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

(COMMISSION DECISION 2003/701/EC)

1. General information

1.1. European notification number:

B/SK/10/04

1.2. Member State of notification:

Slovakia

1.3. Date of consent and consent number:

15.4.2012, 21088/2010-2.2.-4-ZZP 25

2. Report status

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

The final report

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

3.3. Unique identifier, if available:

MON–ØØ6Ø3-6

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))
Borovce	90 m^2	NK603: 7-9 plants/m^2	Sowing: 10.5.2010 Destruction:5.11.2010
Borovce	630 m^2	NK603: 7-9 plants/m^2	Sowing: 16.4.2011 Destruction:17-18.10.2011
Milhostov	1995 m^2	NK603: 7-9 plants/m^2	Sowing: 6.5.2011 Destruction: 26.10.2011
Borovce	360 m^2	NK603: 7-9 plants/m^2	Sowing: 25.4.2012 Destruction: 22.10.2012

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?

No

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

Evaluation of different herbicide treatments.

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 GM 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.

Seeds of NK603 maize were packed in double sealed bags and labelled as "Genetically modified maize" – MON–ØØ6Ø3-6. NK603 seed was transported by car.

Remaining seed was stored and used in next season or destroyed during field trail destruction (crushed seed was ploughed into soil at NK603 experimental field).

6.1.2. During the sowing/planting activities:

- Seed was transported in closed 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 destroyed during field trail destruction (crushed seed was ploughed into soil at NK603 experimental field).

- Competent authorities (Slovak Environmental Inspection) were present during sowing; planting operation was done under supervision of officials.
- 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 (300 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:

- Competent authorities (Slovak Environmental Inspection) were present during harvest and trials destruction.

- Trials were harvested by grain maize - cereal harvester modified to grind the grain to avoid germination. Where silage harvester was available, parts of the trials were destroyed by silage harvester which cut maize plants to small pieces with damage of grain viability (germination).
- Trial crop residues and harvested ground grain were destroyed on experimental sites by their incorporation into the soil with help of ploughing.
- The harvesters and means of transport were cleaned before leaving the field.

6.1.5. Post-harvest measures

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

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 will start** (in the case of a final report, after the last harvest of the GM higher plants),

The post-release monitoring plan is on place since the first harvest of NK603 trials in 2010.

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 trials.

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

— **Observation of resistant relatives** No

— **Observation of resistant insects** Not applicable

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

Once a month during growing season, in case of volunteer plants are detected, they are removed and left on the site for biodegradation.

— **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 trials.

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

Area monitored: adjacent fields to NK603 trials.

— **Observation of resistant relatives** No

— **Observation of resistant insects** Not applicable

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

Once a month during growing season.

— **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 field release: general observations of plant health, sensitivity to diseases and pests, plant development. Any unexpected effects of NK603 shall be recorded.

After harvest/destruction of NK603 trails: monitoring of volunteer during vegetation period of the next 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 these maize is negligible; NK603 is as safe as its conventional counterparts with respect to potential direct effects on human and animal health and the environment.

No difference in growing or development of NK603 respect to its 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 application 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.

DATE: Januar 5th, 2013

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