

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)

**Deliberate release of MON 89034 × NK603 and MON 89034 × MON 88017
for the use in field trials in the Czech Republic**

1. General information

1.1. European notification number: B/CZ/09/03

1.2. Member State of notification: . Czech Republic

1.3. Date of consent and consent number. 27 April 2009, n. 3157/ENV/09

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): MON 89034 × NK603, MON 89034 × MON 88017

Unique identifier, if available: MON-89Ø34-3 × MON- ØØ6Ø3-6 ,
MON-89Ø34-3 × MON-88Ø17-3

⁽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.

3.3. 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) ⁽¹⁾ (m ²)	Identity ⁽²⁾ 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))
Ivanovice na Hané	MON 89034 xNK603: 80 m ² MON 89034 x MON 88017: 80 m ²	MON 89034 xNK603: 7-9 plants/m ² MON 89034 xMON 88017: 7-9 plants/m ²	Sowing : 7/5/2009 Destruction: 14/11/2009
Kroměříž	MON 89034 xNK603: 80 m ² MON 89034 x MON 88017: 80 m ²	MON 89034 xNK603: 7-9 plants/m ² MON 89034 xMON 88017: 7-9 plants/m ²	Sowing: 14/5/2009 Destruction: 26/10/2009

⁽¹⁾ Specify the size of the GM area and, where appropriate, the size of the non-GM area (e.g. non-GM border).

⁽²⁾ 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?

– Yes No Unknown to date

The MON 89034 xNK603 application (EFSA-GMO-NL-2007-38) was submitted in January 2007 and got a positive EFSA opinion in September 2009. On 28 July 2010 the use of MON 89034 x NK603 maize for food, feed, import and processing has been approved by the European Commission in accordance with Regulation (EC) No 1829/2003 on GM food and feed.

The MON 89034 x MON 88017 application (EFSA-GMO-NL-2007-39) was submitted in February 2007 and got a positive EFSA opinion in March 2010. On 17 June 2011 the use of MON 89034 x MON 88017 maize for food, feed, import and processing has been approved by the European Commission in accordance with Regulation (EC) No 1829/2003 on GM food and feed.

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(t) for development purposes

Efficacy testing of plant protection products (herbicides). Agronomic performance testing – yield, germination, plant vigour, plant height, sensitivity to diseases and European Corn Borer.

5.3. Official testing

Not applicable

5.4. Herbicide authorisation

Not applicable

5.5. Deliberate release(s) for demonstration purposes

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):

(describe) No

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 MON 89034 × NK603 and MON 89034 × MON 88017 maize were packed in double sealed bags and labelled as “Genetically modified organism” – MON-89Ø34-3 × MON-ØØ6Ø3-6 for MON 89034 × NK603 and “Genetically modified organism” – MON-89Ø34-3 × MON-88Ø17-3 for MON 89034 × MON 88017. GM maize seed was transported by car.

Remaining seed was stored for use in next seasons or stored for late destruction, or destroyed during field trial destruction (crushed seed was ploughed into soil at MON 89034 × NK603 / MON 89034 × MON 88017 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 for use in next seasons or stored for later destruction, or destroyed during field trial destruction (crushed seed was ploughed into soil at MON 89034 × NK603 and MON 89034 × MON 88017 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 harvested by small plot grain maize - cereal harvester modified to grind the grain to avoid germination. 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 site was 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 were supposed to be controlled by mechanical destruction or non-selective herbicides.

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

Not applicable

6.1.7. Emergency plan(s)

Indicate:

(a) if the release proceeded as planned:

— Yes

(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:

— No

6.2. Post-release monitoring measures

The post-release monitoring plan has been completed. Monitoring was performed in 2009 a 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 MON 89034 × NK603 and MON 89034 × MON 88017 trials

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 are detected, these are removed and left on the site for biodegradation. In 2010, there have been no volunteer maize plants observed at any locations

— **Monitoring of gene flow (specify)** No

— **Appropriate chemical treatment(s) and/or soil treatment(s)** No

— **Others (specify)** No

— **Monitoring measures of adjacent areas**

Duration: One year after harvest of MON 89034 × NK603 and MON 89034 × MON 88017 trials

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

Area monitored: adjacent fields to MON 89034 × NK603 and MON 89034 × MON 88017 trials.

— **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 2010, there have been no volunteer maize plants observed at any locations.
- **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 MON 89034 × NK603 and MON 89034 × MON 88017 field release: general observations of plant health, sensitivity to diseases and pests, plant development. Any unexpected effects of MON 89034 × NK603 and MON 89034 × MON 88017 shall be recorded.

After harvest/destruction of MON 89034 × NK603 and MON 89034 × MON 88017 trial: 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 MON 89034 × NK603 and MON 89034 × MON 88017 is negligible. It is concluded that both MON 89034 × NK603 and MON 89034 × MON 88017 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 MON 89034 × NK603 and MON 89034 × MON 88017 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.

DATE: 19 October 2011