

Deliberate releases B/BE/10/V2

Final report

1. General information

1.1. European notification number

B/BE/10/V2

Two separate notification numbers were given to differentiate between the legal responsibilities of consent holder University of Ghent (B/BE/10/V1) and consent holder BASF Plant Science Company GmbH (B/BE/10/V2), while in practice this physically was one field trial.

1.2. Member state of notification

Belgium

1.3. Date of consent and consent number

4 March 2011, B/BE/10/V2

2. Report status

This is a final report.

3. Characteristics of the release

3.1. Scientific name of recipient organism

Solanum tuberosum ssp tuberosum (common name: potato)

The potatoes were modified to express natural resistance genes against late blight originating from wild relatives of potato.

3.2. Transformation event(s) (acronym(s)) or vectors used

Line number	Parent line	Construct	Resistance genes	Marker
A09-001	Désirée	pBINPLUS-sto1	<i>sto-1</i>	<i>npt-II</i>
A09-003	Désirée	pBINPLUS-sto1	<i>sto-1</i>	<i>npt-II</i>
A09-006	Désirée	pBINPLUS-sto1	<i>sto-1</i>	<i>npt-II</i>
A09-007	Désirée	pBINPLUS-sto1	<i>sto-1</i>	<i>npt-II</i>
A09-010	Désirée	pBINPLUS-sto1	<i>sto-1</i>	<i>npt-II</i>
A09-015	Désirée	pBINPLUS-sto1	<i>sto-1</i>	<i>npt-II</i>
A09-016	Désirée	pBINPLUS-sto1	<i>sto-1</i>	<i>npt-II</i>
A09-018	Désirée	pBINPLUS-sto1	<i>sto-1</i>	<i>npt-II</i>
A15-007	Désirée	pBINAW2-vnt1	<i>vnt-1.1</i>	-
A15-020	Désirée	pBINAW2-vnt1	<i>vnt-1.1</i>	-
A15-028	Désirée	pBINAW2-vnt1	<i>vnt-1.1</i>	-
A15-031	Désirée	pBINAW2-vnt1	<i>vnt-1.1</i>	-
A15-045	Désirée	pBINAW2-vnt1	<i>vnt-1.1</i>	-
A15-064	Désirée	pBINAW2-vnt1	<i>vnt-1.1</i>	-
A15-070	Désirée	pBINAW2-vnt1	<i>vnt-1.1</i>	-
A15-072	Désirée	pBINAW2-vnt1	<i>vnt-1.1</i>	-
A14-018	Désirée	pBINPLUS-vnt1-blb3-sto1	<i>sto-1 - vnt-1.1 - blb-3</i>	<i>npt-II</i>
A14-031	Désirée	pBINPLUS-vnt1-blb3-sto1	<i>sto-1 - vnt-1.1 - blb-3</i>	<i>npt-II</i>
A14-032	Désirée	pBINPLUS-vnt1-blb3-sto1	<i>sto-1 - vnt-1.1 - blb-3</i>	<i>npt-II</i>
A14-042	Désirée	pBINPLUS-vnt1-blb3-sto1	<i>sto-1 - vnt-1.1 - blb-3</i>	<i>npt-II</i>
A14-047	Désirée	pBINPLUS-vnt1-blb3-sto1	<i>sto-1 - vnt-1.1 - blb-3</i>	<i>npt-II</i>
A14-081	Désirée	pBINPLUS-vnt1-blb3-sto1	<i>sto-1 - vnt-1.1 - blb-3</i>	<i>npt-II</i>
A14-083	Désirée	pBINPLUS-vnt1-blb3-sto1	<i>sto-1 - vnt-1.1 - blb-3</i>	<i>npt-II</i>
A14-084	Désirée	pBINPLUS-vnt1-blb3-sto1	<i>sto-1 - vnt-1.1 - blb-3</i>	<i>npt-II</i>
A14-097	Désirée	pBINPLUS-vnt1-blb3-sto1	<i>sto-1 - vnt-1.1 - blb-3</i>	<i>npt-II</i>
A14-099	Désirée	pBINPLUS-vnt1-blb3-sto1	<i>sto-1 - vnt-1.1 - blb-3</i>	<i>npt-II</i>
TS-PH05-026-0048*	P880	VCPMA16	<i>blb-1 - blb-2</i>	<i>ahas</i>

*This line was only planted in the year 2011.

3.3. Unique identifier

The unique identifier for line TS-PH05-026-0048 is BPS-PH048-1. The other lines do not have a unique identifier.

3.4. Please provide the following information as well as the field(s) layout:

Geographical location(s)	Size of the release site(s) (m2)	Identity and amount of GM plants per event released	Duration of the release
2011			
Municipality of Wetteren	Including non-GM borders and reference lines approximately 1050 m2	Identity: See 3.2. Amount: 4 plants/m2	4 May to 21 September 2011
2012			
Municipality of Wetteren	Including non-GM borders and reference lines approximately 1300 m2	Identity: See 3.2 Amount: 4 plants/m2	6 June to 11 October 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?

In 2011 BASF Plant Science submitted an application according to 1829/2003 for cultivation, food and feed use of the GM potato line TS-PH05-026-0048 (application EFSA-GMO-UK-2011-102).

5. Type of deliberate release

Deliberate release for research purposes.

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 measures

6.1.1. Before planting

Measures such as appropriate packing and clear labeling were taken to preserve the correct identity of the GM potatoes and to prevent the spread or admixture of GM potatoes. The GM potatoes were planted on a site where no potatoes had been grown for many years in the past (nor will be in the next few years).

6.1.2. During planting activities

Same measures as before planting. Additionally all personnel involved in the planting of the GM potatoes received a compliance training. Potatoes were very carefully planted manually with verification of line number and plot location. There was no left-over planting material. All delivered GM tubers were planted.

6.1.3. During the period of release

The field trial plot was surrounded by a fence to prevent any unwanted trespassing and any unwanted harvesting of potatoes. Distance to other potato cultivation fields was at least 150m. There was a border of 4 rows of non-GM potato plants of the Nicola variety surrounding the GM potatoes. In 2011 the berries were picked in order to prevent the establishment of a GM potato seed bank in the soil. In 2012 the flowers were picked for the same reason.

6.1.4. At the end of the release

Potatoes were very carefully harvested manually and double packed and labeled before being removed from the site to a location licensed to stock GM potatoes. Harvested potatoes were inactivated by autoclaving. After harvest green parts of plants were carefully screened for remaining tiny tubers, and were left on the field to decompose. Tools were checked for any remaining tuber material.

The trial plot was superficially treated with a cultivator and left bare for one season. No deep-ploughing was applied.

6.1.5. Post-harvest measures

Field trial plots were left bare for one year to be able to spot volunteer potato plants very easily. Monitoring for volunteers took place regularly and volunteer potato plants were inactivated by applying a herbicide.

6.1.6. Other measures

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6.1.7. Emergency plan

After receiving concrete threats from activists to destroy the field trial on the 29th of May 2011, measures were taken to further secure the trial (in 2011). On the 29th of May 2011 armed police forces (86 police men and women) were present to try to prevent the destruction of the trial and to prevent any material being removed from the trial. The police was not able to prevent part of the trial being destroyed by activists. No GM material was removed from the trial. All GM material that was taken out from the soil was recovered from the trial site and the identity of that material was confirmed by PCR. The trial was reinstated for the largest part (by reintroducing non-GM reference plants) and was able to continue.

In 2012 the field trial passed according to plan without any disturbances.

6.2. Post-release monitoring measures

The post-release monitoring measures will continue in 2013. In 2012 post-release monitoring took place on the 2011 trial plot location, resulting in the detection of five volunteer potato plants which were destroyed by applying a herbicide.

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

During the field trial the plot was visited at least twice a month to check on the general situation of the trial and the health of the potatoes. In the period of July, August and September there was a weekly monitoring of the potatoes to score whether or not, and how much they were affected by late blight (*Phytophthora infestans*). For this a Euroblight scoring system was used. In the season after the release the trial plot is being monitored bi-weekly to check on any potato volunteers appearing. This post-harvest monitoring is still ongoing and will continue until two succeeding seasons no potato volunteers have been found anymore.

6.4. Observed effects

There were no observations providing any indications of risks for human health or the environment.

6.4.1. Expected effects

The genetically modified potatoes that carried one or more resistance genes against late blight all proved to be much less susceptible to late blight than non-resistant reference varieties. One line of GM potatoes showed a minor phenotypical alteration of the appearance of the plant in comparison with the parent plant. This is not unexpected, as it is known that tissue culture and/or genetic modification can lead to such effects. Potato is also known to be very vulnerable to somaclonal variation. The elimination of plants showing such alterations is a normal part of plant breeding.

6.4.2. Unexpected effects

There were no unexpected effects observed. Disease vulnerability other than the vulnerability to late blight did not appear to be affected. No differences with regard to interactions with insects were detected.

6.4.3. Other information

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7. Conclusion

The field trial proved the functionality of natural resistance genes against late blight when introduced into cultivated potato. And even though the field trial was attacked in 2011 and part of the trial was destroyed, no genetically modified potato plants were removed from the trial plot. There are no indications of any impacts on human health or the environment resulting from the field trial. The monitoring on volunteers confirmed that even after careful harvesting some tubers can remain in the soil and give rise to volunteer plants in the following year. A monitoring plan is in place to detect and inactivate any volunteers to make sure that no GM potato plants remain and can give rise to spread of GM material.

Date: 11 February 2013