

PART 2 (COUNCIL DECISION 2002/813/EC)

SUMMARY NOTIFICATION INFORMATION FORMAT FOR THE RELEASE OF
GENETICALLY MODIFIED HIGHER PLANTS
(ANGIOSPERMAE AND GYMNOSPERMAE)

In order to tick one or several possibilities, please use crosses (meaning x or X) into the space provided as (.)

A. General information

1. Details of notification

- (a) Notification number IM 11-005
- (b) Date of acknowledgement of notification ..!./....
- (c) Title of the project Application for the release into the environment of potato lines with improved resistance to *Phytophthora infestans* according to the Genetically Modified Organisms Decree, 2012 - 2018
- (d) Proposed period of release From 2012 until 2018

2. Notifier

- (a) Name of institute or company: BASF Plant Science Company GmbH
Carl-Bosch-Strasse 38
D-67056 Ludwigshafen
Germany

3. Is the same GMPT release planned elsewhere, inside or outside the Community [in conformity with Article 6(1)] by the same notifier?

Yes (X) No (.)

If yes, insert the country code(s): DE, SE

Please use the following country codes:

Austria AT; Belgium BE; Germany DE; Denmark DK; Spain ES; Finland FI; France FR; United Kingdom GB; Greece GR; Ireland IE; Iceland IS; Italy IT; Luxembourg LU; Netherlands NL; Norway NO; Portugal PT; Sweden SE

4. Has the same GMPT been notified for release elsewhere, inside or outside the Community, by the same notifier?

Yes (X) No ()

If yes, notification number(s):

B/NL/05/036, B/NL/07/07, B/SE/05/8615, B/DE/05/174, B/DE/06/183,
B/DE/07/191,

B/CZ/07/01, B/GB/06/R42/01

B. Information of the genetically modified plant

1. Identity of the recipient or parental plant

- | | | |
|-----|--|---------------------|
| (a) | Family name | <i>Solanaceae</i> |
| (b) | Genus | <i>Solanum</i> |
| (c) | Species | <i>S. tuberosum</i> |
| (d) | Subspecies (if applicable) | <i>tuberosum</i> |
| (e) | Cultivar/breeding line (if applicable) | P880 |
| (f) | Common name | Potato, Aardappel |

2. Description of the traits and characteristics which have been introduced or modified, including marker genes and previous modifications
- improved resistance to *Phytophthora infestans*
 - marker gene *ahas* (tolerance to Imidazolinones) as selection gene to identify transgenic cells in tissue culture

3. Type of the genetic modification

- | | | |
|-----|-------------------------------|-----|
| (a) | Insertion of genetic material | (X) |
| (b) | Deletion of genetic material | (.) |
| (c) | Base substitution | (.) |
| (d) | Cell fusion | (.) |
| (e) | Other, specify | ... |

4. In the case of insertion of genetic material, give the source and intended function of each constituent fragment of the region to be inserted

- T-DNA borders, pTiT37, from *Arabidopsis thaliana* for stable incorporation into plant chromosome.

- acetohydroxyacid synthase gene (*ahas*, EC 2.2.1.6, 2013 base pairs, mutation S653N) from *Arabidopsis thaliana*, conferring imidazolinone tolerance in plant material.

-Promoter and terminator from nopaline synthase gene, *Agrobacterium tumefaciens*, gene regulation.

-Resistance genes *Rpi-blb1* and *Rpi-blb2* from *Solanum bulbocastanum*, with endogenous promoters and terminators for improved resistance to *Phytophthora infestans*.

5. In the case of deletion or other modification of genetic material, give information on the function of the deleted or modified sequences
...
6. Brief description of the method used for the genetic modification

Plasmid-derived DNA was introduced into the potato lines by *Agrobacterium*-mediated gene transfer technology
7. If the recipient or parental plant is a forest tree species, describe ways and extent of dissemination and specific factors affecting dissemination
...

C. Information relating to the experimental release

1. Purpose of the release (including any relevant information available at this stage) such as agronomic purposes, test of hybridisation, changed survivability or dissemination, test of effects on target or non-target organisms
 - Produce seed potatoes for future trials
 - Produce plant material for further analyses
 - Investigate the general agricultural value of the modified lines
2. Geographical location of the release site
The experimental fields will be located in the community of Steenberg (province Noord-Brabant)
3. Size of the site (m²)
The maximum area for the release will be 10.000 m².
4. Relevant data regarding previous releases carried out with the same GM-plant, if any, specifically related to the potential environmental and human health impacts from the release

Except the better resistance against *Phytophthora infestans* there were no deviations of the GM potato lines in comparison to the non-GM plots. During these trials no unforeseen effects as compared to conventional potato varieties have been observed.

D. Summary of the potential environmental impact of the release of the GMPTs in accordance with Annex II, D2 to Directive 2001/18/EC

Note especially if the introduced traits could directly or indirectly confer an increased selective advantage in natural environments; also explain any significant expected environmental benefits

The genetically modified potato lines contain two NBS-LRR-genes, *Rpi-blb1* and *Rpi-blb2*, from *Solanum bulbocastanum* for conferring improved resistance to *Phytophthora infestans*. Many conventional potato varieties also contain additional NBS-LRR-genes that have been introgressed from wild *Solanum*

species. An intended effect of the introduced trait is an increased survivability in potato fields exposed to *P. infestans*. This possible selective advantage, however, is of importance only in the agricultural field, and will not improve the survivability in the surrounding environment. The reduced need for fungicides on these lines can easily be identified as an environmental benefit.

The *ahas* gene expressed in the potato plants imparts tolerance to the herbicidal active substance Imazamox to the shoots during the selection process in cell culture. This confers no selective advantage in the field since Imidazolinone herbicides are not approved for use on crops in NL and since no field tolerance is expected in the potato plants. No difference with respect to persistence in agriculturally utilised habitats or invasiveness into natural habitats as compared to conventional potato varieties is expected. Through the measures which are taken during the release, distance from or absence of conventionally cultivated potatoes or wild species, the possibility of any gene transfer can be virtually ruled out. Even in the very improbable event that pollen were to be transferred to genetically unmodified potato plants, no consequences are to be expected, since potato propagation conventionally takes place via tubers and not via seeds. The interactions of the genetically modified potato line with non-target organisms and the effects resulting from this will be comparable to those with conventional potato varieties. Furthermore, no toxic or allergenic effects are expected on the basis of the improved resistance to *P. infestans* or the expressed AHAS protein. No effects on biogeochemical processes are expected, other than those that apply also to conventional potatoes.

E. Brief description of any measures taken by the notifier for the control of risks including isolation designed to limit dispersal, for example for monitoring and post-harvest monitoring proposals

- a distance to other commercially grown potatoes of 10 m will be kept
- transportation in closed containment
- careful harvest to avoid volunteers
- destruction of waste material
- no potato crop for the following year to allow volunteer monitoring
- the year following the field trial emerging volunteers will be destroyed by mechanical or herbicide treatment

F. Summary of planned field trials designed to gain new data on the environment and human health impact of the release (where appropriate)