Bayer CropScience
BioScience

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/11/12**

**1.2 Member State of notification: Spain**

**1.3 Date of consent and consent number: 04/04/2011, B/ES/11/12**

## 2. Report status

**2.1 Please indicate whether, according to Article 3 of the present Decision, the current report is:**

- Final Report X
- A post-release monitoring report
  - Final
  - Intermediary

## 3. Characteristics of the release

**3.1 Scientific name of the recipient organism:**

***Gossypium hirsutum***

Bayer CropScience
BioScience

| 3.2 | Transformation event(s) (acronym(s)) or vectors[1] used (if transformation event identity not available)) |
|---|---|

T304-40

| 3.3 | Unique identifier, if available: |
|---|---|

| 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] (m²)** The event T304-40 has been sown, together with other notified events, in the followings locations and with the following total surfaces. | **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)*……) |
|---|---|---|---|
| **-Sevilla**<br>**Termino municipal:**<br>**Dos Hermanas** | **Total surface: m²2150**<br>**T304-40 plots size:**<br>**Protein expression:**<br>**3x4 rows x 0.95 m width and 5.0 m length** | **20 seeds/m²** | **From 13.05.11 until 02.11.11** |
| **-Sevilla**<br>**Termino municipal:**<br>**Brenes** | **Total surface: m²4500**<br>**T304-40 plots size:**<br>**Protein expression:**<br>**3x4 rows x 0.95 m width and 5.0 m length**<br>**Efficacy**<br>**4x4 rows x 0.95 m width and 10.0 m length** | **20 seeds/m²** | **From 13.05.11 until 02.11.11** |

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.

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.

| 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? |
|---|---|

X Yes ☐ No ☐ Unknown to date

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

If yes, specify for which use(s):

- Import X
- Cultivation (e.g. Seed/planting material production)
- Food X
- Feed X
- Pharmaceutical use (or processing for pharmaceutical use)
- Processing for:
  - Food use X
  - Feed use X
  - Industrial use X
- 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 | ☐ |
|---|---|---|

| 5.2 | **Deliberate release(s) for development purposes** | X |
|---|---|---|

– 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):

– Altered agronomic properties (e.g. disease/pest/drought/frost resistance, etc) (Specify)

**Evaluation of the efficacy against Lepidoptera insect pests**

– Altered qualitative properties (prolonged shelf-life, enhanced nutritional value, modified composition, etc) (Specify)

**Protein Expression Study for the evaluation of the new protein in different parts of the plant cultivated under open field conditions.**

– Evaluation of the new expressed protein in different parts of the plant under open field conditions

– Stability of the expression

– Multiplication of lines

– Hybrid vigour study

– Molecular farming[5]

– Phyto-remediation

– Others: (Describe)……..

| 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** | ☐ |
|---|---|---|

[4] For example, 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-besed proteins production, etc.

| | | |
|---|---|---|
| **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 organism** **X**
- **Potential effects on non-target organism**
- **Observations of resistant relatives**
- **Observations of resistant insects**
- **Others: (Describe)** **Protein Expression**

| | | |
|---|---|---|
| **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/planting material lots (distinct from other seeds/tubers/etc) (Describe) **X**

**Seeds were packed in double bags which were closed until sowing. The seed sacks were clearly labelled as containing GM material.**

– 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). **X**

**Seed were stored and transported separate from other no GM seeds. These were securely sealed to ensure containment during transport to the trial site. Only the necessary number of seeds has been transported to the field trials**

– Destruction of superfluous seeds/planting material (Describe the method involved) **X**

**The seeds have been weighted before and after the planting, the sowing machine was calibrated and all remaining have been sent to BayerBioScience N.V. for disposal**.

– Temporal isolation (Specify)

– Rotation (Specify the previous crop(s) **X**

| Province | Village | Previous Crop |
|---|---|---|
| Sevilla | Dos Hermanas | Sorghum |
| Sevilla | Brenes | Wheat/Barley |

– Other(s): (Specify)

*6.1.2 During the sowing/planting activities:*

– Method of sowing/planting. **X**

**Seed drilling machinery**

– Emptying and cleaning of the sowing/planting machinery on the field of release. **X**

**At the end of the individual plot sowing, the remaining seeds in the machine (if any) were collected and destroyed, other remaining seeds have been sent back to Bayer BioScience N.V.**

– Segregation during the sowing/planting (Provide example(s) of containment to prevent spillage during the sowing/planting).

– Other(s): (Specify) **X**

**All people involved with the trials have been trained to prevent involuntary release/spillage. The access to the trials was limited only to authorized people.**

*6.1.3 During the period of release:*

– Isolation distance(s) (x metres) **X**

  – from sexually compatible commercial plant species:

    **more than 200m from non-experimental cotton,**

  – from sexually compatible wild relatives

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

– **Eight rows x 0.95 m around the whole trial were drilled with non-transgenic cotton**

– Cage/net/fence/signpost (Specify)

– Pollen trap (Specify) **X**

**Eight border rows x 0.95 m, were drilled around the whole trial with non-transgenic cotton as a pollen trap**

– 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):……...……..

*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): **X**

**All the harvested has been made by hand. Once the harvest was finished, all vegetable materials have been destroyed chemically and mechanically (cutting and ploughing).**

– Harvest/destruction before the ripeness of the seeds.

– Effective removal of plant parts. **X**

**Yes, by chopping, and ploughing (as described above)**

– Segregated storage and transport of crop/waste (Provide example(s) of containment to prevent spillage of collected seeds/crops/wastes) **X**

**None of the plants or plants part, after harvest, have been transported outside the authorized field trials**

– Clean up of machinery on the release site. **X**

**Yes, machinery thoroughly cleaned.**

– Destination of the waste, treatment of waste/surplus yield/plant residues (Describe). **X**

**The plant residues have been chemically and mechanically destroyed, and incorporated into the soil by ploughing.**

– 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). **X**

**All the fields have been ploughed.**

– Other(s): (Describe)……

*6.1.5 Post-harvest measures*

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

– Frequency of visits (average): **X**

**Approximately every month.**

– Subsequent crop (Specify): **X**

**Any other crop than cotton**

– Crop rotation (Specify) **X**

**Any other crop than cotton.**

– Fallow / no crop (Specify))

– Superficial soil work / no deep ploughing

– False sowing beds

– Control of volunteers (Specify intervals and duration) : **X**

**The release sites will be visited several times after the trial destruction to confirm that the farmer will not drill 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 glufosinate).**

– Appropriate chemical treatment(s) (Specify):

– Appropriate soil treatment(s) (Specify) **X**

**Herbicide application**

– Others (Please specify)

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

*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):

b) If measures according to the emergency plan(s) (Article 6 (2) (a)(vi) and Annex IIIB of Directive 2001/18EC) 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), **X**

– **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:

a) Monitoring measures within site

Duration:

**One year from the date of the destruction of the trial.**

Frequency of visits (average):

**Approximately every month**

– Observation of resistant relatives:
– Observation of resistant insects:
– Control of volunteers (specify interval and duration): **X**

**Regular visits, more frequent if volunteers will be detected.**

– Monitoring of gene flow (specify).
– Appropriate chemical treatment(s) and/or soil treatment(s)
– Others (Specify)

b) 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 population (specify intervals and duration)
– Monitoring of gene flow (specify)
– Appropriate chemical treatment(s) and/or soil treatment(s)
– Others (please 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[6] 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.

## 6.4 Observed effects

### *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 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

### *6.4.2 Expected effect(s)*

[6] Summary Notification Information Format (= SNIF)

'Expected effects' refer to 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 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 the T304-40 event.**

**No difference in growing or development has been detected with GM cotton in comparable way with the conventional cotton. No environment problems have been detected in the trials**

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

**No negative effects on human health and the environment have been observed.**

**Date: 21 December 2011**