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/07/32**
1.2	Member State of notification: ……**Spain**
1.3	Date of consent and consent number: **Aragón: 30/3/2007; Cataluña: 10/5/2007**
2.	**Report status**
2.1	Please indicate whether, according to Article 3 of the present Decision, the current report is

– ☒ The final report **for 2007 cultivation**

– A post-release monitoring report

  – ? Final ? Intermediary

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) …….. **GA21** ……..
3.3	Unique identifier, if available: **MON-00021-9**……..

[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) lay-out:

Geographical location(s) (administrative region and, where appropriate, grid reference)	**Size of the release site(s)**[2]	**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)*……)
Tamarite de Litera-24 (Huesca):	**4000 m²**	**~ 7 plants/m²**	**27/04/07 – 24/09/07**
Tamarite de Litera-14 (Huesca):	**4000 m²**	**~ 7 plants/m²**	**27/04/07 – 23/09/07**
Barbens (Lleida)	**2500 m²**	**~ 7 plants/m²**	**24/05/07 – 24/10/07**
Bellpuig (Lleida)	**2500 m²**	**~ 7 plants/m²**	**29/05/07 – 25/10/07**
Gurb (Barcelona)	**2500 m²**	**~ 7 plants/m²**	**25/05/07 – 26/10/07**
Lleida -110	**10000 m²**	**~ 7 plants/m²**	**26/05/07 – 27/10/07**
Lleida – 167	**7500 m²**	**~ 7 plants/m²**	**25/05/07 – 31/10/07**

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 ☐ Unknown to date

If yes, indicate the country(-ies) of notification : **U.K**.……..

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 sub-type(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 ☐

[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.

5.2	Deliberate release(s) for development purposes	☒

– Event screening
– Proof of concept[4]
☒ 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)
– Improved agronomic properties (e.g. disease/pest/drought/frost resistance, etc) (Specify)
– Improved qualitative properties (prolonged shelf-life, enhanced nutritional value, modified composition, etc) (Specify)
– Stability of the expression
– Multiplication of lines
– Hybrid vigour study
– Molecular farming[5]
– Phyto-remediation
– Others: ……..

5.3	Official testing	☐

– Variety registration on a national variety catalogue
  – DUS (= Distinctness Uniformity Stability)
  – 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	☐

– 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

Without prejudice to the specific environmental risk assessment as well as to the consent conditions, the notifier shall provide the following information **in respect of any effect for human health or the**

[4] E.g. testing the new trait under environmental conditions.

[5] '*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.

environment. 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.

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/planting material lots (distinct from other seeds/tubers/etc)
  Seeds were packed in small paper bags, which remained closed until planting. Each paper bag was clearly labelled with the test entry code comparable to the code in the protocol. Each small paper bag contained the seed for one plot.
  All the paper bags composing a trial were contained into a sealed and labelled box.

- ☒ 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)
  Seed were transported in a triple package and were managed in the trials by qualified staff. Transport of the seeds to the field was done on the day of planting.
- ☒ Destruction of superfluous seeds/planting material (Describe the method involved)
  All the prepared seeds were used for the planting, therefore there were no superfluous seeds.
- Temporal isolation (Specify)
- Rotation (Specify the previous crop(s))
- Other(s): (Specify) ……..

6.1.2 During the sowing/planting activities:

- ☒ Method of sowing/planting
  Sowing was carried out with a microplot field trial machine

- ☒ Emptying and cleaning of the sowing/planting machinery on the field of release
  All equipment used to seed was free of plant material before entering the trial site. After sowing, all the equipment used for planting was cleaned on the trial site to eliminate unintended transport of any seed or plant material from the trial site. The residual seed recovered during the process of cleaning were buried in the soil of the alley of the trial

- ☒ Segregation during the sowing/planting (Provide example(s) of containment to prevent spillage during the sowing/planting)
  The planting procedure with individual plot seed bags avoids seed mixing during the planting operation. After each individual plot sowing any seeds remaining in the micro-plot planter were sown at the end of the plot or the micro-plot planter recovers in a dedicated device all the seeds eventually non planted in each plot.

- Other(s): (Specify)……..

6.1.3 During the period of release:

- ☒ Isolation distance(s) (x metres) from sexually compatible plant species, both wild relatives and crops
  The field trials were at least 200m isolated from other maize fields

- ☒Border row(s) (with the same crop or a different one, with a non-transgenic crop, x metres, etc)
  At least eight border rows of conventional maize of a similar maturity surrounded the trials
- Cage/net/fence/signpost (Specify)
- ☒Pollen trap (Specify)
  The border of conventional maize is also a pollen trap. At the end of the release , these border rows were destroyed like the rest of the trials.

- Removal of GM inflorescences before flowering (Indicate the frequency of the removal)
- Removal of bolters/relatives/hybrid partners (Indicate the frequency of the removal, x metres around the GM field, etc*)*
- Other(s): (Specify) ……..

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 was done with an experimental combine, which provides data automatically on grain yield and moisture. The harvested grain remains contained inside the combine until the end of the operation.
  All the harvested grain not sampled was buried inside the trial area.
  All the remaining plant material after harvest was ploughed and incorporated into the soil.
- Harvest/destruction before the ripeness of the seeds
- Effective removal of plant parts
- Segregated storage and transport of crop/waste (Provide example(s) of containment to prevent spillage of collected seeds/crops/wastes)
- ☒Clean up of machinery on the release site
  The combine and all the equipment used for harvesting and plant material destruction were cleaned before leaving the field trial area.

- ☒Destination of the waste, treatment of waste/surplus yield/plant residues (Describe)
  All the remaining plant material after harvest was ploughed and incorporated into the soil.

- ☒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)
  Field trial area was chopped several times to destroy the plant material and ploughed to incorporate the remaining plant material into the soil.
  Conventional soil cultural practices in the area were followed after the trial termination.
- Other(s): (Describe)……..

6.1.5 Post-harvest measures

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

I. ☒Frequency of visits (average) : **Approximately every two months**
- ☒ Subsequent crop (Specify) :
  Commercial maize will not be grown on the trial sites in 2008
- ☒ Crop rotation (Specify)
  Commercial maize will not be grown on the trial sites in 2008
- Fallow / no crop (Specify)
- Superficial soil work/no deep ploughing
- False-sowing beds
- ☒Removal of volunteers (Specify intervals and duration)
  Specific monitoring will be implemented along the following year. Any volunteer maize appearing in the field will be eliminated before flowering. Specific monitoring

will be done within the comprised period between soil preparation for planting and pre-flowering time (from end of March to end of July)

- Appropriate chemical treatment(s) (Specify)
- Appropriate soil treatment(s) (Specify)
- Others (Please specify)

6.1.6 Other(s) measure(s): (Describe)

6.1.7 Emergency plan(s)

Indicate

I. if the release proceeded as planned

- ☒ Yes
- No (Describe for which reason? E.g. Vandalism, climatic conditions, etc) :…….

I. 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):……..

I.1 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 afore-mentioned 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: **1 year since field trial harvesting.**
  Frequency of visits (average): **Approximately one visit every two months.**
  - Observation of resistant relatives N/A
  - Observation of resistant insects N/A
  - Removal of volunteers (specify intervals and duration) **at regular visits, special focus from end of March to end of July)**
  - Monitoring of gene flow (specify) N/A
  - Appropriate chemical treatment(s) and/or soil treatment(s) N/A
  - Others (Specify) N/A
- Monitoring measures of adjacent areas N/A

  Duration:
  Frequency of visits (average):
  Area monitored:

- Observation of resistant relatives
- Observation of resistant insects
- Removal of volunteers (specify intervals and duration)
- Monitoring of gene flow (specify)
- Appropriate chemical treatment(s) and/or soil treatment(s)
- Others (please specify)

I.1 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[6] Part B need to be specified in detail.

Direct monitoring on trial sites will record any unexpected or unusual event.

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.

6.4 Observed effect(s)

6.4.1 Explanatory note

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

Expected effect(s)

The potential effects, which were already identified in the environmental risk assessment of the notification and could therefore be anticipated shall be addressed under this section.

Notifiers should supply data from the deliberate release(s) which validate the assumptions made in the environmental risk assessment.

The GA21 maize hybrids have developed following good agronomic characteristics and their tolerance to glyphosate has been confirmed.

[6] Summary Notification Information Format (= SNIF)

Unexpected effect(s)[7]

'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 effect have been detected.

No adverse effect on human health or environment has been 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.

I. 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.

The trials proceed as planned and no unexpected effects or observation were detected. Therefore the outcome of the risk assessment remains unchanged as a result of these trials.

DATE : January, 03, 2008

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