)

- sunflower

☐ - Fallow/no crop (specify)

☐ - Superficial soil work / no deep ploughing

☐ - False-sowing beds

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

- During the following season, the release sites will be visited regularly and at least 1-2 times before flowering to control and manage the potential occurrence volunteers.
- Although probability of volunteer emergence is very low, they will be monitored and if any volunteers emerge, they will be destroyed prior to flowering, with a herbicide treatment other than glifosate 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)

6.1.7 Emergency plan(s)

Indicate :

a) If the release proceeded as planned :

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

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),

X - 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.

Specify :

☐- Monitoring measures within site

- Frequency of visits (average)
- Control of volunteers (specify intervals and duration)
- 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.

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 <u>unexpected</u> and <u>unintended effect(s).</u>
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 <u>case-by-case basis</u>.

[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.

- In the trials carried out, no loss of efficacy of MON 89034 maize plants on *Ostrinia* was detected.

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 unexpected effects occurred.

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.

- No negative effect of any kind has occurred and the fenotypical behavior of MON 89034 is similar with the conventional maize.

DATE : 12 December 2013

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