

**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)

General information

1.1. European notification number: B/CZ/09/01

1.2. Member State of notification: Czech Republic

1.3. Date of consent and consent number:

Application number č.j.:1784/ENV/09, 22.4.2009

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 L.

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

Bt11 x MIR162 x MIR604 x GA21, Bt11 x MIR604 x GA21, Bt11 x GA21, MIR162
andMIR604

3.3. Unique identifier, if available:

SYN-BTØ11-1xSYN-IR162-4xSYN-IR6Ø4-5xMON-ØØØ21-9.

SYN-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9

SYN-BTØ11-1xMON-ØØØ21-9

SYN-IR162

SYN-IR6Ø4

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))
VÚP Troubsko: cadastral Popůvky, number of parcels - 709/1, number of square 600-1160, numberof soilblock 7002/5	2880m2/ 6480 m2	9 plants /m ²	Planting: 21.4.2009 Destruction: 2.11.2009
ZVÚ Kroměříž, s.r.o. Jarohněvice 237/1 a 236/1 Půdníblok 1806/5	1368m2/ 4320m2	7-8plants /m ²	Planting: 14.5.2009 Destruction: 27.10.2009
VÚRV Praha-Ruzyně, pokusná stanice Ivanovice naHané Pozemek 2412,2410	583m2/ 3888 m2	8plants /m2	Planting: 06.5.2009 Destruction: 15.11.2009
NutriVet, s.r.o. Pohořelice p.č.6383 KÚ PohořelicenadJihlavou	840m2/ 3802 m2	8plants /m2	Planting: 13.5.2009 Destruction:14.12.2009

In the table there is mentioned the GM surface/the whole trial area surface. The total surface of the release includes border rows, alleys and as appropriate, other genetically maize trials subject of other notifications within the surrounding borders.

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?

Unknown to date

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

The purpose of releasing GMHP into the environment was to find out agronomical data of the different genetic events of maize and find out biological efficacy and phytotoxicity of maize herbicides.

The purpose of the combined marketing of GM maize Bt11xMIR162xMIR604xGA21, Bt11xMIR604xGA21, Bt11xGA21, MIR162 and MIR604 in the environment field trials are:

1. Composite: for the production of maize Bt11xMIR162xMIR604xGA21, Bt11xMIR604xGA21, MIR162 and MIR604 benchmarking
2. Agronomy: in order to obtain further information on the agronomic characteristics of Bt11xMIR162xMIR604xGA21, Bt11xMIR604xGA21, MIR162 and MIR604 in Czech and European conditions
3. Efficiency: to obtain additional information regarding the performance of Bt11xMIR604xGA21 and Bt11xGA21 maize against target pests in Czech and European conditions

5.3. Official testing

Not applicable

5.4. Herbicide authorisation

Not applicable

5.5. Deliberate release(s) for demonstration purposes

Not applicable

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:

- Seeds of GM maize were packed in the closed bags up to planting. Bags were labelled as “GENETICALLY MODIFIED ORGANISM”. Additional labelling: “NOT FOR PLANTING, FOOD and FEED USE”, “NO TRANSFER BY UNAUTHORIZED PERSONS”. GM maize seed was transported by car in the same day as planting.
- Remains of seed (after sowing experiment) were destroyed by crushing after sowing the experimental area and buried at the experimental plot where conducted GM corn field

6.1.2. During the sowing/planting activities:

- Planting was carried out by microplot field trial planter, only in the Pohorelice site it was done by hand planter.
- Manipulations with seed material were done by authorized/trained staff only directly on experimental area.
- Planter was cleaned after field operation. Seed found in cleaning process was buried on experimental area.
- Remains of seed (after sowing experiment) were destroyed by crushing after sowing the experimental area and buried at the experimental area

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 were labelled (in all corners) by warning : “ATTENTION! GMO! DO NOT ENTER! NOT FOR FEED USE! TREATED BY CHEMICALS!”
- Where possible, sunflower was used as a bee attractive plant next to the trial area

6.1.4. At the end of the release:

- Harvest was done manually at Pohorelice, or with microplot combine at Ivanovice na Hané and Jarohněvice, or with a Farmer combine at Popuvky. Samples were taken in Ivanovice na Hané and Jarohněvice.
- Trials were usually harvested by special small plot maize harvester. Harvested grain was after determinations (yield, moisture) evenly scattered on the experimental plot. Buffer rows were destroyed together with tested crop.
- Trial crop residues (GM area and border rows) and harvested ground grain were destroyed on experimental sites by their incorporation into the soil with help of crushing and ploughing. Fertilizers were used to support biodegradation of biomass.
- The harvesters were cleaned before leaving the experimental field.

- The samples collected for analysis were hermetically packed at the site of release in a clearly labelled triple container and shipped to France for analysis.

6.1.5. Post-harvest measures

All remaining plants were crushed and buried on experimental area by stubble –tillage followed by deep tillage.

Different crop from maize was sown on the release site for one year following the trial and during that year, at time of vegetation period, potential volunteer plants were controlled by mechanical destruction.

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 monitoring plan for GM maize into the environment was implemented from the harvest of GM maize trials in 2009.

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 Bt11 x MIR162 x MIR604 x GA21,
Bt11 x MIR604 x GA21, Bt11 x GA21, MIR162 and MIR604 trial.

Frequency of visits (average):

Once per month during growing season by responsible persons.

— **Observation of resistant relatives**

No

— **Observation of resistant insects**

No

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

Once a month during growing season. In 2010 year in Kromeriz, Troubsko and Ivanovice any volunteers were not detected. At Pohorelice release site some volunteers were observed at a very early stage of development and were mechanically removed.

— **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

- the same as trial area

Duration:

Frequency of visits (average):

Area monitored:

— **Observation of resistant relatives**

— **Observation of resistant insects**

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

— **Monitoring of gene flow (specify)**

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

— **Others (specify)**

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

During the experimental cultivation of Bt11xMIR162xMIR604xGA21, Bt11xMIR604xGA21, Bt11xGA21, MIR162 and MIR604: observations of vegetation health, susceptibility to diseases and pests, plant growth and development were done. Any unexpected effects of Bt11xMIR162xMIR604xGA21, Bt11xMIR604xGA21, Bt11xGA21, MIR162 and MIR604 have been recorded.

After harvest/ destruction of trials to Bt11xMIR162xMIR604xGA21, Bt11xMIR604xGA21, Bt11xGA21, MIR162 and MIR604: monitoring of volunteers during the next year growing season.

6.4. Observed effect(s)

6.5. 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.

6.5.1. Expected effect(s)

No difference in growing or development of Bt11 x MIR162 x MIR604 x GA21, Bt11 x MIR604 x GA21, Bt11 x GA21, MIR162 and MIR604 with respect to their conventional counterparts has been recorded.

No adverse effects have been observed for human and animal health or the environment.

6.5.2. Unexpected effects

No unexpected effects have been recorded.

6.5.3. Other information

No other information.

Conclusion

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

Syngenta company for technical reasons stopped from 2010 up to end of releasing in the environment all activities in term of above mentioned Genetic Modified High Plants.

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.

Final report is submitted in collaboration with following institutes: VÚRV Praha, v.v.i., ZVÚ Kroměřížs.r.o., VÚP Troubsko a NutriVetPohořelice, s.r.o.

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