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/05/13
1.2 Member State of notification: Spain
1.3 Date of consent and consent number: 29/06/2005

2. REPORT STATUS

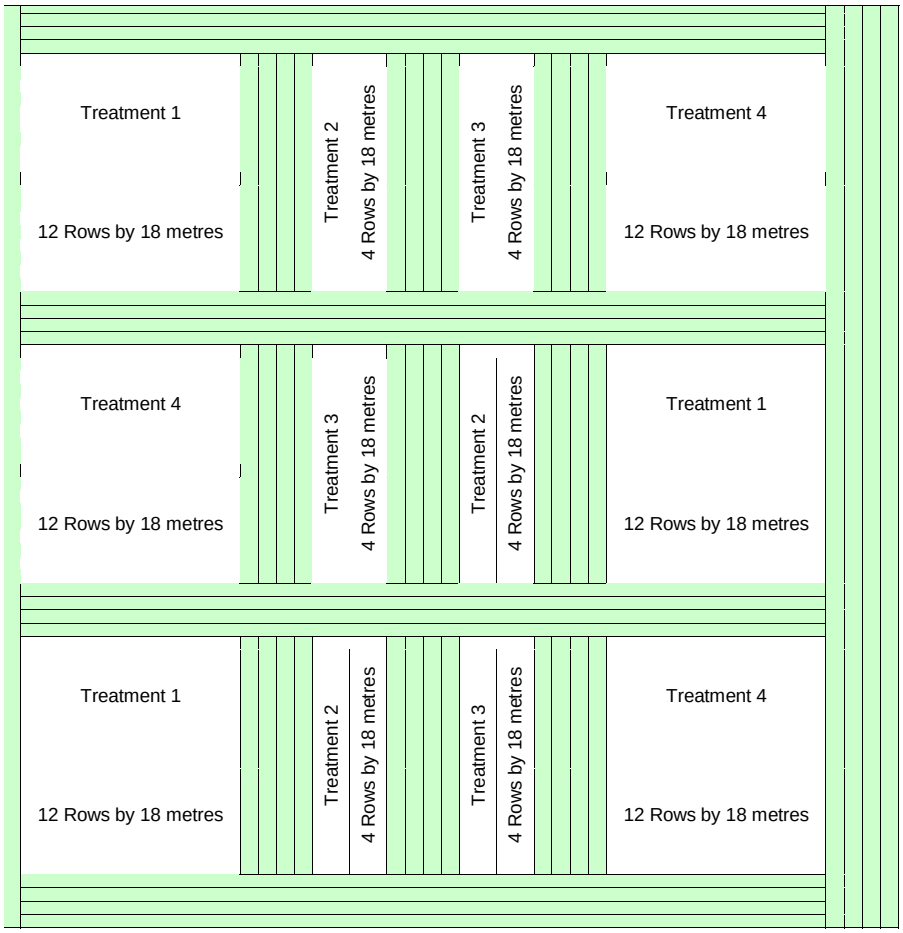
2.1 Please indicate whether, according to Article 3 of the present Decision, the current report is :
√ the final report
- a post-release monitoring report
- final - intermediary

3. CHARACTERISTICS OF THE RELEASE

3.1 Scientific name of the recipient organism: Gossipium hirsutum
3.2 Transformation event(s) (acronym(s) or vectors1 used (if transformation event identity not available): 281-24-236/3006-210-23 cotton
3.3 Unique identifier, if available: DAS-24236-5XDAS-21023-5
3.4 Please provide the following information as well as the field(s) layout :
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)** (m^2)	**Identity and approximate number of GM higher plants per event actually released**	**Duration of the releases**
Término Municipal: L'Aldea (TARRAGONA) **Polígono: 3** **Parcela: 1**	10.000 m2	(PSC355-no MG: 9300 semillas) MXB-9 cry1F evento: 3100 semillas MXB-7 cry1Ac evento 3100 semillas cry1F/cry1Ac evento (Widestrike): 9300 semillas.	From: 27/07/05 Until: 02/12/2005

See trial design below



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:

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):

3

5.1 Deliberate release(s) for research purposes ☒

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. 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 farming3
- 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

[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.

- 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)

Seeds were packed in triple bags which are closed until planting. Each bag was clearly labeled..

☒ - 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 stored and transported separate from other seeds. Only seed needed for starting the trial were transported on that way to the field.

☒ - Destruction of superfluous seeds/planting material (describe the method involved).

Seeds from each bag were counted before seeding, remaining seeds were buried.

☐ - Temporal isolation (specify)

☐ - Rotation (specify the previous crop)

☐ - Other(s) : (specify) .....

6.1.2 During the sowing/planting activities:

☒ - Method of sowing/planting (describe)

Seeds were planted with a standard sowing machine which allows an easy cleaning of the remaining seeds.

☒ - Emptying and cleaning of the sowing machinery on the field of release.

At the end of the individual plot sowing, the remaining seeds in the machine (if any) were buried at the end of the plot.

☒ - Segregation during the sowing (provide example of containment to prevent spillage during the sowing/planting).

The seed bags had the required seeds.

☐ Other(s): (specify)

All personnel involved with the trials have been trained to prevent involuntary release/spillage.

6.1.3 During the period of release:

☒ - Isolation distance (x meters)

From sexually compatible commercial plant species – more than 60 m from non-experimental cotton.

From sexually compatible wild relatives

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

Four border rows were seeded around the whole trial with a non-transgenic commercially available hybrid of similar relative maturity as a pollen trap. At the end of the release, these rows were destroyed and treated as transgenic plants.

☐ - Cage/net/fence/signpost (specify)

☐ - Pollen trap (specify)

☐ - 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)
The plants were chopped and ploughed.
☐ - 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)
None of the seeds or plant parts were moved outside the trial site.
☒ - Clean up of machinery on the release site.
All the machinery used was cleaned on the release site.
☒ - Destination of the waste, treatment of waste/ surplus yield/plant residues (describe)
Waste plants were discarded at the trial area for naturally composting.
☒ - 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)
Trials area has been turned over in autumn and the plant material as chopped and buried
☐ - 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) Aproximately every two months
☒ - Subsequent crop (specify)
The following crop will be any crop different from commercial cotton
☒ - Crop rotation (specify)
The following year will be any crop different from commercial cotton
☐ - Fallow/no crop (specify)
☐ - Superficial soil work / no deep ploughing
☐ - False-sowing beds
☐ - Control of volunteers (specify intervals and duration).
The release site will be visited several times after the trial destruction to confirm that the farmer will not sow commercial cotton on that site and to control potential volunteer plants. If needed, any undesired plant emerged would be mechanically destroyed or by using herbicides (other than glyphosate).
☐ - 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:
☒ 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

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 postrelease monitoring report),
- **The post-release monitoring plan has been completed** (in the case of the final postrelease 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.

The destruction of the trial took place on December the 2nd. The post-release monitoring plan is on going. Until December 2006 the trial site will be visited regularly in order to check the presence of volunteers. Volunteers would be controlled by mechanical means herbicide treatment (other than glufosinate ammonium). There were not volunteers in the trial site so far.

Specify:

 Monitoring measures within site

Duration: from December 2005 to October 2006

Frequency of visits (average): approximately every two months

Observation of resistant relatives

Observation of resistant insects

Control of volunteers (specify intervals and duration) Regular visits, more frequent if some volunteers are detected.

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 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.
The observations were and will be done visually.

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).
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.

The environment risk assessment has not identified any risk for the human health or the environment as a result of the release into the environment of 281-24-236/3006-210-23 cotton. The 281-24-236/3006-210-23 cotton plants have developed normally, in a comparable way with the non GM near isogenic line. No environment problems were detected in the trial

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 abservations, tis section should be as detailed as possible to allow a proper interpretation of the data.

Is has been observed a poor germination in both 281-24-236/3006-210-23 cotton and non-GM cotton probably due to the late planting date and high temperatures.

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 else to report

[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.

The trials have been carried out in the predicted manner. No negative effects to human health or the environment have been observed. 281-24-236/3006-210-23 cotton plants have grown as expected.