REPORT OF THE RESULT OF DELIBERATE RELEASE INTO THE ENVIRONMENT OF GENETICALLY MODIFIED HIGHER PLANTS IN ACCORDANCE WITH ARTICLE 10 OF DIRECTIVE 2001/18/EC

(COMMISSION DECISION 2003/701/EC)

1. General information

1.1. European notification number:

B/CZ/06/04

1.2. Member State of notification:

Czech Republic

1.3. Date of consent and consent number:

6 March 2009, 16573/ENV/09 (application number 86423/ENV/08)
8 April 2010, 30776/ENV/10 (application number 3954/ENV/10)
22 March 2011, 24107/ENV/11 (application number 780/ENV/11)

2. Report status

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

The post release monitoring report - final.

3. Characteristics of the release

3.1. Scientific name of the recipient organism:

Zea mays

3.2. Transformation event(s) (acronym(s)) or vectors used (if transformation event identity not available):

NK603

NK603 × MON 810

3.3. Unique identifier, if available:

MON-ØØ6Ø3-6

MON-ØØ6Ø3-6 × MON-ØØ81Ø-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) (m^2)	Identity and approximate number of GM higher plants per event actually released (number of seeds/plants per m^2)	Duration of the release(s) (from ... (day/month/year) until...(d/m/y))
Opolany	NK603: 27000 m^2	NK603: 7-9 plants/m^2	Sowing: 20/4/2011 Destruction:21/11/2011
Nabočany	NK603: 108 m^2 NK603 × MON 810: 108 m^2	NK603: 7-9 plants/m^2 NK603 × MON 810: 7-9 plants/m^2	Sowing: 18/4/2011 Destruction:24/6/2011
Ivanovice na Hané	NK603 × MON 810: 480 m^2	NK603 × MON 810: 7-9 plants/m^2	Sowing: 21/4/2011 Destruction: 31 /10/2011
Čáslav	NK603 × MON 810: 672 m^2	NK603 × MON 810: 7-9 plants/m^2	Sowing: 22/4/2011 Destruction: 18 /11/2011

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

NK603 maize was approved on 19 July 2004 for import, feed use and processing in the EU under Directive 2001/18/EC (Commission Decision 2004/643/EC). Food and food ingredients derived from NK603 were approved under Regulation (EC) No. 258/97 (Commission Decision 2005/448/EC) and existing feed materials, feed additives and food additives produced from NK603 were listed in the Community Register, according to Regulation (EC) No. 1829/2003[1]. An application for cultivation of varieties of NK603 in the European Union was submitted under Regulation (EC) No. 1829/2003 and a positive scientific opinion has been adopted by EFSA (published on 11 June 2009).

The placing on the market of products containing, consisting of or produced from NK603 × MON 810 was authorized in the EU in accordance with Regulation 1829/2003 on 24 October, 2007 (Commission Decision 2007/701/EC). An application for authorization of NK603 × MON 810 cultivation in the EU has been submitted in accordance with Regulation 1829/2003 (EFSA-GMO-NL-2005-26).

5. Type(s) of deliberate release(s)

5.1. Deliberate release(s) for research purposes

Not applicable

5.2. Deliberate release(s) for development purposes

Efficacy testing of plant protection products (herbicides). Evaluation of different herbicide treatments. Agronomic performance testing – yield, germination, plant vigour, plant height,

[1] http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=16

sensitivity to diseases and European Corn Borer. Evaluation of crop protection methods under different tillage systems, assessment of insect abundance.

5.3. Official testing

Not applicable

5.4. Herbicide authorisation

Not applicable

5.5. Deliberate release(s) for demonstration purposes

Some of the field trials were used for demonstration purposes to show glyphosate tolerant maize technology to farmers and technical audience.

5.6. Seeds multiplication

Not applicable

5.7. Deliberate release(s) for biosafety/risk assessment research

Not applicable

5.8. Other(s) types) of deliberate release(s):

Not applicable

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)

6.1.1. Before the sowing/planting:

- It was confirmed a minimum isolation distance of 200 m from other commercial maize fields and 600 m from organic maize crop.
- Seeds of NK603 and NK603 × MON 810 maize were packed in double sealed bags and labelled as “Genetically modified organism” – MON-ØØ6Ø3-6 for NK603 and “Genetically modified organism” – MON-ØØ6Ø3-6 × MON-ØØ81Ø-6 for NK603 × MON 810. Additional labelling: “not for planting, or food and feed use”, “no transfer to unauthorized personnel” GM maize seed was transported by car.
- Remaining seed was stored and used in next season, or stored for later destruction, or destroyed during field trail destruction (crushed seed was ploughed into soil at NK603/ NK603 × MON 810 experimental field).

6.1.2. During the sowing/planting activities:

- Seed was transported in closed, double sealed bags; manipulation with seed material done only by authorized/trained staff.
- Sowing machinery was cleaned after field operation, no seed was left in the planter after planting of trials.

- Remaining seed was stored and used in next season, or stored for later destruction, or destroyed during field trail destruction (crushed seed was ploughed into soil at NK603/NK603 × MON 810 experimental field).
- A minimum of eight rows of conventional maize were planted as pollen barrier surrounding the trial.

6.1.3. During the period of release:

- The minimal isolation distance of 200 m from other conventional maize (600 m from organic maize crops), together with the eight rows of non transgenic maize surrounding the trials, were used to prevent most of the possibility of hybridization with other maize plants.
- Trials have been monitored regularly during the period of the deliberate release for potentially occurring, direct or indirect, adverse environmental effects. During the visits, no adverse environmental effects were observed. No adverse effects were recorded regarding to human or animal safety.
- Trials were labelled (in all corners) by warning : "Genetically modified organism, Do not enter, Not for feed use, Treated by chemicals"

6.1.4. At the end of the release:

- Trials were usually harvested by special grain maize – small plot cereal harvester modified to grind the grain to avoid germination. Standard harvester was used on some locations, with additional grain milling on the testing sites. Buffer rows were destroyed together with tested crop.
- Trial crop residues and harvested ground grain were destroyed on experimental sites by their incorporation into the soil with help of ploughing. Fertilizers were used to support biodegradation of biomass.
- The harvesters were cleaned before leaving the experimental field.

6.1.5. Post-harvest measures

The release sites were sown with a crop different from maize for one year following the trial and during this year (2012), at time of vegetation period, potential volunteer plants were supposed to be controlled by mechanical destruction or non-selective herbicides.

Special measures were applied for Nabocany site. Due to fact that trial destruction was done before flowering of GM maize, monitoring of volunteer plants was not performed in 2012. Potential regrowth of destroyed plants was monitored once a two weeks during July, on monthly basis in August, September and October 2011. No plants of maize were found after trial destruction on release site including adjacent areas.

6.1.6. Other(s) measure(s): (describe):

Not applicable.

6.1.7. Emergency plan(s)

Indicate:

(a) if the release proceeded as planned:

The release proceeded as planned.

(b) if measures according to the emergency plans) (Article 6(2)(a)(vi) and Annex III.B of Directive 2001/18/EC) had to be taken:

These measures were not necessary.

6.2. Post-release monitoring measures

Please indicate whether

— **the post-release monitoring plan has been completed.**

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.

Specify:

— **Monitoring measures within site**

Duration: One year after harvest of NK603 and NK603 × MON 810 trial.

Frequency of visits (average): Once a month during growing season.

— **Observation of resistant relatives** No

— **Observation of resistant insects** No

— **Control of volunteers (specify intervals and duration)**

Once a month during growing season, in case that volunteer plants were detected, these would be removed and left on the site for biodegradation. In 2012 year, there have been no volunteer maize plants observed at any location.

— **Monitoring of gene flow (specify)** Not applicable

— **Appropriate chemical treatment(s) and/or soil treatment(s)** Not necessary

— **Others (specify)** No

— **Monitoring measures of adjacent areas**

Duration: One year after harvest of NK603 and NK603 × MON 810 trial.

Frequency of visits (average): Once a month during growing season.

Area monitored: adjacent fields to NK603 and NK603 × MON 810 trial.

— **Observation of resistant relatives** No

— **Observation of resistant insects** No

— **Control of volunteers and/or monitoring of feral populations (specify intervals and duration)**

Once a month during growing season. In 2012 year, there have been no volunteer maize plants observed at any location.

— **Monitoring of gene flow (specify)** Not applicable

— **Appropriate chemical treatment(s) and/or soil treatment(s)** Not necessary

— **Others (specify)** No

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

During NK603 and NK603 × MON 810 field release: general observations of plant health, sensitivity to diseases and pests, plant development. Any unexpected effects of NK603 and NK603 × MON 810 shall be recorded.

After harvest/destruction of NK603 and NK603 × MON 810 trail: monitoring of volunteer during vegetation period of 2012 year.

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.

No unexpected effects have been recorded.

6.4.2. Expected effect(s)

The environmental risk assessment has indicated that the environmental risk of NK603 and NK603 × MON 810 is negligible. It is concluded that both NK603 and NK603 × MON 810 are as safe as their conventional counterparts with respect to potential direct effects on human and animal health and the environment.

No difference in growing or development of NK603 and NK603 × MON 810 respect to their conventional counterparts has been recorded. No adverse effects have been observed for human and animal health or the environment.

6.4.3. Unexpected effects

No unexpected effects have been recorded.

6.4.4. Other information

No other information.

7. Conclusion

Field trials were carried out according to the applications, approvals, and in line with specific legislation regulating GMO's.

All the measures to avoid potential dissemination of seed, or any other plant material were taken, as a prevention of potential hybridization with other maize plants, minimal isolation distance was applied together with "buffer" rows of conventional maize, surrounding the trials.

We have not observed any negative effects on human and animal health, or the environment.

In 2012 year, there have been no volunteer maize plants observed at any location.

DATE: January 29, 2013