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/10/04

1.2. Member State of notification: Romania

1.3. Date of consent and consent number: 4/14.06.2010

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

[x]final [ ]intermediary

3. Characteristics of the release

3.1. Scientific name of the recipient organism: Zea mays,

3.2. Transformation event(s) (acronym(s)) or vectors I1) used (if transformation event identity not available): 6981

3.3. Unique identifier, if available: VCO- Ø1981-5.

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) (l) (m^2)	Identity(2) and approximate number of CM higher plants per event actually released (number of seeds/plants per m^2)	Duration of the release(s) [from... (day/month/year)... to... (d/m/y)]
CTS Satu Mare,Satu Mare	0		
CTS Dalga,Călărasi	4000	8 pl/sq.m.	21.05.2012-25.09.2012
SCDA Caracal,Olt	0		

(1)Specify the size of the GMarca and, where appropriate, the size of the non-GM area (e.g. non-GM border).

(2) Vectors used

The last test was in 2012.

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 [x]Unknown to date

If yes, indicate the country(ies) of notification:.....

If yes, specify for which use(s):

— Import
— Cultivation (e.g. seed/planting material production)
— Food
— Feed
— Pharmaceutical vise (or processing for pharmaceutical vise)
— Processing for
— Food use
— Feed use
— Industrial use
— Others (specify):.....

5. Type(s) of deliberate rehase(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 (x)

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).....
— Altered agronomic properties (e.g. discasc/pcst/drought/frost-rcsistancc, etc.) (specify). **tolerance to glyphosate**
— 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
— Phyto-rcmcdiation
— Others: ..... (describe).....

5.3. Official testing [x]

- Variety registration on a national variety catalogue
  i) DUS (= Distinctness, Uniformity and Stability)
  ii) 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 [x]

— 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

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 norifier a choice among different measures. Tick the examples where appropriate:

Observed distance of 200 m from surface with other conventional corn. Also has made a buffer of 6 rows of conventional maize which is sown around the area of genetically modified material, and that subject to the same rules on destruction of plant material

6.1.1. Before the sowing/planting:

— Clear labelling of the CM seeds/planting material lots (distinct from other seeds/tubers/etc.) (describe)

Small paper bags are closed until planting. On the labels of bags is written the unique identifier code of the transgenic corn, VCO- Ø1981-5 and it is mentioned that "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 seeds transport was made in the original**

paper bags.

— Destruction of superfluous seeds/planting material (describe the method involved)
— Temporal isolation (specify)

— Rotation (specify the previous crop(s)) **wheat**

— Other(s): (specify).

6.1.2. During the sowing/planting activities:

— Method of sowing/planting **manually.**

— Emptying and cleaning of the sowing/planting machinery on the field of release **Cleaning of field equipment used during sowing/planting after each use. This operation was carried out within the GM trial perimeter.**

— Segregation during the sowing/planting (provide example(s) of containment to prevent spillage during the sowing/planting) **Each lot of seeds was clearly seperated using special bags („contains genetically modified organisms" and unique identifier code).**
— Other(s): (specify)..

6.1.3. During the period of release:

— Isolation distance(s) (x metres) **200 m from any other corn crop.**

— from sexually compatible commercial plant species,
— from sexually compatible wild relatives. **not applicable , because corn crop doesn't have a sexually compatible wild plant species in Europe**
— Border row(s) (with the same crop or a different one, with a non-transgenic crop, x metres, etc.) **6 rows with conventional corn crop- 4,2 m.**

— Cage/net/fence/signpost (specify)

— Pollen trap (specify) **6 border rows non GMO corn around the trial, to create a pollen trap . This border will be destroyed like the rest of trial.**

— Removal of GM inflorescences before flowering (indicate the frequency of the removal)
— Removal of boltcrs/rclativcs/hybrid partners (indicate the frequency of the removal, x metres around the GM field, etc.)
— Other(s): (specify): .....\

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) **The plants were chopped and after incorporated into the soil by deep plough in the presence of Environmental National Guard and Direction for Agriculture and Rural Development who wrote the reports certify about correct field GMO destroyed.**
— Harvest/destruction before the ripeness of the seeds
— Effective removal of plant parts

— Segregated storage and transport of crop/waste (provide cxamplc(s) of containment to prevent spillage of collected seeds/crops/wastes)
— Clean up of machinery on the release site **All equipments and tools were very carefully cleaned, after all uses in the GMO fields.**
— Destination of the waste, treatment of waste/surplus yield/plant residues (describe) **All plants were destroyed by chopping and incorporated to the soil by deep plough.**
— 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)
— Othcr(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): **Biannual**
— Subsequent crop (specify) **sunflower**
— Crop rotation (specif)') **wheat , sunflower**
— Fallow/no crop (specify)
— Superficial soil work/no deep ploughing
— False-sowing beds
— Control of volunteers (specify intervals and duration)
During the next season, the sites will be visited regularly at least once before flowering to control the potential occurrence of volunteers Although the possibility of occurrence of volunteer plants is very low and in case of, a herbicide of volunteers will be used for its destruction other than glyphosate.

— Appropriate chemical treatments) (specify)
— Appropriate soil treatment^) (specify)
— Others (specify).....

6.1.6. Other(s) measure(s): (describe):

6.1.7. Emergencyplan(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

Post-release monitoring plan is to begin (if a final report after the last harvest of GMO plants) and according to the authorization, shall be made two years after the harvest.

Due to the fact that the current report, format can be used for the final and post-release monitoring report(s), the notifier is ashed 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-rclcasc 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
Duration:
Frequency of visits (average):
— Observation of resistant relatives
— Observation of resistant insects
— Control of volunteers (specify intervals and duration)
— Monitoring of gene flow (specify)
— Appropriate chemical treatment^) and/or soil treatments)
— Others (specify)

— Monitoring measures of adjacent areas
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 treatments) and/or soil treatments)
— Others (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 (+) part B need to be specified in detail.
No effects were observed other than conventional maize

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.

In these periods visual monitoring was made in accordance with the authorization

and no unexpected effects occurred.

In this section will be specified:

6.4. Observed effect(s)

6.4.1. Explanatory note

All results of the deliberate rclcasc(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, arc provided hcrcundcr. 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.irc.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. Notificrs should supply data from the deliberate rclcasc(s) which validate the assumptions made in the environmental risk assessment.

Corn hybrid tested behaved in agronomic as expected and were not identified adverse environmental impacts.

6.4.3. Unexpected effect(s)

'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 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.

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 rclcasc(s) and, where appropriate, make reference to any kind of product the notifier intends to notify at a later stage.

During the deliberate release into the environment was not revealed any adverse effect on human health or on the environment and the behavior of the corn hybrid 6981 phenotype was similar to that of conventional corn.
The information provided in this report is not considered confidential

03.12.2014

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