

REPORT ON RESULTS

Notification B/ES/04/20

Trials in the Autonomous Region of Aragon

(In accordance with Annex XI of RD 178/2004, of 30th January)

1. GENERAL INFORMATION

1.1 European notification number

B/ES/04/20

1.2 Member State of Notification

Spain

1.3 Date of consent and consent number

22nd March 2005 (number 64104)

2. REPORT STATUS

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

a **FINAL** post-release monitoring report

3. CHARACTERISTICS OF THE RELEASE

3.1 Scientific name of the recipient organism

Zea mays

3.2 Transformation events [acronym(s) or vector(s) used (if transformation event identity not available)]

NK603xMON810

3.3 Unique identifier, if available

MON-00603-6 x MON-00810-6

3.4 Please provide the following information, as well as the field(s) layout

Geographical location(s) (administrative region and, where appropriate, grid reference)	Size of the release site(s) (event NK603 x MON810 m2)	Identity and approximate number of GM higher plants per event actually released	Duration of the releases
Almudevar (Huesca)	20 m2 x 3 rep x 10 hybrids + 20 m2 x 3 rep x 3 hybrids = 780 m2	NK603 X MON810 hybrids ~7 plants /m2	Sowing: 3 May 2005 Destruction: 2 November 2005
Estadilla (Huesca)	10 m2 x 3 rep x 10 hybrids + 10 m2 x 3 rep x 3 hybrids = 390 m2	NK603 X MON810 hybrids ~7 plants /m2	Sowing: 25 April 2005 Destruction: 2 November 2005

Comments: Huerto (Huesca) was rejected because of non-sufficiently uniform irrigation.

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 at a later stage?

An authorisation for placing on the market, including cultivation, in the European Union has been submitted.

5. TYPE(S) OF DELIBERATE RELEASES

5.1 Deliberate releases for research purposes

N/A.

5.2 Deliberate releases for development purposes

N/A.

5.3 Official testing

Trials before the Register application:

They aim at completing the description and evaluating the Agronomic Value of a series of experimental hybrids, whose cultivation has been notified to the Spanish Office of Plant Varieties, so that they are considered as preliminary to the new hybrids Register Application next year.

The 05CRN88 trials protocol (code notified to the Spanish Office of Plant Varieties for these trials) contain 16 varieties of FAO 400-500 cycle, from which 3 are NK603 x MON8107, 10 are NK603, (considered in B/ES/04/19), and the remaining are conventional.

The 05CRN89 trials protocol (code notified to the Spanish Office of Plant Varieties for these trials) contain 40 varieties of FAO 600-700 cycle, from which 10 are NK603 X MON810, 17 are NK603 x MON810 (considered in B/ES/04/19), and the remaining are conventional

5.4 Herbicide authorization

N/A

5.5 Deliberate releases for demonstration purposes

N/A

5.6 Seeds Multiplication

N/A

5.7 Deliberate releases for biosafety /risk assessment research (please, specify)

N/A

5.8 Other type of deliberate releases

N/A

6. METHODS AND RESULTS OF THE RELEASE, MANAGEMENT AND MONITORING MEASURES IN RESPECT OF ANY RISK TO HUMAN HEALTH OR THE ENVIRONMENT

6.1 Risk management measures

6.1.1 Before the sowing

- An isolation distance of minimum 200m has been checked.
- Genetically modified seeds were packed in two closed bags and were appropriately labelled by qualified staff.

6.1.2 During the sowing and planting

- Seeds were transported in closed bags and were managed in the trials by qualified staff, already warned about the preventive measures to be taken to avoid any dissemination.
- Sowing was done with a perfectly clean sowing machine, avoiding losses in the soil.
- To prevent any involuntary seed release, all the remaining seed bags have been buried in a minimum 50 cm-deep pitch. Before taking the sowing machine outside the crop area, the sowing cones were verified to be clean.
- Competent authorities have been informed on the sowing dates and their official staff members have checked the sowings.

6.1.3 During the period of release

- Trials have been monitored on several dates during the growing season, and have been visited by some experts and competent authorities.
- No negative effect has been observed in “non target” organisms, or in arthropofauna, or in biodiversity generally.
- Pollen shed dates have been notified.
- No incidence has been observed.

6.1.4 At the end of the release

- Authorities were informed on the harvesting dates, and they were present.
- Every material taken away from the site has been kept separately and clearly identifiable.
- The grains have been buried in an approximately 2,5 metre-deep pitch and have been covered with a minimum of 50-75 cm earth layer.
- The grains were transported to the pitch in the combine itself. If the ditch was far from the original site, the grains were then transported in a trailer.
- The trials crop residues have been destroyed with tillage, chopped (with a chopper or an offset disc harrow) and then, buried or ploughed up with several blades passes.
- The combine and means of transport have been cleaned before leaving the field.

6.1.5 Post-harvest measures

The release site will be watched on during the year following the trials, and up to the maize flowering period, in order to destroy any eventual volunteers of maize. This destruction will no longer be necessary when the NK603 X MON810 modification is authorised for cultivation in the European Union.

6.1.6 Other(s) measure(s) (please, describe)

Not relevant

6.1.7 Emergency plans

All the biosafety measures planned to avoid volunteers have been applied.

Please indicate:

a) if the release proceeded as planned

The release proceeded as planned.

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

They were not necessary.

6.2 Post-release monitoring measures

The monitoring results confirm that NK603 X MON810 maize plants present the same risk to human and animal health or the environment as any conventional varieties.

According to the cases mentioned below, please indicate the monitoring measures adopted

Please specify:

Monitoring measures within site

Field trials will be visited during the following growing season to destroy any germinated plants.

Monitoring measures in surrounding areas

Surrounding fields to the trials will be visited during the following growing season to destroy any germinated plants.

6.3 Plan for observation(s)/method(s) involved

General observations on plants health, illness sensitivity, plants development; furthermore, any unexpected and unusual characteristic will be recorded.

6.4 Observed effect(s)

No unexpected effect was observed.

6.4.1 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.

NK603 X MON810 maize plants presented no risk to human or animal health or the environment.

6.4.2 Expected effect(s)

NK603 X MON810 maize plants grew normally and presented a crop and yield cycles similar to their isogenic conventional counterparts.

Results are sent to the Spanish Office of Plant Varieties for further studies.

6.4.3 Unexpected effect(s)

No unexpected effect has been observed

6.4.4 Other information

N/A

7. CONCLUSION

Field trials were carried out as planned. The minimum barrier of 6 rows of conventional maize planted surrounding the field acted as a pollen barrier.

NK603 X MON810 hybrids behaved as expected. NK603 X MON810 hybrids results are sent to the Spanish Office of Plant Varieties for evaluation.

Date: 28th November 2005

A handwritten signature in blue ink that reads "Juan Alvarado Aldea". The signature is written in a cursive style with a large, sweeping initial 'J'.

Signed: Juan Alvarado Aldea

REPORT ON RESULTS

Notification B/ES/04/20

Trials in the Autonomous Community of Castilla La Mancha

(In accordance with Annex XI of RD 178/2004, of 30th January)

1. GENERAL INFORMATION

1.1 European notification number

B/ES/04/20

1.2 Member State of Notification

Spain

1.3 Date of consent and consent number

15 February 2005.

2. REPORT STATUS

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

a **FINAL** post-release monitoring report

3. CHARACTERISTICS OF THE RELEASE

3.1 Scientific name of the recipient organism

Zea mays

3.2 Transformation events [acronym(s) or vector(s) used (if transformation event identity not available)]

NK603XMON810

3.3 Unique identifier, if available

MON-00603-6 x MON-00810-6

3.4 Please provide the following information, as well as the field(s) layout

Geographical location(s) (administrative region and, where appropriate, grid reference)	Size of the release site(s) (event NK603 x MON810 m2)	Identity and approximate number of GM higher plants per event actually released	Duration of the releases
Malpica (Toledo)	10 m2 x 3 rep x 10 hybrids =300 m2.	NK603 X MON810 hybrids ~7-8 plants /m2	Sowing: 27 April 2005 Destruction: 6-7 October 2005

Comment: Torrijos was replaced by Malpica

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 at a later stage?

An authorisation for placing on the market, including cultivation, in the European Union has been submitted.

5. TYPE(S) OF DELIBERATE RELEASES

5.1 Deliberate releases for research purposes

N/A.

5.2 Deliberate releases for development purposes

N/A.

5.3 Official testing

Trials before the Register application:

They aim at both completing the description and evaluating the Agronomic Value of a series of experimental hybrids, whose cultivation has been notified to the Spanish Office of Plant Varieties, so that they are considered to be preliminary to the new hybrids Register Application next year.

The 05CRN89 trials protocol (code notified for these trials to the Spanish Office of Plant Varieties) contain 40 varieties of FAO 600-700 cycle, from which 10 are NK603 x MON810, 17 are NK603 (considerated in B/ES/04/19) and the remaining are conventional.

5.4 Herbicide authorization

N/A

5.5 Deliberate releases for demonstration purposes

N/A

5.6 Seeds Multiplication

N/A

5.7 Deliberate releases for biosafety /risk assessment research (please, specify)

N/A

5.8 Other type of deliberate releases

N/A

6. METHODS AND RESULTS OF THE RELEASE, MANAGEMENT AND MONITORING MEASURES IN RESPECT OF ANY RISK TO HUMAN HEALTH OR THE ENVIRONMENT

6.1 Risk management measures

6.1.1 Before the sowing

- An isolation distance of minimum 200m has been checked.
- Genetically modified seeds were packed in two closed bags and were appropriately labelled by qualified staff.

6.1.2 During the sowing and planting

- Seeds were transported in closed bags and were managed in the trials by qualified staff, already warned about the preventive measures to be taken to avoid any dissemination.
- Sowing was done with a perfectly clean sowing machine, avoiding losses in the soil.
- To prevent any involuntary seed release, all the remaining seed bags have been buried in a 50 cm-deep pitch within the trial site. Before taking the sowing machine outside the crop area, the sowing cones were verified to be clean.
- Competent authorities have been informed on the sowing dates and their official staff members have checked the sowings.
- In order to minimize the appearance of wild species, and following the Junta Castilla-La Mancha recommendations for notifications B/ES/04/19 and B/ES/04/20, the trial was surrounded by a 50 cm-high plastic netting.

6.1.3 During the period of release

- Trials have been monitored on several dates during the growing season, and have been visited by some experts and competent authorities.
- No negative effect has been observed in “non target” organisms, or in arthropofauna, or in biodiversity generally.
- Pollen shed dates have been notified.
- Incidences, if any, have been notified. The facts mentioned below are the only incidence worthy of mention:

07/09/05 – During a control visit, Monsanto technicians noticed two fields of sorghum (species incompatible with maize) at less than 200 m from the trials and a maize field at near 70-80 m of the GM maize trials. These fields seem to come from sowings in July 2005, when GM maize was at the beginning of the pollen shed period.

09/09/05 - Although pollen transference between GM maize to the conventional maize field seems impossible, the competent authorities were faxed and informed about it (National Biovigilance Committee and the autonomous government of Castilla-La Mancha, Junta de Castilla-La Mancha).

14/09/05 - Field visit with the Head of the Variety Register Service of the Spanish Office of Plant Varieties (Ministry of Agriculture, Fisheries and Food), during which the advanced ripeness state of GM field trials could be observed, whereas there was no evidence of ears with pollen-receiving silks in the nearby maize field.

16/09/05 - After reaching a compensation deal with the field owner, the conventional maize field sown at 70-80 m from the GM varieties trials was destroyed.

6.1.4 At the end of the release

- Authorities were informed on the harvesting dates, and they were present.
- Every material taken away from the site has been kept separately and clearly identifiable.
- Trials have been harvested with a cereal combine.
- The grains have been buried in an approximately 2,5 metre-deep pitch in the plot number 937 from the 10th area (data from the Regional Cadastre), in the dump belonging to the council of Malpica, in front of Inspector Domingo Jose Otal Lasheras, as the Spanish Office of Plant Varieties' representative (Ministry of Agriculture, Fisheries and Food).
- The grains were transported from the plot to the ditch in a trailer.
- The trials crop residues have been destroyed with tillage, chopped with an offset disc harrow and then, buried or ploughed up with several blades passes.
- The combine and means of transport have been cleaned before leaving the field.

6.1.5 Post-harvest measures

The release site will be watched on during the year following the trials, and up to the maize flowering period, in order to destroy any eventual volunteers of maize. This destruction will no longer be necessary when the NK603 X MON810 modification is authorised for cultivation in the European Union.

6.1.6 Other(s) measure(s) (please, describe)

Not relevant

6.1.7 Emergency plans

All the biosafety measures planned to avoid volunteers have been applied.

Please indicate:

a) if the release proceeded as planned

The release proceeded as planned, except for the detection, on September 7th, of a maize silage field in second harvest, in the vicinity (around 75-80 m distant from the trial sites). After notifying it to the competent authorities, on September 9th, and having reached an agreement with the maize field's owner, the field was chopped and destroyed before pollen release and receiving silks appeared on September 16th.

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

They were not necessary.

6.2 Post-release monitoring measures

The monitoring results confirm that NK603 X MON810 maize plants present the same risk to human and animal health or the environment as any conventional varieties.

According to the cases mentioned below, please indicate the monitoring measures adopted

Please specify:

Monitoring measures within site

Field trials will be visited during the following growing season to destroy any germinated plants.

Monitoring measures in surrounding areas

Surrounding fields to the trials will be visited during the following growing season to destroy any germinated plants.

6.3 Plan for observation(s)/method(s) involved

General observations on plants health, illness sensitivity, plants development; furthermore, any unexpected and unusual characteristic was recorded.

6.4 Observed effect(s)

No unexpected effect was observed

6.4.1 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.

NK603 X MON810 maize plants presented no risk to human or animal health or the environment.

6.4.2 Expected effect(s)

NK603 X MON810 maize plants grew normally and presented a crop and yield cycles similar to their isogenic conventional counterparts.

Results are sent to the Spanish Office of Plant Varieties for further studies.

6.4.3 Unexpected effect(s)

No unexpected effect has been observed

6.4.4 Other information

N/A

7. CONCLUSION

Field trials were carried out as planned. The minimum barrier of 6 rows of conventional maize planted surrounding the field acted as a pollen barrier.

NK603 X MON810 maize hybrids behaved as expected. NK603 hybrids results are sent to the Spanish Office of Plant Varieties for evaluation.

Date: 28th November 2005

A handwritten signature in blue ink that reads "Juan Alvarado Aldea". The signature is written in a cursive style with a large, sweeping initial 'J'.

Signed: Juan Alvarado Aldea

REPORT ON RESULTS

Notification B/ES/04/20

Trials in the Autonomous Region of Castilla y Leon

(In accordance with Annex XI of RD 178/2004, of 30th January)

1. GENERAL INFORMATION

1.1 European notification number

B/ES/04/20

1.2 Member State of Notification

Spain

1.3 Date of consent and consent number

3rd May 2005

2. REPORT STATUS

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

a **FINAL** post-release monitoring report

3. CHARACTERISTICS OF THE RELEASE

3.1 Scientific name of the recipient organism

Zea mays

3.2 Transformation events [acronym(s) or vector(s) used (if transformation event identity not available)]

NK603xMON810

3.3 Unique identifier, if available

MON-00603-6 x MON-00810-6

3.4 Please provide the following information, as well as the field(s) layout

Geographical location(s) (administrative region and, where appropriate, grid reference)	Size of the release site(s) (event NK603 x MON810 m2)	Identity and approximate number of GM higher plants per event actually released	Duration of the releases
Fuentes de Ropel (Zamora)	20 m2 x 3 rep x 3 hybrids = 180 m2.	NK603 x MON810 hybrids ~5 plants /m2	Sowing: 10 May 2005 Destruction: 7 July 2005
Cisterniga (Valladolid)	20 m2 x 3 rep x 3 hybrids = 180 m2.	NK603 x MON810 hybrids ~7 plants /m2	Sowing: 10 May 2005 Destruction: 30 November

Comments

Fuentes de Ropel trials were destroyed very soon as in some plots few plants emerged due to low vigor seeds, or due to severe armyworms attacks, (*Agriotis* sp.). Therefore, there was no risk of seed dispersal.

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 at a later stage?

An authorisation for placing on the market, including cultivation, in the European Union has been submitted.

5. TYPE(S) OF DELIBERATE RELEASES

5.1 Deliberate releases for research purposes

N/A.

5.2 Deliberate releases for development purposes

N/A.

5.3 Official testing

Trials before the Register application:

They aim both at completing the description and evaluating the Agronomic Value of a series of experimental hybrids, whose cultivation has been notified to the Spanish Office of Plant Varieties, so that they are considered to be preliminary to the new hybrids Register Application next year.

The 05CRN88 trials protocol (code for these trials notified to the Spanish Office of Plant Varieties) contain 16 varieties of FAO 400-500 cycle, from which 7 are NK603, 3 are NK603 x MON810 (considered in B/ES/04/20), and the remaining are conventional.

5.4 Herbicide authorization

N/A

5.5 Deliberate releases for demonstration purposes

N/A

5.6 Seeds Multiplication

N/A

5.7 Deliberate releases for biosafety /risk assessment research (please, specify)

N/A

5.8 Other type of deliberate releases

N/A

6. METHODS AND RESULTS OF THE RELEASE, MANAGEMENT AND MONITORING MEASURES IN RESPECT OF ANY RISK TO HUMAN HEALTH OR THE ENVIRONMENT

6.1 Risk management measures

6.1.1 Before the sowing

- An isolation distance of minimum 200m has been checked.
- Genetically modified seeds were packed in two closed bags and were appropriately labelled by qualified staff.

6.1.2 During the sowing and planting

- Seeds were transported in closed bags and were managed in the trials by qualified staff, already warned about the preventive measures to be taken to avoid any dissemination.
- Sowing was done with a perfectly clean sowing machine, avoiding losses in the soil.
- To prevent any involuntary seed release, all the remaining seed bags have been buried in a 50 cm-deep pitch within the trial site. Before taking the sowing machine outside the crop area, the sowing cones were verified to be clean
- Competent authorities have been informed on the sowing dates and their official staff members have checked the sowings.

6.1.3 During the period of release

- Trials have been monitored on several dates during the growing season, and have been visited by some experts and competent authorities.
- No negative effect has been observed in “non target” organisms, or in arthropofauna, or in biodiversity generally.

- Pollen shed dates have been notified.
- Incidences, if any, have been notified. The only incidence worthy of mention is the destruction of Fuentes de Ropel trial; it was destroyed very soon because there were not enough emerged plants of some varieties. The competent authorities were notified about this situation.

6.1.4 At the end of the release

- Authorities were informed on the harvesting dates, and they were present.
- In Cisterniga, the trial has been harvested with a cereal combine. Before being taken to the plot, it was cleaned and free of grains residues.
- The harvested grains were placed in an insulated trailer, and were later buried in a ditch prepared to this end.
- The trials crop residues have been destroyed with a chopper and buried with several blade passes.
- Both the combine and the trailer were cleaned before leaving the plot.

6.1.5 Post-harvest measures

The release site will be watched on during the year following the trials, and up to the maize flowering period, in order to destroy any eventual volunteers of maize. This destruction will no longer be necessary when the NK603 x MON810 modification is authorised for cultivation in the European Union.

6.1.6 Other(s) measure(s) (please, describe)

Not relevant

6.1.7 Emergency plans

All the biosafety measures planned to avoid volunteers have been applied.

Please indicate:

a) if the release proceeded as planned

The release proceeded as planned, except for the destruction of Fuentes de Ropel trial as explained above.

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.

They were not necessary.

6.2 Post-release monitoring measures

The monitoring results confirm that NK603 x MON810 maize plants present the same risk to human and animal health or the environment as any conventional varieties.

According to the cases mentioned below, please indicate the monitoring measures adopted

Please specify:

Monitoring measures within site

Field trials will be visited during the following growing season to destroy any germinated plants.

Monitoring measures in surrounding areas

Surrounding fields to the trials will be visited during the following growing season to destroy any germinated plants.

6.3 Plan for observation(s)/method(s) involved

General observations on plants health, illness sensitivity, plants development; furthermore, any unexpected and unusual characteristic was recorded.

6.4 Observed effect(s)

No unexpected effect was observed

6.4.1 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 s.

NK603 x MON810 maize plants presented no risk to human or animal health or the environment.

6.4.2 Expected effect(s)

NK603 x MON810 maize plants grew normally and presented a crop and yield cycles similar to their isogenic conventional counterparts.

Results are sent to the Spanish Office of Plant Varieties for further studies.

6.4.3 Unexpected effect(s)

No unexpected effect has been observed

6.4.4 Other information

N/A

7. CONCLUSION

Cisterniga trial was carried out as planned. The minimum barrier of 6 rows of conventional maize planted surrounding the field acted as a pollen barrier.

NK603 x MON810 maize hybrids behaved as expected. hybrids results are sent to the Spanish Office of Plant Varieties for evaluation.

Fuentes de Ropel trial was destroyed before harvest; therefore its data will not be sent to the Spanish Office for Plant Varieties.

Date: 30th November 2005



Signed: Juan Alvarado Aldea

REPORT ON RESULTS

Notification B/ES/04/20

Trials in the Foral Community of Navarra

(In accordance with Annex XI of RD 178/2004, of 30th January)

1. GENERAL INFORMATION

1.1 European notification number

B/ES/04/20

1.2 Member State of Notification

Spain

1.3 Date of consent and consent number

3rd May 2005 (number 0829).

2. REPORT STATUS

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

a **FINAL** post-release monitoring report

3. CHARACTERISTICS OF THE RELEASE

3.1 Scientific name of the recipient organism

Zea mays

3.2 Transformation events [acronym(s) or vector(s) used (if transformation event identity not available)]

NK603xMON810

3.3 Unique identifier, if available

MON-00603-6 x MON-00810-6

3.4 Please provide the following information, as well as the field(s) layout

Geographical location(s) (administrative region and, where appropriate, grid reference)	Size of the release site(s) (event NK603 x MON810 m2)	Identity and approximate number of GM higher plants per event actually released	Duration of the releases
Buñuel (Navarra)	10 m2 x 3rep x 3 hybrids = 90 m2	NK603 X MON810 hybrids ~7 plants /m2	Sowing: 26 April 2005 Harvest: 25 October Destruction: see comments

Comments: On October 25th, Buñuel's plot was ploughed and harrowed. But crops and grains residues were not buried enough, so, as soon as the weather allows it, the field will be tilled again.

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 at a later stage?

An authorisation for placing on the market, including cultivation, in the European Union has been submitted.

5. TYPE(S) OF DELIBERATE RELEASES

5.1 Deliberate releases for research purposes

N/A.

5.2 Deliberate releases for development purposes

N/A.

5.3 Official testing

Trials before the Register application:

They aim both at completing the description and evaluating the Agronomic Value of a series of experimental hybrids, whose cultivation has been notified to the Spanish Office of Plant Varieties, so that they are considered to be preliminary to the new hybrids Register Application next year.

The 05CRN88 trials protocol (code for these trials notified to the Spanish Office of Plant Varieties) contain 16 varieties of FAO 400-500 cycle, from which 3 are NK603 x MON810, 10 are NK603 (considered in B/ES/04/19), and the remaining are conventional.

5.4 Herbicide authorization

N/A

5.5 Deliberate releases for demonstration purposes

N/A

5.6 Seeds Multiplication

N/A

5.7 Deliberate releases for biosafety /risk assessment research (please, specify)

N/A

5.8 Other type of deliberate releases

N/A

6. METHODS AND RESULTS OF THE RELEASE, MANAGEMENT AND MONITORING MEASURES IN RESPECT OF ANY RISK TO HUMAN HEALTH OR THE ENVIRONMENT

6.1 Risk management measures

6.1.1 Before the sowing

- An isolation distance of minimum 200m has been checked.
- Genetically modified seeds were packed in two closed bags and were appropriately labelled by qualified staff.

6.1.2 During the sowing and planting

- Seeds were transported in closed bags and were managed in the trials by qualified staff, already warned about the preventive measures to be taken to avoid any dissemination.
- Sowing was done with a perfectly clean sowing machine, avoiding losses in the soil.
- To prevent any involuntary seed release, all the remaining seed bags have been buried in a 50 cm-deep pitch within the trial site. Before taking the sowing machine outside the crop area, the sowing cones were verified to be clean.
- Competent authorities have been informed on the sowing dates and their official staff members have checked the sowings.

6.1.3 During the period of release

- Trials have been monitored on several dates during the growing season, and have been visited by some experts and competent authorities.
- No negative effect has been observed in “non target” organisms, or in arthropofauna, or in biodiversity generally.
- Pollen shed dates have been notified.
- Incidences, if any, have been notified.

6.1.4 At the end of the release

- Authorities were informed on the harvesting dates, and they were present.
- Trials have been harvested with a cereal combine.
- The grains have been buried in an approximately 2 metre-deep pitch and has been covered with a minimum of 50 cm earth layer.
- The grains were transported to the pitch in a trailer. The pitch was located in the plot number 654 from the 2nd area.
- The trials crop residues have been destroyed, first chopped (in the harvesting machinery), and then ploughed and harrowed. As soon as the weather allows it, the field will be tilled again, in order to bury up the crops and grains residues.
- The combine and means of transport have been cleaned before leaving the field.

6.1.5 Post-harvest measures

The release site will be watched on during the year following the trials, and up to the maize flowering period, in order to destroy any eventual volunteers of maize. This destruction will no longer be necessary when the NK603 X MON810 modification is authorised for cultivation in the European Union

6.1.6 Other(s) measure(s) (please, describe)

Not relevant

6.1.7 Emergency plans

All the biosafety measures planned to avoid volunteers have been applied.

Please indicate:

a) if the release proceeded as planned

The release proceeded as planned.

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

They were not necessary.

6.2 Post-release monitoring measures

The monitoring results confirm that NK603 x MON810 maize plants present the same risk to human and animal health or the environment as any conventional varieties.

According to the cases mentioned below, please indicate the monitoring measures adopted

Please specify:

Monitoring measures within site

Field trials will be visited during the following growing season to destroy any germinated plants.

Monitoring measures in surrounding areas

Surrounding fields to the trials will be visited during the following growing season to destroy any germinated plants.

6.3 Plan for observation(s)/method(s) involved

General observations on plants health, illness sensitivity, plants development; furthermore, any unexpected and unusual characteristic was recorded.

6.4 Observed effect(s)

No unexpected effect was observed

6.4.1 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.

NK603 X MON810 maize plants presented no risk to human or animal health or the environment.

6.4.2 Expected effect(s)

NK603 maize plants grew normally and presented a crop and yield cycles similar to their isogenic conventional counterparts.

Results are sent to the Spanish Office of Plant Varieties for further studies.

6.4.3 Unexpected effect(s)

No unexpected effect has been observed.

6.4.4 Other information

N/A.

7. CONCLUSION

Field trials were carried out as planned. The minimum barrier of 6 rows of conventional maize planted surrounding the field acted as a pollen barrier. NK603 X MON810 hybrids behaved as expected. NK603 X MON810 hybrids results are sent to the Spanish Office of Plant Varieties for evaluation.

Date: 30th November 2005



Signed: Juan Alvarado Aldea