Application for Authorisation of Phytophthora Resistant Potato PH05-026-0048 for Food and Feed Uses, Processing and Cultivation according to Regulation (EC) No 1829/2003

Unique Identifier BPS-PHØ48-1

Part VII Summary

1. GENERAL INFORMATION

1.1. Details of application

a)	**Member State of application** United Kingdom
b)	**Application number** Not available at time of application.
c)	**Name of the product (commercial and other names)** The product is PH05-026-0048 potato. The unique identifier is BPS-PHØ48-1.
d)	**Date of acknowledgement of valid application** Not available at time of application.

1.2. Applicant

a)	**Name of applicant** BASF Plant Science Company GmbH
b)	**Address of applicant** Carl-Bosch-Str. 38 D-67056 Ludwigshafen Germany
c)	**Name and address of the representative of the applicant established in the Union (if applicant is not established in the Union)** The applicant for PH05-026-0048 potato is established in the European Union.

1.3. Scope of the application

a) GM food
   [x] Food containing or consisting of GM plants
   [x] Food produced from GM plants or containing ingredients produced from GM plants
b) GM feed
   [x] Feed containing or consisting of GM plants
   [x] Feed produced from GM plants
c) GM plants for food or feed use
   [x] Products other than food and feed containing or consisting of GM plants with the exception of cultivation
   [x] Seeds and plant propagating material for cultivation in Europe

All specified uses for PH05-026-0048 potato indicated in this scope refer to the same uses as for any other conventional potato variety. The scope does not include progeny of PH05-026-0048 potato obtained via conventional breeding.

1.4. Is the product or the uses of the associated plant protection product(s) already authorised or subject o another authorisation procedure within the Union?

Yes [ ]	No [x]

1.5. Has the GM plant been notified under Part B of Directive 2001/18/EC?

Yes [x]	No [ ]

1.6. Has the GM plant or derived products been previously notified for marketing in the Community under Part C of Directive 2001/18/EC?

Yes [ ]	No [x]

1.7. Has the product been notified/authorised in a third country either previously or simultaneously?

Yes [ ]	No [x]

1.8. General description of the product

a) Name of the recipient or parental plant and the intended function of the genetic modification

Phytophthora resistant potato PH05-026-0048 was developed by Agrobacterium-mediated transformation of the potato variety Fontane with two resistance genes, *Rpi-blb1* and *Rpi-blb2*, isolated from the wild potato *Solanum bulbocastanum*. The expression of both genes imparts broad-spectrum resistance to late blight disease caused by the oomycete, *Phytophthora infestans*. The *csr1-2* gene encoding acetohydroxyacid synthase from *Arabidopsis thaliana* was included in the transformation process as a marker conferring tolerance to imidazolinone herbicides during selection in tissue culture.

b) Types of products planned to be placed on the market according to the authorisation applied for and any specific form in which the product must not be placed on the market (seeds, cut-flowers, vegetative parts, etc.) as a proposed condition of the authorisation applied for

The scope of the application comprises the cultivation of PH05-026-0048 potato, processing and all uses of the product for food, feed, non-food and non-feed purposes as applicable for any conventional potato variety.

c) Intended use of the product and types of users

PH05-026-0048 potato will be grown in the European Union. The intended use of the product and the types of users will be as for any conventional potato variety.

d) Any specific instructions and/or recommendations for use, storage and handling, including mandatory restrictions proposed as a condition of the authorisation applied for

PH05-026-0048 potato will be used, stored, and handled as is currently done for any conventional potato variety. No mandatory restrictions during use, storage or handling are proposed as a condition of the authorisation.

e) If applicable, geographical areas within the EU to which the product is intended to be confined under the terms of the authorisation applied for

PH05-026-0048 potato is suitable for cultivation in all those geographical regions of the European Union that grow conventional potatoes.

f) Any type of environment to which the product is unsuited

PH05-026-0048 potato is suitable for cultivation in all types of environments where conventional potatoes are grown.

g) Any proposed packaging requirements

PH05-026-0048 potato and products will be packaged as any other conventional potato product.

h) Any proposed labelling requirements in addition to those required by law and when necessary a proposal for specific labelling in accordance with Articles 13(2), (3) and 25(3) of Regulation (EC) No 1829/2003. In the case of GMOs plants, food and/or feed containing or consisting of GMO plants, a proposal for labelling has to be included complying with the requirements of Annex IV, A(8) of Directive 2001/18/EC

According to Regulations (EC) 1829/2003 and (EC) 1830/2003 operators handling or using foods and feeds produced from PH05-026-0048 potato are required to be aware of the legal obligations regarding traceability and labelling. The applicant will communicate such obligations to all parties involved. Processing of PH05-026-0048 potato results in food and feed products. These will be labelled according to Regulation (EC) 1829/2003 with “produced from genetically modified potato” or “contains genetically modified potato”. No additional labelling in addition to the GM labelling requirements foreseen in regulations (EC) 1829/2003 and 1830/2003 is proposed.

i) Estimated potential demand

(i) In the Union: The demand will be in the range of the demand for any conventional newly developed potato variety that is especially suitable for processing into e.g. French fries, and provides for broad-spectrum resistance against late blight caused by *P. infestans*.
(ii) In export markets for EU supplies: The demand will be similar to the demand for food or feed products from any newly developed potato variety that is especially suitable for processing into e.g. French fries.

j) Unique identifier in accordance with Regulation (EC) 65/2004

In accordance with Commission Regulation (EC) 65/2004 and the OECD guidance for the designation of a unique identifier for transgenic plants (ENV/JM/MONO(2002)7), the unique identifier is BPS-PHØ48-1.

1.9. Measures suggested by the applicant to take in case of unintended release or misuse as well as measures for disposal and treatment

Based on the conclusions of the risk assessment, no special measures need to be taken in case of unintended release or misuse or for disposal and treatment.

In the case of unintended release or misuse of to PH05-026-0048 potato, mechanical means or selective use of herbicides can be employed to control PH05-026-0048 potato like any other conventional potato.

2. INFORMATION RELATING TO THE RECIPIENT OR (WHERE APPROPRIATE) PARENTAL PLANTS

2.1. Complete name

a) Family name *Solanaceae*
b) Genus *Solanum*
c) Species *tuberosum*
d) Subspecies *tuberosum*
e) Cultivar/breeding line or strain Fontane
f) Common name Potato

2.2. Geographical distribution and cultivation of the plant, including the distribution within the Union

The origin of potato lies in two areas in South America, the high Andes from eastern Venezuela to northern Argentina and the lowlands of south-central Chile. The potato was first introduced in Europe in 1567 and spread from there worldwide. Potato is cultivated across Europe and is considered one of the most important crop plants globally. Wild related species, *Solanum nigrum* and *Solanum dulcamara*, are found throughout Europe, but efficient incompatibility barriers prevent hybridization with *Solanum tuberosum*.

2.3. Information concerning reproduction (for environmental safety aspects)

(i) Mode(s) of reproduction

Potato reproduces mainly vegetatively via tubers, known as seed tubers or seed potatoes. Reproduction is also possibly sexually via botanical seed (true seed). Under field conditions selfing is most likely, however the majority of cultivated potato varieties show reduced pollen fertility or even pollen sterility. A frequently observed phenomenon is shedding of flowers after pollination, so that no berries or seed develop. Thus flower formation does not in all cases lead to the formation of potato berries and berry development might be rare.

(ii) Specific factors affecting reproduction

Tubers can persist in the soil, however under European conditions plants rapidly become infected with a range of viral and fungal diseases. Due to sensitivity to frost, the survival of tubers also depends upon winter temperatures.

(iii) Generation time

Potato is a perennial plant which in Europe is grown annually from vegetative tubers. Due to unfavourable climatic conditions and disease pressure the generation time of potato is one year.

2.4. Sexual compatibility with other cultivated or wild plant species (for environmental safety aspects)

Commercially cultivated potatoes are compatible with other cultivated potato varieties. The tetraploid *S. tuberosum* is not compatible with the wild related species *S. nigrum* and *S. dulcamara* occurring in Europe.

2.5. Survivability (for environmental safety aspects)

a) Ability to form structures for survival or dormancy

Potatoes may survive as tubers or as seeds in the soil.

b) Specific factors affecting survivability

Under European conditions tubers persist poorly in cold, wet soils and plants become rapidly infected with a range of fungal and viral diseases. Tubers are generally frost sensitive and are destroyed by a frost period of 25 hours at -2 °C or a frost period of five hours at -10 °C. True seeds overwinter regardless of temperature.

2.6. Dissemination (for environmental safety aspects)

a) Ways and extent of dissemination

Potato is mainly self-pollinating. The pollen, if present, may be deposited by bumblebees in the immediate surroundings of the pollen source. Pollen dispersal via wind is also possible and may lead to minimal dispersal of pollen beyond the immediate vicinity of the potato field. Dissemination of tubers and true seed, if present, is normally limited to the area of cultivation.

b) Specific factors affecting dissemination
The extent of pollen dispersal in potato is related to the species, availability of insect pollinators, weather conditions and the fertility of the cultivar. Tubers may spread during transportation and handling, but in general derived plants will not establish themselves due to unfavourable environmental conditions, such as frost during winter, fungal and viral diseases and other species' competition.

2.7. Geographical distribution within the Union of the sexually compatible species (for environmental safety aspects)

Commercially cultivated potatoes are compatible with other cultivated potato varieties. Potatoes are normally grown in all member states of the European Union. The tetraploid *S. tuberosum* is not compatible with the wild related species *S. nigrum* and *S. dulcamara* occurring in Europe.

2.8. In the case of plant species not normally grown in the Member State(s), description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts (for environmental safety aspects)

Potatoes are normally grown in all member states of the European Union.

2.9. Other potential interactions, relevant to the GM plant, of the plant with organisms in the ecosystem where it is usually grown, or used elsewhere, including information on toxic effects on humans, animals and other organisms (for environmental safety aspects)

Potato like every other plant is known to interact with other organisms in the environment including microorganisms, viruses, insects, birds, and mammals. Potato is susceptible to a range of pests and diseases. There are some compounds in potato that are not favourable for human or animal nutrition, such as glycoalkaloids and protease inhibitors. Processing methods applied to potato are well known and have a long history of safe use.

3. MOLECULAR CHARACTERISATION

3.1. Information relating to the genetic modification

a) Description of the methods used for the genetic modification

PH05-026-0048 potato was produced via Agrobacterium-mediated transformation of potato leaf tissue.

b) Nature and source of the vector used

A binary vector derived from pPZP200 was used for the transformation of the potato tissue.

c) Source of donor DNA used for transformation, size and intended function of each constituent fragment of the region intended for insertion

The T-DNA fragment in plasmid VCPMA16 contains two gene cassettes to confer the resistance against late blight: (i) *Rpi-blb1* promoter from *S. bulbocastanum* (1173 bp), *Rpi-blb1* coding sequence from *S. bulbocastanum* (3592 bp), *Rpi-blb1* terminator from *S. bulbocastanum* (406 bp); (ii) *Rpi-blb2* promoter from *S. bulbocastanum* (1545 bp), *Rpi-blb2* coding sequence from *S. bulbocastanum* (3890 bp), *Rpi-blb2* terminator from *S. bulbocastanum* (2530 bp). In addition, the T-DNA fragment contains the *csr1-2* gene (2013 bp) from *Arabidopsis thaliana*, which encodes a mutant acetohydroxyacid synthase (S653N) and is flanked by the nopaline synthase promoter (288 bp) and terminator (253 bp) from *Agrobacterium tumefaciens*. The T-DNA in VCPMA16 has a size of 16,363 bp and is delimited by pTiT37 right and left T-DNA border regions originating from *A. tumefaciens.*

3.2. Information relating to the GM plant

3.2.1. Description of the trait(s) and characteristics which have been introduced or modified

Phytophthora resistant potato PH05-026-0048 was developed by Agrobacterium-mediated transformation of the potato variety Fontane with two resistance genes, *Rpi-blb1* and *Rpi-blb2*, isolated from the wild potato *S. bulbocastanum*. The protein products encoded by the resistance genes, BLB1 and BLB2 proteins, impart broad-spectrum resistance to late blight caused by the oomycete, *P. infestans*. The *csr1-2* gene encoding acetohydroxyacid synthase from *A. thaliana* was included in the transformation process as a marker conferring tolerance to imidazolinone herbicides during selection in tissue culture.

3.2.2. Information on the sequences actually inserted or deleted

a) The copy number of all detectable inserts, both complete and partial

The T-DNA derived from plasmid VCPMA16 was integrated at a single locus and as a single copy in the potato genome.

No DNA sequences other than those derived from the T-DNA of the plasmid VCPMA16 were integrated into the PH05-026-0048 potato genome. Southern blot analyses clearly indicated that no elements derived from the backbone of the plasmid either linked or unlinked to the insert were detected in the genome of PH05-026-0048 potato.

b) In case of deletion(s), size and function of the deleted region(s)

PH05-026-0048 potato was obtained via insertion of a plasmid-derived T-DNA fragment. Deletions of the genomic potato DNA were not intended in order to obtain the desired trait.

c) Sub-cellular location(s) of insert(s) (nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination

The insert of PH05-026-0048 potato was integrated into the nuclear genome of potato. The integration of the insert was confirmed by Southern blot, PCR, and DNA sequence analyses.

d) The organisation of the inserted genetic material at the insertion site

The insert in PH05-026-0048 potato comprises a single functional copy of the *Rpi-blb1* gene cassette, the *Rpi-blb2* gene cassette and the *csr1-2* gene cassette as revealed by Southern blot and DNA sequence analyses of the insert and the flanking genomic potato DNA.

e) In case of modifications other than insertion or deletion, describe function of the modified genetic material before and after the modification as well as direct changes in expression of genes as a result of the modificaiton

Not applicable.

3.2.3. Information on the expression of the insert

a) Information on developmental expression of the insert during the life cycle of the plant

The expression levels of the BLB1, BLB2 and AtAHAS (acetohydroxyacid synthase) proteins were determined by enzyme-linked immunosorbent assay using specific antibodies. The levels of BLB1 and BLB2 proteins, encoded by the *Rpi-blb1* and *Rpi-blb2* genes, were not detectable at any of the growth stages in the tissues analyzed. The expression of the AHAS protein was detectable but not quantifiable at the developmental stages analyzed.

b) Parts of the plant where the insert is expressed

The expression levels of the BLB1, BLB2 and AtAHAS proteins were determined in leaves, roots, flowers, developing and mature tubers, pollen, berries, and whole plants. The BLB1 protein was only detectable but not quantifiable in mature tubers, and non-detectable in all other tissues. The BLB2 protein was non-detectable in any of the tissues analyzed. The AHAS protein was detectable but not quantifiable in the tissues analyzed. The endogenous potato AHAS protein could not be distinguished from the newly expressed Arabidopsis AHAS protein by the detection method employed, thereby indicating an extremely low expression level for this protein in PH05-026-0048 potato.

3.2.4. Genetic stability of the insert and phenotypic stability of the GM plant

The genetic stability of the insert in PH05-026-0048 potato was demonstrated across multiple generations of vegetatively propagated material by Southern blot analyses.

The phenotypic stability of potato was confirmed by the stable low expression of the BLB1 and BLB2 proteins across multiple locations and years, and the stability of the trait of Phytophthora resistance across multiple locations.

3.2.5. Information (for environmental safety aspects) on how the GM plant differs from the recipient plant in

a) Mode(s) and/or rate of reproduction

No changes in the reproduction characteristics compared to the mother variety Fontane have been observed in the agronomic and phenotypic assessments for PH05-026-0048 potato.

b) Dissemination

No changes in the dissemination characteristics compared to the mother variety Fontane have been observed in the agronomic and phenotypic assessments for PH05-026-0048 potato.

c) Survivability

No changes in the survival characteristics compared to the mother variety Fontane have been observed in the agronomic and phenotypic assessments for PH05-026-0048 potato.

d) Other differences

Throughout the field trials conducted over two growing seasons at multiple locations PH05-026-0048 potato did not show any biologically relevant changes in agronomic or phenotypic characteristics when compared to the mother potato variety Fontane or conventional potato varieties in the same trials.

3.2.6. Any change to the ability of the GM plant to transfer genetic material to other organisms (for environmental safety aspects)

a) Plant to bacteria gene transfer

The horizontal gene transfer of intact genes from PH05-026-0048 potato into bacteria and the expression of the genetic information encoded by them would involve complex processes that need several steps all having an extremely low probability of occurrence.

As demonstrated by Southern blot analyses no genetic elements other than those derived from the T-DNA in plasmid VCPMA16 that could affect the mobility of DNA have been inserted into PH05-026-0048 potato. Therefore no changes, as compared to commercial potato varieties, are expected in the ability of PH05-026-0048 potato to transfer genetic material to bacterial.

b) Plant to plant gene transfer

Potato reproduces mainly vegetatively via tubers, though reproduction is also possible sexually via true seeds. *S. tuberosum* is not compatible with the wild related species *S. nigrum* and *S. dulcamara*, therefore any cross pollination or plant to plant gene transfer would only be possible to commercial potato varieties.

Genetic material can only be transferred to other potato varieties by pollen. No changes in flower morphology have been observed for PH05-026-0048 potato. Therefore no changes compared to conventional potatoes regarding the transfer of genetic material to other potatoes are expected.

4. COMPARATIVE ANALYSIS

4.1. Choice of the conventional counterpart and additional comparators

The mother potato variety Fontane with a history of safe use served as comparator in the safety studies. In addition, multiple conventional potato varieties were included throughout the two growing seasons as references, and to establish the range of natural variability.

4.2. Experimental design and statistical analysis of data from field trials for comparative analysis

Field trials with PH05-026-0048 potato were conducted in the 2009 and 2010 growing seasons at locations in the European Union representative for areas of commercial potato cultivation. At all trial locations, the plants were grown under standard agronomic practices in a complete randomized block design in four replicates.

4.3. Selection of material and compound for analysis

The selection of the key nutrients and antinutritional substances of potato analyzed as part of the comparative safety assessment was based upon the consensus document for potato prepared by OECD. A total of 49 components were analyzed in the tuber samples, including proximates, fiber, fructose, glucose, sucrose, starch, vitamin C, minerals, amino acids, fatty acids, and antinutrients.

4.4. Comparative analysis of agronomic and phenotypic characteristics

Agronomic and phenotypic characteristics of PH05-026-0048 potato in comparison to the mother variety Fontane and conventional potato varieties were recorded in field trials over two growing seasons at multiple locations in the European Union. The characteristics evaluated included growth habit, frequency of flowers, and frequency of fruits. In addition various plant development parameters were assessed like days to and uniformity of emergence, crop vigor, plant stand uniformity, day to flowering and the growth stage at haulm killing prior to harvest. Further, agronomic parameters measured comprised plant height, and tuber yield. The focus of the disease and pest evaluation was on virus infection, incidence of potato soft rot bacteria, Colorado potato beetle infection as well as the severity of late blight disease caused by *P. infestans*. In addition, the tubers were evaluated for resistance to wart disease.

4.5. Effect of processing

Standard processing methods were applied to the production of e.g. French fries from PH05-026-0048 potato. The composition of the derived processed fractions was determined. In addition the presence of the BLB1, BLB2 and AHAS proteins in the potato products i.e. French fries derived from PH05-026-0048 potato was determined. The results of the analyses demonstrated that the BLB1, BLB2 and AHAS proteins are not detectable.

5. TOXICOLOGY

a) Toxicological testing of newly expressed proteins

The newly expressed proteins in PH05-026-0048 potato, BLB1, BLB2 and AHAS were assessed for their safety.

- The source organisms of the proteins are *S. bulbocastanum* and A. *thaliana*, which are not known to be pathogenic to humans or animals nor are they known to be the source of toxic proteins.
- The BLB1, BLB2 and AHAS proteins do not share sequence homology with known protein toxins.
- The BLB1 protein is present in tubers of wild potatoes that have been consumed by Native Americans. The BLB2 protein is contained in two commercially cultivated potato varieties in the EU, which have been consumed safely. Both proteins share high sequence identity with resistance proteins present in all crop species. The AHAS protein is ubiquitous in plants and is not known to be toxic. There has been a long history of safe production of crops containing the AHAS enzyme with the same S653N amino acid substitution, as that in the *csr1-2* gene encoded AHAS present in PH05-026-0048 potato.
- The expression levels of all three newly expressed proteins are considered negligible.

The results from the safety evaluation demonstrate that the BLB1, BLB2 and Arabidopsis AHAS enzyme can be regarded as safe.

b) Testing of new constituents other than proteins

The trait introduced into PH05-026-0048 potato is the increased resistance against Phytophthora. The *csr1-2* gene encoded AHAS enzyme from Arabidopsis confers tolerance to imidazolinone herbicides during selection in tissue culture. Thus no novel constituents other than proteins are formed.

c) Information on natural food and feed constituents

The results of the comparative compositional analysis for PH05-026-0048 potato revealed that though statistically significant differences were identified for some of the components, those were not consistent across years and remained well within the ranges of natural variation for conventional potato varieties. PH05-026-0048 is equivalent to the mother variety Fontane and comparable to other conventional potato varieties.

d) Testing of the whole GM food/feed

Based on the results of the comparative compositional analysis performed no hazards were identified and therefore no testing of the whole food or feed was indicated.

6. ALLERGENICITY

a) Assessment of allergenicity of the newly expressed protein

The newly expressed proteins in PH05-026-0048 potato BLB1, BLB2 and AtAHAS were assessed for their allergenic potential.

- The source organisms of the proteins are *S. bulbocastanum* and *A. thaliana*, which are not known to have allergenicity potential.
- Bioinformatics analyses did not provide any indication of potential allergenicity. The BLB1, BLB2 and AtAHAS proteins do not share potentially immunologically relevant amino acid sequence segments or structure with know allergens.
- The BLB1 and BLB2 proteins very homologous to resistance proteins present in all plants and are not known to be allergenic.
- The AHAS protein is ubiquitous in plants and is not known to be allergenic.
- The BLB1, BLB2 and AtAHAS proteins are rapidly digested in simulated mammalian gastric (SGF) as well as intestinal fluids (SIF), similar to conventional dietary proteins in food products.

These results demonstrate that the BLB1, BLB2 and AHAS proteins lack any characteristics of allergenic proteins and are as safe as other proteins present in conventional crops with a history of safe use.

b) Assessment of allergenicity of the whole GM plant

Potatoes have a history of safe use in human food and animal feed, and in general, are not considered a source of allergens. PH05-026-0048 potato does not express any new proteins with allergenic characteristics.

7. NUTRITIONAL ASSESSMENT

a) Nutritional assessment of GM food

The compositional equivalence of PH05-026-0048 potato as compared to its mother potato variety Fontane and other conventional potato varieties was demonstrated by the analysis of key nutrients and antinutrients. PH05-026-0048 potato is as nutritious as the mother variety Fontane and other conventional potato varieties.

b) Nutritional assessment of GM feed

Please refer to Point above.

8. EXPOSURE ASSESSMENT – ANTICIPATED INTAKE/EXTENT OF USE

PH05-026-0048 potato is intended to be used as any other commercial potato variety. The PH05-026-0048 potato and derived food and feed as well as non-food and non-feed products are expected to replace a portion of similar products derived from conventional potato varieties.

9. RISK CHARACTERISATION FOR THE SAFETY ASSESSMENT OF GM FOOD AND FEED

The scientific evaluation of the characteristics of PH05-026-0048 potato as part of the food and feed safety assessment did not reveal any potential adverse effects or hazards for human or animal health. In the context of the intended uses and taking into account the anticipated exposure of food and feed products derived from PH05-026-0048 potato the risk to human or animal health is determined to be negligible. The conclusions of the comprehensive molecular characterization, compositional, toxicological and nutritional assessment indicate that the food and feed derived from PH05-026-0048 potato is as safe and as nutritious as food and feed derived from its conventional comparator and other conventional potato varieties with a history of safe use.

10. POST-MARKET MONITORING ON GM FOOD/FEED

PH05-026-0048 potato is compositionally and nutritionally equivalent to conventional potato varieties. Further, none of the characteristics of the Phytophthora resistant potato have been changed in a way that would be measurable in human food or animal feed or are intended to have an effect on human food or animal feed. PH05-026-0048 potato is processed as any other conventional potato into food products. The by-products of the PH05-026-0048 processing are used as any other potato processing by-products in animal feeding. No post-market monitoring of the GM food and feed is required.

11. ENVIRONMENTAL RISK ASSESSMENT

11.1. Mechanism of interaction of the GM plant and target organisms

The expression of the resistance genes, *Rpi-blb1* and *Rpi-blb2*, conferred to PH05-026-0048 potato imparts resistance to late blight disease caused by the pathogen *P. infestans*. The resistance is based on the interaction pathogen-specific proteins (effectors) and host-specific proteins (resistance proteins). The plant recognizes the effector proteins and this recognition reaction triggers a signaling cascade that culminates in the local programmed death of the infected cell, the hypersensitive response. Upon infection by Phytophthora the BLB1 protein in PH05-026-0048 potato detects the presence of E-BLB1 (the corresponding effector) and the defence reaction is induced. In an independent detection reaction the BLB2 protein senses the E-BLB2 (the corresponding effector) triggering the hypersensitive response. Thereby the pathogen infection is effectively stopped. The senescence of cells as a result of the hypersensitive response is restricted to single or only very few cells, and restricts the growth and spread of Phytophthora to other parts of the plant. The pathogen cannot propagate within dead cells.

The AHAS enzyme expressed by the *csr1-2* gene in PH05-026-0048 potato is not targeted against any organisms.

11.2. Potential changes in the interaction of the GM plant with the biotic environment resulting from the genetic modification

a) Persistence and invasiveness

As recorded in a series of field trials over two growing seasons, the survival, multiplication, or dissemination characteristics of PH05-026-0048 potato as compared to the mother potato variety and other conventional potato varieties are not altered in such a way, that the likelihood of unintended environmental effects due to the establishment and survival of PH05-026-0048 potato would be any different to that of conventional potato varieties.

The risk for PH05-026-0048 potato therefore to become persistent and invasive or to have a selective advantage or disadvantage due to the introduced trait of Phytophthora resistance or the expression of the *csr1-2* gene encoded AtAHAS enzyme is considered to be negligible.

b) Selective advantage or disadvantage

Please refer to Point D.9.1.

c) Potential for gene transfer

Plant to bacteria. Based on current scientific knowledge the probability of the transfer of any functional gene derived from PH05-026-0048 potato to bacteria under natural conditions is extremely low. The introduced traits in PH05-026-0048 do not change the ability of the potato to transfer genetic material to bacteria. There are no sequences inserted that could be involved in transfer of genetic material between potato and bacteria. The risk of a possible transfer of functional genes from PH05-026-0048 potato to microorganisms is considered negligible.

Plant to plant. *S. tuberosum* is sexually not compatible with the wild related species *S. nigrum* and *S. dulcamara*, therefore any cross pollination or gene flow, if at all possible, would only occur to commercial potato varieties. Like its mother variety Fontane, PH05-026-0048 potato is flowering and produces berries at medium frequencies. Thus fertile pollen that is produced by PH05-026-0048 potato may lead to cross pollination with compatible conventional potato varieties. In the event that vertical gene transfer would occur and those potato plants form berries and mature seeds, this could result in volunteer plants in the following season. Gene transfer or outcrossing *per se* is not considered an adverse effect. Neither the Phytophthora resistance trait, nor the selectable marker gene in PH05-026-0048 potato confer any selective advantage or disadvantage. There are no reasons to assume that the resultant volunteer plants would have any selective advantage compared to conventional potato plants.

In conclusion, the risk that a gene transfer from PH05-026-0048 potato to either bacteria or plants would lead to an adverse environmental impact was determined to be negligible.

d) Interactions between the GM plant and target organisms

The interaction of the PH05-026-0048 potato with the target organism *P. infestans* was evaluated for its potential to result in adverse effects on the environment. Two potential effects were identified. It is possible that the late blight resistance conferred by the introduced genes *Rpi-blb2* and *Rpi-blb2* could be overcome by evolving Phytophthora strains, which would (i) lead to a product failure and (ii) the occurrence of a pathogen with an altered mechanism towards the plant's defence system. Both potential effects do not constitute an adverse effect or risk to the environment. In case of product failure farmers would apply the same management practices as for any conventional potato variety with high, medium or low resistance to late blight, following the advice of national or regional late blight surveillance organizations. The effect an altered pathogen strain would have on the environment is deemed to be comparable to, and not any different from the situation where previous race-specific resistance mechanisms were overcome by evolving Phytophthora strains. The cultivation of PH05-026-0048 potato does not pose any greater environmental impact than the cultivation of the broad range of conventionally bred potato cultivars equipped with a variety of resistance mechanism against diseases and pests.

e) Interactions of the GM plant with non-target organisms

Like any plant, potato is known to interact with other organisms in the environment including microorganisms, insects, birds, and mammals. PH05-026-0048 potato is modified for resistance against Phytophthora and expresses the *csr1-2* encoded AHAS protein from Arabidopsis (AtAHAS). As described, none of the characteristics of PH05-026-0048 potato, investigated as part of the comprehensive compositional, agronomic, phenotypic, or toxicological studies, bears any greater potential to adversely affect non-target organisms than those of conventional potato varieties. Neither the resistance proteins nor the AHAS enzyme harbour any toxic properties. The risk for harmful effects of PH05-026-0048 potato on non-target organisms in the environment, either through direct or indirect interactions is therefore determined to be negligible.

f) Effects on human health

The safety of PH05-026-0048 potato to human and animal health as compared to the mother potato variety and conventional potato varieties was confirmed by several studies and is based on: (i) the familiarity to the Phytophthora resistance trait, (ii) the presence of homologous R genes and the corresponding gene products in all conventional potato varieties, (iii) the presence of the *Rpi-blb1* gene in tuber-bearing Solanum species consumed by Native Americans, and the presence of the *Rpi-blb2* gene in commercial potato varieties, (iv) the absence of sequence homology or similarities of the BLB1 and BLB2 proteins to known allergens or toxins, (v) the instability of the BLB1 and BLB2 proteins in simulated digestive environments, (vi) the negligible exposure to the protein products expressed by the *Rpi-blb1* and *Rpi-blb2* genes, (vii) the extensive knowledge of the biological activity of AHAS enzymes, (viii) the ubiquitous nature of AHAS enzymes in the plant kingdom, (ix) the absence of sequence homology or similarities of the AtAHAS enzyme (the *csr1-2* encoded AHAS protein from Arabidopsis) to known allergens or toxins, (x) the instability of the AtAHAS protein in simulated digestive environments and at increased temperature, and (xi) the compositional equivalence of tubers and processed fractions, to the comparator and other conventional potato varieties. Further, to date no adverse health effects were reported from field trials conducted with PH05-026-0048 tubers or from processing the tubers at an experimental scale. Taken together, these data support the conclusion that PH05-026-0048 potato is as safe to human and animal health as conventional potatoes. The risk for any adverse effects to human or animal health via exposure to and consumption of PH05-026-0048 potato in food or feed products is considered negligible and comparable to that of commercial potato varieties.

g) Effects on animal health

See Section 11.2.(f)

h) Effects on biogeochemical processes

During cultivation, potato interacts directly or indirectly with soil organisms, and is susceptible to soil borne fungal or bacterial diseases. PH05-026-0048 potato is modified for broad-spectrum resistance against Phytophthora and expresses the *csr1-2* encoded AHAS protein from Arabidopsis. None of the characteristics of PH05-026-0048 potato, investigated as part of the comprehensive compositional, agronomic, phenotypic or toxicological studies bear any greater potential to adversely affect soil non-target organisms than those of conventional potato varieties. Characteristics such as yield, susceptibility to diseases, survival or dissemination were determined to be comparable to the mother variety Fontane and conventional potato varieties, except for the late blight resistance. Resistance genes and homologues to the *Rpi-blb1* and *Rpi-blb2* genes and the corresponding gene products, which confer the trait of late blight resistance, are present in all conventional potato varieties as part of the plant's immune system. Therefore, and as compared to the mother variety Fontane and other conventional potato varieties, no characteristics were identified that potentially could cause any adverse effects on soil non-target organisms and thereby could affect the biogeochemical processes. Based on this evidence, the risk for potential adverse effect on biogeochemical processes resulting from the interaction of PH05-026-0048 potato with soil dwelling non-target organisms is considered negligible and comparable to that of conventional potato varieties.

i) Impacts of the specific cultivation, management and harvesting techniques

The methods of cultivation, crop management, tuber production, and harvesting that will be applied to PH05-026-0048 potato will not be different from those used for the cultivation and production of conventional potato varieties. PH05-026-0048 potato does not harbor any characteristics that would necessitate specific applications of plant protection products, different crop rotation practices, or any different soil management practices. Therefore, the risk for potential adverse effects of PH05-026-0048 potato on the environment due to specific cultivation, management, and harvesting techniques as compared to conventional practice in potato production is considered negligible.

11.3. Potential interactions with the abiotic environment

Considering the introduced trait in PH05-026-0048 potato, the comprehensive data confirming its compositional and agronomic equivalence to conventional potato varieties and the large variability of potato in responding to environmental abiotic factors, the risk of PH05-026-0048 potato to cause adverse effects on the biotic environment due to potential changes in its interaction with the abiotic environment is considered negligible.

11.4. Risk characterisation for the environmental risk assessment

Considering the biology of the recipient plant, the potato variety Fontane, the characteristics of the PH05-026-0048 potato, the properties and consequences of the modification, the receiving environment, and the scale of the release, the risk assessment concluded that the overall risk of cultivating PH05-026-0048 potato in the European Union for processing, food and feed use is negligible.

12. ENVIRONMENTAL MONITORING PLAN

a) General (risk assessment, background information)

The scope of this application according to Regulation (EC) No 1829/2003 includes the cultivation of PH05-026-0048 potato in the European Union. An environmental monitoring plan for PH05-026-0048 potato conforming to Annex VII of Directive 2001/18/EC, and further supplemented by the guidance notes in Council Direction 2002/811/EC, was prepared. The objective of the monitoring plan is: (i) to confirm that any assumptions regarding the occurrence and impact of potential adverse effects of the GMO or its use in the environmental risk assessment (ERA) are correct, and (ii) to identify the occurrence of adverse effects of the GMO or its use on human health or the environment, which were not anticipated in the ERA.

Considering the biology of the recipient plant, the potato variety Fontane, the characteristics of the PH05-026-0048 potato, the properties and consequences of the modification, the receiving environment, and the scale of the release, the risk assessment concluded that the overall risk of cultivating PH05-026-0048 potato in the European Union for processing, food and feed use is negligible.

b) Interplay between environmental risk assessment and monitoring

An environmental risk assessment has been conducted to evaluate the potential adverse effects of PH05-026-0048 potato on human and animal health and the environment. The conclusions of this ERA confirm that the potential risks to human and animal health or the environment arising from placing on the market PH05-026-0048 potato can be considered negligible. Therefore, case-specific monitoring is considered not necessary under the scope of this application. A general surveillance plan based on Directive 2001/18/EC, Annex VII was prepared.

c) Case-specific GM plant monitoring (approach, strategy, method and analysis)

Case-specific monitoring is only required to verify the assumptions of the environmental risk assessment. Based on the results of the ERA there is no scientific evidence of a potential adverse effect, linked to the genetic modification in PH05-026-0048 potato. It is therefore concluded, that case-specific monitoring is not required.

d) General surveillance of the impact of the GM plant (approach, strategy, method and analysis)

The objective of general surveillance is to identify unanticipated adverse effects, direct or indirect, immediate and/or delayed of the GM plants, their products and their management to human health or the environment that were not anticipated in the environmental risk assessment. However, in order to safeguard against any adverse effects on human and animal health and the environment general surveillance of PH05-026-0048 will be undertaken for the duration of the authorization.

General surveillance will focus on those geographic regions within the European Union where PH05-026-0048 potato will be grown, and those environments that will be directly exposed to PH05-026-0048 potato. The time frame for the general surveillance will comprise the entire authorization period with an annual reporting scheme. The main elements of the general surveillance for PH05-026-0048 potato will be: (i) a farm-based survey system (farm questionnaires), the key instrument to gather relevant monitoring data, and to allow statistical evaluation; (ii) information gathered by existing and accessible networks; (iii) complemented by the stewardship program installed by the authorization holder; (iv) and the collated findings based on the monitoring of scientific publications, accessible internet sites of official bodies and monitoring programs. The authorization holder will assume responsibility for general surveillance in the areas where PH05-026-0048 potato is grown and monitor for any potential adverse effects of its cultivation at farm level. This relates in particular to the tools of the farm questionnaire and the company stewardship program. In addition, information collected on PH05-026-0048 potato by official bodies, existing monitoring programs or published in the scientific literature, and accessible to the authorization holder, will be evaluated and included in the reporting by the authorization holder to the European Commission and as specified in the authorization.

e) Reporting the results of monitoring

Reporting will be carried out according to the conditions specified in the authorization. Reports will be submitted on an annual basis to the Commission and as specified in the authorization.

13. DETECTION AND EVENT-SPECIFIC IDENTIFICATION TECHNIQUES FOR THE GM PLANT

A quantitative event-specific detection PH05-026-0048 potato and control materials are provided to DG Joint Research Centre, European Union Reference Laboratory, according to Regulation (EC) No 1829/2003.

14. INFORMATION RELATING TO PREVIOUS RELEASES OF THE GM PLANT (FOR ENVIRONMENTAL SAFETY ASPECTS9

14.1. History of previous releases of the GM plant notified under Part B of the Directive 2001/18/EC and under Part B of Directive 90/220/EEC by the same notifier

a) Notification number Environmental releases for PH05-026-0048 potato were carried out in Belgium, the Czech Republic, Germany, The Netherlands, Sweden, and the United Kingdom. Belgium: B/BE/10/V Czech Republic: B/CZ/07/01 Germany: B/DE/05/174, B/DE/06/183, B/DE/07/191 The Netherlands: B/NL/05/03, B/NL/07/07 Sweden: B/SE/05/8615, B/SE/11/652 United Kingdom: B/GB/06/R42/1
b) Conclusions of post-release monitoring No unexpected effects or observations have been detected to date. No adverse effects on human health or the environment have been observed or reported during these releases.
c) Results of the release in respect to any risk to human health and the environment (submitted to the Competent Authority according to Article 10 of Directive 2001/18/EC) Final reports presenting the results of the releases are available at http://gmoinfo.jrc.ec.europa.eu/

14.2. History of previous releases of the GM plant carried out outside the Community by the same notifier

a) Release country There have been no previous releases of PH05-026-0048 potato carried out outside the Community.
b) Authority overseeing the release Not applicable.
c) Release site Not applicable.
d) Aim of the release Not applicable.

e) Duration of the release Not applicable.
f) Aim of post-releases monitoring Not applicable.
g) Duration of post-releases monitoring Not applicable.
h) Conclusions of post-release monitoring Not applicable.
i) Results of the release in respect to any risk to human health and the environment Not applicable.