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/ES/13/10

1.2 Member State of notification: Spain

1.3 Date of consent and consent number: 15/April/2013 Aragón.

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*

3.2 Transformation event(s) (acronym(s) or vectors[1] used (if transformation event identity not available): pAG3541 – 1 transformation event, VCO-Ø1981-5.

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

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

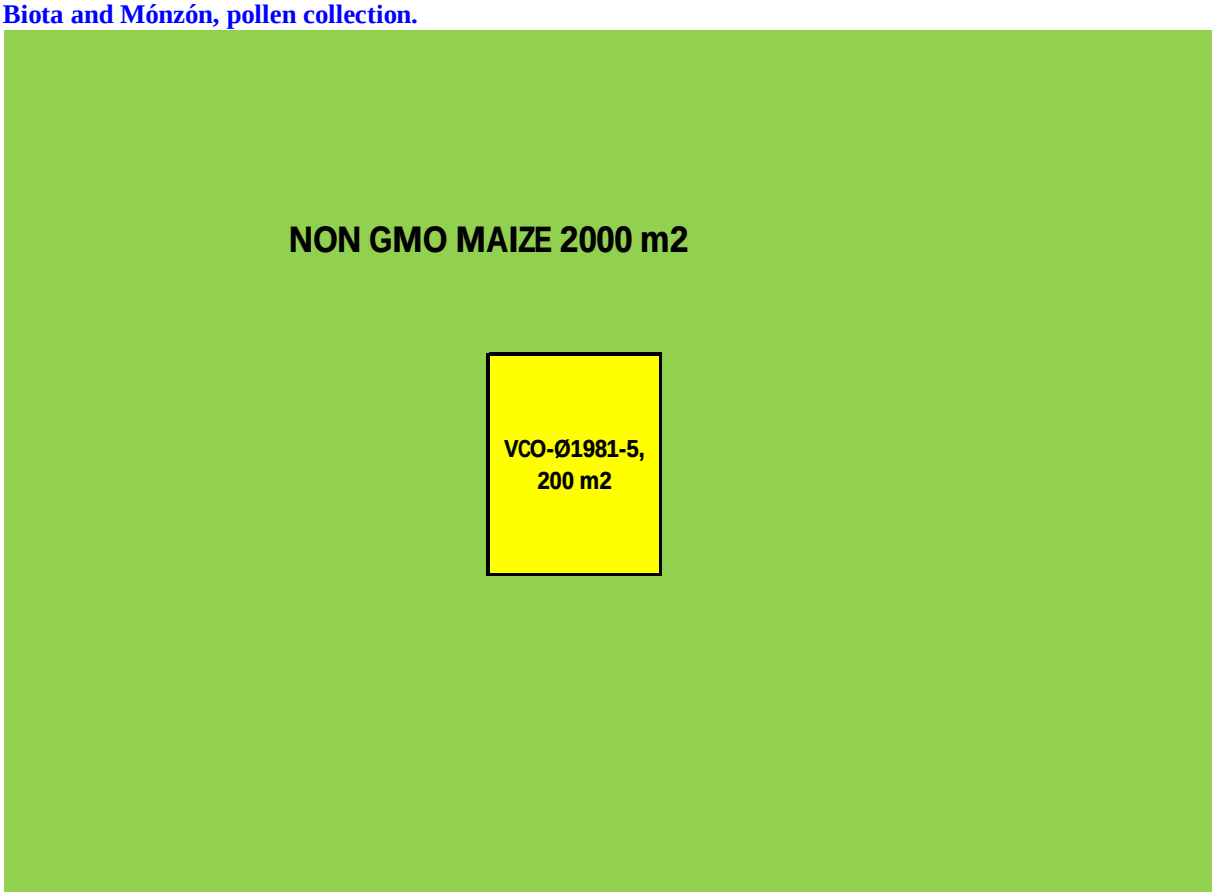
[1] In the case of small-scale field trials where several lines may be tested, the vectors used should be mentioned, which gives insight into the introduced traits and/or genetic elements. In the case of large-scale trials, the number of events notified is limited to only one or a few events.

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)
Biota, Zaragoza	**2.000m2 used, 200 m2 of GMO plants**	**VCO-Ø1981-5 1.400 GMO plants**	**23/May/2013 sowing 13/Nov/2013 harvest**
Monzón, Huesca	**1.325m2 used, 715 m2 of GMO plants**	**VCO-Ø1981-5 5.440 GMO plants**	**5/June/2013 sowing 26/Nov/2013 harvest**

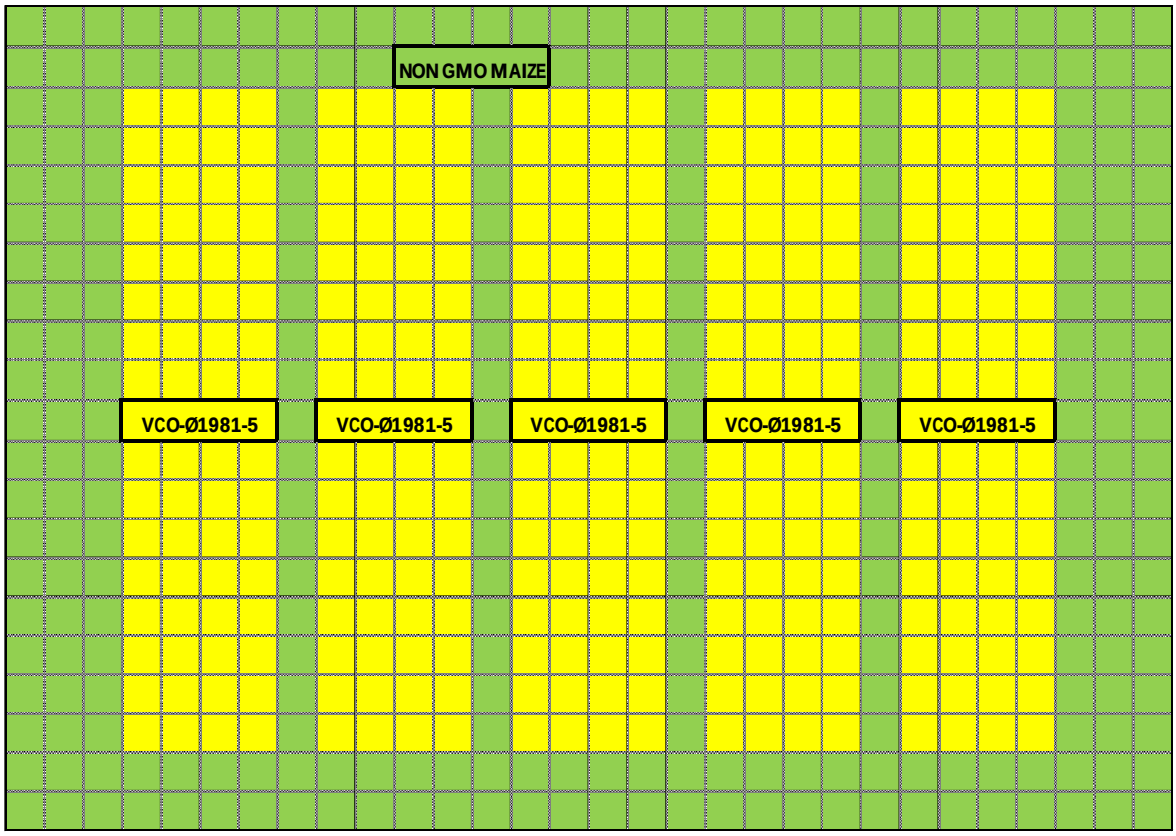
In all cases 8 rows of non GMO maize of similar cycle was sown in the laterals of the trial. At the beginning and end of the trial a plot 6.5 meters long of non GMO maize of similar cycle is sown.

([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

Biota and Mónzón, pollen collection.



Monzón, pure line trial



4 Any kind of product that the notifier intends to notify at 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?

4.2 ☐ **Yes** ■ **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 use (or processing for pharmaceutical use).

- Processing for pour.

    - 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). X

- 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].

[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-synthesised pharmaceuticals, plant-made pharceuticals, plant-based proteins production, etc.

- 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.

- 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 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 (distinct from other seeds/tubers/etc.) (describe).
  The GMO seeds were placed in individual envelops of 30 or 50 seeds, each envelop labeled with the corresponding transformation event codeVCO-Ø1981-5 and the name of the experimental variety.
- 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 envelops were placed, in the sowing order in cardboard boxes then in a polypropylene bag, sealed before transport. The seeds preparation was done in the Laboratory of Limagrain in France. Transport was made in a Limagrain car by persons aware of the nature of the seeds and that have received training in GMO handling.
- Destruction of superfluous seeds/planting material (describe the method involved).
  After sowing, the remaining seeds were destroyed in the release site by deep burying. The planter was carefully cleaned on the experimental field (in the borders).
- Temporal isolation (specify).
  No temporal isolation.

- Rotation (specify the previous crop).
  Biota: cereal wheat
  Monzón: ray-grass

- Other(s): (specify) .....

6.1.2 During the sowing/planting activities:

- Method of sowing/planting.
  Planting was using a sowing machine for experimental trials. A system of auto cleaning sends the remaining seeds in a container where the seeds are collected.

- Emptying and cleaning of the sowing machinery on the field of release.
  The sowing machine was cleaned on the release site; remaining seeds were collected by an aspiration system after opening the sowing elements.

- Segregation during the sowing (provide example of containment to prevent spillage during the sowing/planting).
  Each bag of seeds was open only on the release site; after control of the label and of the position of the plot (using a map/design of the assay), the seeds were poured into the sowing elements.

- Other(s): (specify)

6.1.3 During the period of release:

- Isolation distance (x meters)

  - From sexually compatible commercial plant species.
  - **Biota: 574 m from maize**
  - **Monzón : 260 m from maize**

  - From sexually compatible wild relatives.

  Maize has no wild relatives in Spain

- 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 GM maize.

- Cage/net/fence/signpost (specify).
  No
- Pollen trap (specify).
  No
- Removal of GM inflorescences before flowering (indicate the frequency of removal).
  No
- Removal of bolters/relatives/hybrid partners (indicate the frecuency of the removal, x metres around the GM field, etc).
  No

- 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). **Before pollen emission some tassels were covered with paper bags labeled with the event name and genotype name, after pollen emission the bags were carefully removed to collect the pollen that was placed in paper bags (two bags) labeled and transported to Limagrain Laboratory in France by trained personal of Limagrain in a Limagrain car.**

- Harvest / destruction before the ripeness of the seeds.

Grain harvest is done by a combine. Later the grain is recovered from the machine and buried in the liberation site in presence of technicians from the "Comunidad Autónoma" that is the Local Competent Authority.

- Effective removal of plant parts.

Chopping of the plant parts and bury in the liberation site.

- Segregated storage and transport of crop/waste (provide examples of containment to prevent spillage of collected seeds/crops/wastes).
  No grain was collected at harvest in this experiment.

- Clean up of machinery on the release site.
  The combine is cleaned of rests of grain and other plant material in the liberation site, the residues are buried in place.

- Destination of the waste, treatment of waste/ surplus yield/plant residues (describe).
  Buried on the experimental release site.
- 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).
  Soil preparation for next crop that is not maize.

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) **Monthly**.

- Subsequent crop (specify).

Biota: cereal, barley already sown.
Monzón: raygrass, sowing due on this time

- Crop rotation (specify).

- Fallow/no crop (specify).
- Superficial soil work / no deep ploughing.
- False-sowing beds.
- Control of volunteers (specify intervals and duration).
- Appropriate chemical treatment(s) (specify).
- Appropriate soil treatment(s) (specify).
- Other(s) (specify)

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

The monthly visits make sure there is no re-grown of maize. Not found till now.

6.1.7 Emergency plan(s).

Indicate:

a) If the release proceeded as planned:
- **Yes X**
- No (describe for which reason, e.g. vandalism, climatic conditions, etc.) **No incidence to report**

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 X**
- 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 monitoring plan post-release goes on. The monthly visits have nothing to report till now.

- **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

  Duration: **one year**

  Frequency of visits (average): **monthly**

  - Observation of resistant relatives.
  - Observation of resistant insects.
  - Control of volunteers (specify intervals and duration).
    Control of volunteers for one year monthly, nothing to report till now.
  - Monitoring of gene flow (specify).
  - Appropriate chemical treatment(s) and/or soil treatment(s).
  - Others (specify).

- Monitoring measures of adjacent areas:

  Duration: **One year, at the same time of the visits to the release site, to date no incidence or re-growth to report in the adjacent plots.**

  Frequency of visits (average): **monthly**

  Area monitored:

  - Observation of resistant relatives.
  - Observation of resistant insects.
  - **Control of volunteers X**
    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.
During the field trial observations made do not lead to change the conclusions of the risk assessment made in the application. No changes were found, as compared to conventional maize in terms of persistence or invasiveness, advantages, potential of transfer of genetic material, or biological interactions, etc. The only difference found was the tolerance to the herbicide glyphosate which is the trait introduced into these transgenic maize plants.

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).
Nothing has been detected in effects over the human health or environment, different to the effects related to a normal maize cultivation in the relative to agriculture land preparation, etc.
No unexpected or unintended effect to report.

[4] Summary notification information format (=SNIF)

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.
Nothing could be detected in relation to biodiversity in general different to what can happen with a normal non GMO maize cultivation.

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.

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.
Nothing could be detected in relation to biodiversity in general different to what can happen with a normal non GMO maize cultivation.

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

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

appropriate, make reference to any kind of product the notifier intends to notify at a later stage.

DATE: **Elorz 5 December 2013.**

Enrique Sánchez-Monge