**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**

**(COMMISSION DECISION 2003/701/EC)**

*LOGO OF THE COMPANY OR RESEARCH INSTITUTE (OPTIONAL)*

*The report format shall be completed by the notifier. The notifier shall fill in the report format according to the proposed form (tick boxes and/or, as far as possible, specific keywords to use in text fields). The notifier shall illustrate as much as possible the reported data by means of diagrams, figures and tables. Statistical data could also be provided where relevant.*

*In the case of multi-sites, multi-events and/or multi-annual release(s), the notifier shall provide a general overview of the measures taken and effects observed for the full duration of the consent.*

*The space provided after each item is not indicative of the depth of the information required for the purposes of this report.*

*1. General information*

1.1. European notification number: **B/ES/10/40**

1.2. Member State of notification: **SPAIN**

1.3. Date of consent and consent number**.**

**Consent number 00777/2010 may 12th of 2010, from Director General de Medio Ambiente y del Agua del Gobierno de Navarra.**

*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, Cultivar (A188 X B73)**

3.2. Transformation event(s) (acronym(s)) or vectors ([1]) used (if transformation event identity not available): **pAHC25-CAD-RNAi-NOS**

3.3. Unique identifier, if available:.....**No applicable.....**.

([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(r)-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.

| | | | |
|---|---|---|---|
| BORDER (W T) | | | |
| | | | |
| Border ( WT) | WT | CAD-RNAi-1 | Border (WT) |
| | | | |
| Border ( WT) | CAD-RNAi-1 | WT | Border (WT) |
| | | | |
| Border ( WT) | WT | CAD-RNAi-1 | Border (WT) |
| | | | |
| BORDER (WT) | | | |

| 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)) |
|---|---|---|---|
| **Trial field of (ITGA) Located in Santesteban (Navarra)** | **Total 206.8$m^2$: 47.04 $m^2$ + 159.76 $m^2$ of no –MG border** | **Total 480 plants: 72 WT plants and 72 CAD-RNAi-1 plants and 336 border plants (WT)** | **From 05/07/2010 to 13/10/2010** |

([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.

*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 **X No** ☐ 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

  — 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 **X**

5.2. Deliberate release(t) for development purposes: **Not Applicable**

— 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: .....(describe).....

5.3. Official testing **Not Applicable**

— Variety registration on a national variety catalogue

  — DUS (**D**istinctness, **U**niformity and **S**tability)

  — VCU (**V**alue of **C**ultivation and **U**se)

— Others: (specify).....

5.4. Herbicide authorisation **Not applicable**

5.5. Deliberate release(s) for demonstration purposes **Not applicable**

5.6. Seeds multiplication **Not applicable**

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([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 pharmaceuticals, plant-based proteins production, etc.

5.7. Deliberate release(s) for biosafety/risk assessment research **Not applicable**

— 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) types) of deliberate release(s): **Not applicable**

(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)**

**It has not been necessary to apply any risk-management measures. Everything happened as expected.**

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/planting material lots (distinct from other seeds/tubers/etc.) (describe)

**All maize seedlings used for field planting (WT and OMG line) were transported in individual trays, well labelled in both sides (in and outside)**

— 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)

**All the maize plants material was transported to the field in Iden Biotechnology vehicle.**

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

**The superfluous planting materials (tassels…) were transported back to the laboratory and were destroyed by autoclaving**.

— Temporal isolation (specify)

**Not applicable**

— Rotation (specify the previous crop(s))

**In the previous year (2009) was a prairie.**

— Other(s): (specify).. **Not applicable**.....

**6.1.2.** During the sowing/planting activities**:**

— Method of sowing/planting

**Planting of maize seedling was manually.**

— Emptying and cleaning of the sowing/planting machinery on the field of release

**Not Applicable**

— Segregation during the sowing/planting (provide example(s) of containment to prevent spillage during the sowing/planting)

**Not Applicable**

— Other(s) (specify)..

**Not Applicable**

6.1.3. During the period of release:

— Isolation distance(s) (x metres)

— from sexually compatible commercial plant species,

**The distance from other maize plants growing in the same experimental area was at least 160 m as it was required in the resolution document.**

— from sexually compatible wild relatives.

**Not Applicable. There are not compatible wild type plants.**

— Border row(s) (with the same crop or a different one, with a non-transgenic crop, x metres, etc.)

**The distance between lines was 0.9 m, and between plants of the same lines was 0.3 m. In addition there were some physical barriers between the field trial and other maize plants like for example buildings, other crops and fences.**

— Cage/net/fence/signpost (specify)

**Each repetition was marked by using wooden sticks.**

**Each experimental unit was indicated by signpost well labelled with the date, name of each line (WT, pAHC25-CAD-RNAi-1)**

— Pollen trap (specify)

**Not Applicable**

— Removal of GM inflorescences before flowering (indicate the frequency of the removal)

**Inflorescences from all maize plants (WT and GM) were removed once merged before flowering stage.**

— Removal of bolters/relatives/hybrid partners (indicate the frequency of the removal, x metres around the GM field, etc.)

**Not Applicable**

— Other(s): (specify):

**Not Applicable**

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) Harvest /destruction before the ripeness of the seeds.**

**Harvest was done manually; whole maize plants including leaves, stems, tassels, of WT and GM were harvested in individual bags well labelled from both sides of the bag, and well sealed. A total of 12 bags (2 per line X 2 lines (WT + 1 OMG) X 3 repetitions) were used.**

**All the rest of plant material and waste that had not been used, were collected in autoclaving bags and were destroyed by autoclaving the next day of harvest.**

**Harvest/ destruction befor the ripeness of the seeds.**

**Not Applicable**

— Effective removal of plant parts

— **Not Applicable**

— Segregated storage and transport of crop/waste (provide example(s) of containment to prevent spillage of collected seeds/crops/wastes)

— All plants material harvest (stems, leaves, tassels) well labelled, were transported by ITGA vehicle to the Iden Biotecnology laboratory, stored in stove at 70 C for further analysis and characterization

All the rest of plant material and waste that had not been used, were collected in autoclaving bags and were destroyed by autoclaving the next day of harvest.

— Clean up of machinery on the release site

**Not Applicable**

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

**All the waste regenerated during the harvest, was destroyed by autoclaving the next day of harvest.**

— 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)

**No treatments were necessary as the whole maize plants were harvested.**

— Other(s): (describe).....

**On October 13th of 2010, after harvest the field were cleaned up and all the waste collected in autoclaving bags were destroyed by autoclaving, in Iden Biotechnology laboratory**.

6.1.5. Post-harvest measures

Please indicate which measures were taken on the release site after the harvest:

Frequency of visits (average):..

Weekly by the technician of experimental field (ITGA)

— Subsequent crop (specify)

**Prairie**

— Crop rotation (specify)

**Prairie only**

— Fallow/no crop (specify)

**Not Applicable**

— Superficial soil work/no deep ploughing

**Pass of Rotavator**

— False-sowing beds

**Not Applicable**

— Control of volunteers (specify intervals and duration)

**Every week, staff from experimental field (ITGA) will control if there is any maize seedling germinating in the field. In case this happens, we will be informed and we will proceed to destroy the plant material by autoclaving.**

— Appropriate chemical treatment(s) (specify)

**Not applicable**

— Appropriate soil treatment(s) (specify)

**Not Applicable**

— Others (specify)

**Not Applicable**

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

**Not Applicable**

Emergency plan(s**)**

Indicate: **Not Applicable**

(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 plans) (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 week after harvest**

— 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.

**Maize propagation is sexual and therefore we eliminated all the inflorescences and tassels of both (WT and GM maize plants) in order to prevent pollen and viable grain production. The only post release monitoring will be the control of maize sprouting although we do not expect much sprouting as the field was cleaned after harvest.**

Specify:

— Monitoring measures within site

**Duration: from October 2010 to May 2011**

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

— Observation of resistant relatives. **Not Applicable**

— Observation of resistant insects. **Not Applicable**

— Control of volunteers (specify intervals and duration).

**Every week ITGA staff will control if any maize seedling are growing, once we get informed we will proceed and destroy the material by autoclaving.**

— Monitoring of gene flow (specify). **Not applicable**

— Appropriate chemical treatment(s) and/or soil treatment(s). **Not Applicable**

— Others (specify). **Not Applicable**

— Monitoring measures of adjacent areas.

**Not Applicable, as the possibility of pollen production and viable seed production was eliminated.**

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)/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 ([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.

**We have not observed any adverse effect of the GM on weeds seeds either pest. All the weeds and pest detected were the typical ones that affected in the same way both the control and the GM plants.**

**We have not observed any effect of the GM on human health. No person handling the material (stems and leaves ) had any symptom (no allergy). In the same way, we have not observed any effect of the GM on animal health.**

6.4. Observed effect(s)

6.5. 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.

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([4]) Summary notification information format (= SNIF).

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 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.jrc.it.

**As we have already mentioned, no effect of GM plants was detected on environment neither on human health during the growing and harvesting period.**

6.5.1. Expected effect(s)

**No effects were observed.**

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.

6.5.2. Unexpected effects ([5])

**We have not observed any unexpected effect. Nevertheless, we will keep on monitoring the possible effect of the GM plants released on 2010 to confirm that they do not have any effects on growth and development of the next cultivated plant in the same field on 2011.**

'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.

6.5.3. 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.

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([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.

**Taking into account the results obtained in previous green house experiments and this field trial we can conclude that.**

1. **Morphologically we did not observe any differences between control plants (growing both in the border and in the experimental field) and GM ones, with the exception that transgenic maize has shown some chlorotic spots in their leaves.**
2. **We did not observe any effects of the GM plants on environment, human health and animal health. The effect of weeds and pests was the same in both control (WT) and transgenic lines (GM). The handling of the GM did not affected human health.**

**Date** **Pamplona, November 4th, 2010**

*The information provided in this report is not considered confidential in accordance with Article 25 of Directive 2001/18/EC. This does not prevent the competent authority from requiring additional information from the notifier, both confidential and non-confidential. In the case of confidential data, it should be provided in an Annex to the report format, with a non-confidential summary or general description of these data, which will be made available to the public.*