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/04/12

1.2 Member State of notification : Spain

1.3 Date of consent and consent number : April 16th 2004

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): NK603

3.3 Unique identifier, if available : MON-ØØ6Ø3-6

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)
La Rinconada (Sevilla)	**Total surface of the trial : 2205 m^2 GM area : 254 m^2**	**Hybrids NK603: ~ 6 plants/m²**	**From 18/05/04 to 6/10/04**

([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

See the trial layout in Annex 1.

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 (notified by MONSANTO) ☐ 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)
- 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 : (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 relativesrésistantes

[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 small paper bags which are closed until planting. Each paper bag was clearly labeled with the test entry code comparable to the codes in the protocol.

☑ - 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).
Kernels of each paper bag were counted before seeding. All seeds were planted.

☐ - 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 two rows sowing machine which allows the cleaning of the remaining seeds and avoids any mixture of 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 sown at the end of the plot. That way, all the seeds intended to be planted in that plot, were planted in the surface limited for that purpose.

☑ - Segregation during the sowing (provide example of containment to prevent spillage during the sowing/planting).
Only two rows was planted by time and therefore only one kernel packet was open.

☑- Other(s) : (specify)
Nobody from another company got access to the trial seeds and all the seeds were sown in the field.

6.1.3 During the period of release :

☑ - Isolation distance (x meters)
From sexually compatible commercial plant species – more than 200 m from non-experimental maize.
~~- 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. The seed used as a border was a non-transgenic commercially available hybrid of similar relative maturity. At the end of the release, these rows were chopped like the rest of the trial.
☐ - 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 kernels were harvested, weighted and buried in a 2 meters-deep ditch. The rest of 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 ploughed in autumn and two kind of harrows were used to chop and bury the rest of the plants
☐ - 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 maize

☑ - Crop rotation (specify)
The following year will be any crop different from commercial maize

☐ - 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 at least three times after the trial destruction. As the main concern is being sure that the farmer will not sow commercial maize on that site, the visits will be done during the months close to the maize sowing time(mid-February, soil preparation; mid-May, maize sowing time), later at mid-June another visit will be done in order to check the control of volunteers. If needed, any undesired plant emerged would be destroyed by means of machines or by a herbicide treatment (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 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.

The destruction of the trial was made on October 6th 2004. The post-release monitoring plan is on going. Until October 2005 the trial site will be visited regularly in order to check the presence of volunteers. In that case, they would be controlled by means of machines or a herbicide treatment (other than glyphosate). There were not volunteers in the trial site so far. No commercial maize will be sown in that site during 2005

Specify :

☑- Monitoring measures within site
Duration : from October 2004 to October 2005
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[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.

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.

[4] Summary notification information format (=SNIF)

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 intentional relase of the genetically modified maize NK603. No environment problems were detected in this 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.

Neither damage nor any kind of negative effects on human health or environment 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.

Nothing

[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.

All the control measures were taken in order to avoid the pollen and kernels release from the genetically modified plants.
Neither damage nor any kind of negative effects on human health or environment were observed.

No risk for the human health or the environment has been identified as a result of the intentional release of the genetically modified maize in this trial.

The proposed measures in the notification and the control measures taken seem to be consistent with the aim of assuring the environment and human health safety.

DATE : 3rd February 2005

ANNEX 1: Diseño del ensayo