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)

LOGO OF THE COMPANY OR RESEARCH INSTITUTE (OPTIONAL)

The report format shall be completed by the notifier. The notifier shall fill in the report format according to the proposed form (tick boxes and/or, as far as possible, specific keywords to use in text fields). The notifier shall illustrate as much as possible the reported data by means of diagrams, figures and tables. Statistical data could also be provided where relevant.

In the case of multi-sites, multi-events and/or multi-annual release(s), the notifier shall provide a general overview of the measures taken and effects observed for the full duration of the consent.

The space provided after each item is not indicative of the depth of the information required for the purposes of this report.

1. General information

1.1. European notification number: B/CZ/13/01

1.2. Member State of notification: Czech Republic

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

x the final report

— a post-release monitoring report

— ☐ final ☐ intermediary

2. Characteristics of the release

2.1. Scientific name of the recipient organism: *Zea mays* L.

2.2. Transformation event(s) (acronym(s)) or vectors ([1]) used (if transformation event identity not available): NK603

2.3. Unique identifier, if available: MON-ØØ6Ø3-6

([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.

2.4. 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) ([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))
Central Bohemia Region, Odřepsy,	29160 (43848 incl. Non-GM border)	NK603: 7-9 plants/m2	15.5.2013 - 8.11. 2013
Central Bohemia Region, Odřepsy,	29160 (43848 incl. Non-GM border)	NK603: 7-9 plants/m2	13.5.2014 - 3.11. 2014

([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.

3. Any kind of product that the notifier intends to notify at a later stage

3.1. 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

4. 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):

4.1. Deliberate release(s) for research purposes ☒

4.2. Deliberate release(t) for development purposes ☐

4.3. Official testing ☐

4.4. Herbicide authorisation ☐

4.5. Deliberate release(s) for demonstration purposes ☐

4.6. Seeds multiplication ☐

(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 pharmaceuticals, plant-based proteins production, etc.

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

4.8. Other(s) types) of deliberate release(s): ☐

(describe) .....

5. *Method(s), result(s) of the release, management and monitoring measure(s) in respect of any risk to human health or the environment*

5.1. Risk management measure(s)

5.1.1. Before the sowing/planting:

x Clear labelling of the GM seeds/planting material lots (distinct from other seeds/tubers/etc.) Labelling: Pozor, GMO! MON-ØØ6Ø3-6

x 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)

Transport in double packing, labelled, stored in closed locations.

x Destruction of superfluous seeds/planting material (describe the method involved)

Superfluous seeds destructed during harvest.

x Temporal isolation (specify)

Seeds stored in locked room without entrance of non-authorised persons.

x Rotation (specify the previous crop(s))

Forecrops and succeeding crops were cereals.

— Other(s): (specify).....

5.1.2. During the sowing/planting activities:

— Method of sowing/planting

x Emptying and cleaning of the sowing/planting machinery on the field of release

x Segregation during the sowing/planting (provide example(s) of containment to prevent spillage during the sowing/planting)

Non-GM border rows were sown first, later, after cleaning of sowing machine GM maize was sown. All the seeds found during final cleanind were considered GM and treated as superfluous seeds – see above.

— Other(s) (specify).....

5.1.3. During the period of release:

x Isolation distance(s) (x metres)

— from sexually compatible commercial plant species,

Isolation distance to conventional maize fields was 200 m. There were no maize fields in surroundings in 2013 and distance to closest field with conventional maize was ca. 450 m in 2014.

— from sexually compatible wild relatives.

No sexually compatible wild relatives occur in the region.

x Border row(s) (with the same crop or a different one, with a non-transgenic crop, x metres, etc.)

8 border rows of conventional hybrid maize were sown as isolation to prevent pollen dispersal.

— Cage/net/fence/signpost (specify)

— Pollen trap (specify)

— Removal of GM inflorescences before flowering (indicate the frequency of the removal)

— Removal of bolters/relatives/hybrid partners (indicate the frequency of the removal, x metres around the GM field, etc.)

— Other(s): (specify):.....

5.1.4. At the end of the release:

x Harvest/destruction methods (of crop or parts of it)/other means (e.g. sampling and analysis of sugar beet pulp) (describe) Harvest /destruction before the ripeness of the seeds

In the term of the harvest machinery was used for harvesting this trial only operated by trained stuff. Combine harvester was used, only grain was harvested. Crop residues were left on the trial site. Grains were immediately crushed and spread on the site of release.

x Effective removal of plant parts

All the plant parts (crop residues and crushed grain) were left on trial site and incorporated into the soil.

x Segregated storage and transport of crop/waste (provide example(s) of containment to prevent spillage of collected seeds/crops/wastes)

All the plant parts were left on trial site, no parts were transported out of the filed. Machinery used for in-filed transportation was cleaned at the end of the harvest.

x Clean up of machinery on the release site

All the machinery was cleaned up after the harvest. Cleaning was realised on the release site. Major attention was given to the machinery manipulating with whole (non-crushed) seeds – harvester, crusher.

x Destination of the waste, treatment of waste/surplus yield/plant residues (describe)

All the plant material including crushed seeds was left on release site and incorporated into the soil.

x Post-harvest treatment and cultivation measures on the release site (describe the method(s) for preparing and managing the release site at the end of the release, including cultivation practices)

Stubble tillage was applied immediately after the harvest. Deep ploughing later incorporated all the plant parts into the soil.

— Other(s): (describe).....

5.1.5. Post-harvest measures

Please indicate which measures were taken on the release site after the harvest:

Frequency of visits (average): due to late term of harvest (November) and unfavourable conditions for maize emergence and survival no other measures were taken after soil tillage. In following year site monitoring was realised in monthly intervals during vegetation period.

x Subsequent crop (specify)

Spring wheat.

x Crop rotation (specify)

Maize has been grown after cereal forecrop, subsequent crop also cereals.

— Fallow/no crop (specify)

x Superficial soil work/no deep ploughing

Stubble tillage after the harvest, followed by ploughing to incorporate crop residues.

— False-sowing beds

— Control of volunteers (specify intervals and duration)

— Appropriate chemical treatment(s) (specify)

— Appropriate soil treatment(s) (specify)

— Others (specify)

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

.....

.....

5.1.7. Emergency plan(s)

Indicate:

(a) if the release proceeded as planned:

x Yes

— No (describe for which reason, e.g. vandalism, climatic conditions, etc.)

.....

(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:

x No

— Yes (describe): .....

5.2. 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),

Yes.

— **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.

Specify:

— Monitoring measures within site

Duration: One year after GM maize growing.

Frequency of visits (average): Monthly during vegetation period.

— Observation of resistant relatives

— Observation of resistant insects

x Control of volunteers (specify intervals and duration)

Monitoring is focused on the occurrence of volunteer maize plants. In case of their occurrence they have to be uprooted, mechanically destroyed and left on the site for desiccation.

— Monitoring of gene flow (specify)

— Appropriate chemical treatment(s) and/or soil treatment(s)

— Others (specify)

— Monitoring measures of adjacent areas

Duration: One year after GM maize growing.

Frequency of visits (average): Monthly during vegetation period.

Area monitored: fields adjacent to release site.

— Observation of resistant relatives

— Observation of resistant insects

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

Monitoring is focused on the occurrence of volunteer maize plants. In case of their occurrence they have to be uprooted, mechanically destroyed and left on the site for desiccation.

— Monitoring of gene flow (specify)

— Appropriate chemical treatment(s) and/or soil treatment(s)

— Others (specify)

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

The aim of the release was to assess soil tillage technologies and mulch cover and their influence on maize yield and possible chemical weed management using HT technology. In spite of the fact that maize is widely grown in the Czech Republic and that glyphosate is one of the most frequently used herbicide active ingredient, no other negative effects to human health or to the environment compared to the conventional maize growing were expected.

Soil tillage used: conventional ploughing (CT), soil conservation – reduced tillage (RT)

Cover crop mulch: Crimson clover - *Trifolium incarnatum* (CC), Lazy phacelia – *Phacelia tanacetifolia* (PH), white mustard – *Sinapis alba* (YM), winter barley – *Hordeum sativum* (WB).
Herbicide treatments:
1. Maister (post) 150g.ha^{-1}+ Mero 1l.ha^{-1} BBCH 12-13
2. Split RR Roundup Rapid 2.4l.ha^{-1} BBCH 12-13 + Roundup Rapid 2.4l.ha^{-1} BBCH 17-18
3. TM RR Roundup Rapid 2.4l.ha^{-1} + Guardian Extra 2.6l.ha^{-1} EPOST (BBCH 12-13).

5.4. Observed effect(s)

5.4.1. Expected effect(s)

Average maize yield and differences between tested variants varied during trial duration. No significant yield reduction compared to conventional soil tillage and chemical weed management was found – see fig. 1 and 2.

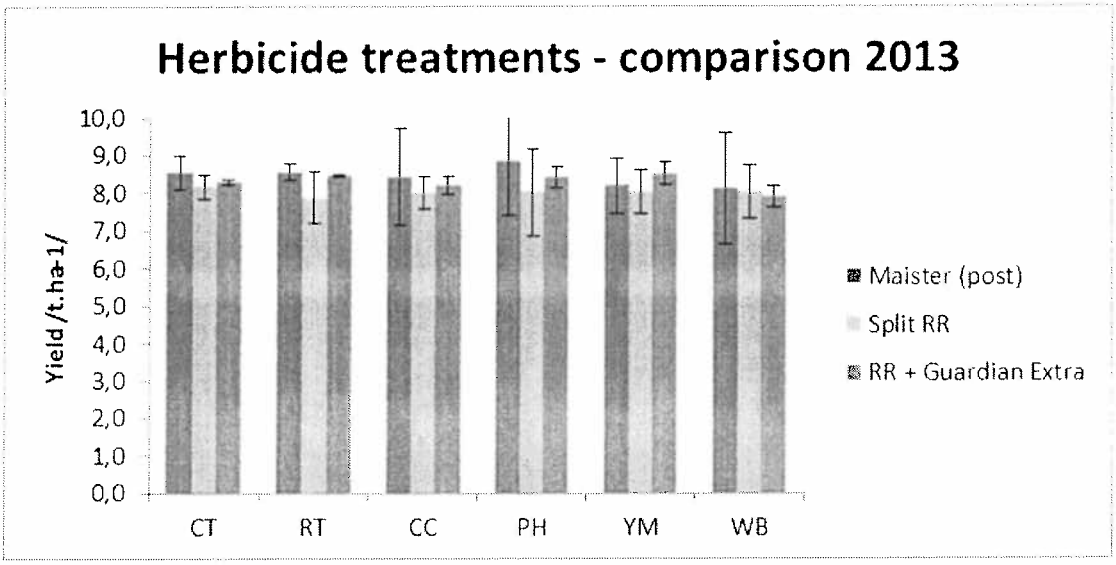

Fig. 1. – Maize yields of tested variants in 2013

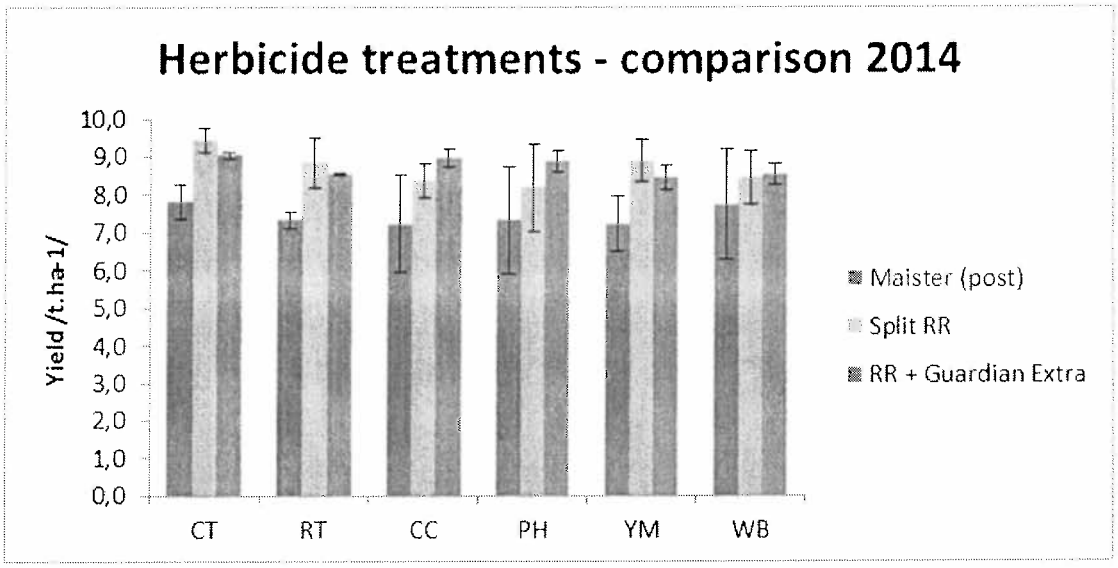

Fig. 2. – – Maize yields of tested variants in 2014

5.4.2. Unexpected effects ([5])

No unexpected effects were observed.

5.4.3. Other information

No other information related to possible risks was obtained.

([5]) Without prejudice to Article 8 of Directive 2001/18/EC as regards handling of modifications or new information

6. Conclusion

Release of genetically modified maize NK603 into the environment was realised according to the permission of Czech Ministry of Environment No. 79513/ENV/13 dated 4.11.2013. During the time of the release no harmful effects to the environment were observed.

DATE: 27.2.2015

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