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 88017 maize for the use in field trials in the Czech Republic

1. General information

1.1. European notification number: B/CZ/08/03

1.2. Member State of notification: Czech Republic

1.3. Date of consent and consent number. 4 December 2008, n. 89841/ENV/08

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 ([1]) used (if transformation event identity not available): MON 88017

Unique identifier, if available: 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))
Žabovřesky	2.500 m^2	7-10 plants/m2	Sowing : 11/5/2009 Destruction: 12/10/2009 Sowing : 10/6/2010 Destruction: 18/10/2010 Sowing : 6/5/2010 Destruction: 17/10/2010

([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

MON 88017 maize is approved in EU for food, feed, import and processing in accordance with Regulation (EC) No 1829/2003 (Commission Decision 2009/814/CE).

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 ☒

Evaluation of abundance of invertebrates in GM maize crop, comparisons with conventional maize, treated with standard agronomical practices.

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 used for feed and food, and 600 m from organic maize crop.

Seeds of MON 88017 maize were packed in double sealed bags and labelled as "Genetically modified organism" – MON-88Ø17-3. GM maize seed was transported by car.

Remaining seed was stored for use in next seasons or stored for late destruction.

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.

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 used for food and feed, (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:

2009: field trial was harvested/destroyed by forage chopper, biomass was spread on the field. Buffer rows were destroyed together with tested crop.
2010 and 2011: field trial was harvested/destroyed by forage chopper, biomass was destroyed in authorized biogas station at Dubne farm. Buffer rows were destroyed together with tested crop.

Trial crop residues (all maize crop in 2009), were destroyed on experimental site by their incorporation into the soil with help of ploughing. Fertilizers were used to support biodegradation of biomass.

The harvester (forage chopper) was cleaned before leaving the experimental field.

6.1.5. Post-harvest measures

All maize crop residues were incorporated into the soil by ploughing. The release site will be 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 are 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 will be performed after harvest of trial, in 2011 and 2012.

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 trial

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

— **Observation of resistant relatives** Not applicable

— **Observation of resistant insects** Not applicable

— **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.

— **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 trial

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

Area monitored: adjacent fields to MON 88017 trial.

— **Observation of resistant relatives** Not applicable

— **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, in case that volunteer plants are detected, these 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

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

During MON 88017 field release: general observations of plant health, sensitivity to diseases and pests, plant development. Evaluation of invertebrates species abundance. Any unexpected effects of MON 88017 shall be recorded.

After harvest/destruction of the trail: 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 88017 is negligible. It is concluded that MON 88017 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 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, used for food and feed, 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: 21 October 2011