Application for Authorisation of Amylopectin Potato AM04-1020 for Food and Feed Uses, Processing and Cultivation according to Regulation (EC) No 1829/2003

Unique Identifier BPS-A1Ø2Ø-5

Part II Summary

A. GENERAL INFORMATION

1. Details of application

a)	**Member State of application** Sweden
b)	**Application number** Not available at time of application.
c)	**Name of the product (commercial and other names)** The product is amylopectin potato AM04-1020. The unique identifier is BPS-A1Ø2Ø-5.
d)	**Date of acknowledgement of valid application** Not available at time of application.

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 person established in the Community who is responsible for the placing on the market, whether it be the manufacturer, the importer or the distributor, if different from the applicant (Commission Decision 2004/204/EC Art 3(a)(ii))** Amylopectin potato AM04-1020 will be placed on the market as any other starch potato variety in the European Union. It will be cultivated, processed and used by those in the value chain currently involved in these processes for conventional starch potatoes.

3. Scope of the application

[x] GM plants for food use
[x] Food containing or consisting of GM plants
[x] Food produced from GM plants or containing ingredients produced from GM plants
[x] GM plants for feed use
[x] Feed containing or consisting of GM plants
[x] Feed produced from GM plants
[x] Import and processing (Part C of Directive 2001/18/EC)
[x] Seeds and plant propagating material for cultivation in Europe (Part C of Directive 2001/18/EC)

In addition the application also covers products other than food and feed containing or consisting of amylopectin potato AM04-1020. All specified uses for amylopectin potato AM04-1020 indicated in this scope refer to the same uses as for any other starch potato.

4. Is the product being simultaneously notified within the framework of another regulation (e.g. Seed legislation?)?

Yes [ ]	No [x]

5. Has the GM plant been notified under Part B of Directive 2001/18/EC and/or Directive 90/220/EEC?

Yes [x]	No [ ]
If *no*, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC	

6. Has the GM plant or derived products been previously notified for marketing in the Community under Part C of Directive 2001/18/EC or Regulation (EC) 258/97?

Yes [ ]	No [x]

7. Has the product been notified in a third country either previously or simultaneously?

Yes [ ]	No [x]

8. General description of the product

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

The amylopectin potato AM04-1020 was developed by Agrobacterium-mediated transformation of the starch potato variety Kuras with an RNA interference construct resulting in greatly reduced expression of granule bound starch synthase. In the starch fraction, tubers of AM04-1020 potato contain greater than 98% amylopectin, the branched-chain component, concomitant with much reduced levels of amylose. 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

The scope of the application comprises the cultivation of amylopectin potato AM04-1020, processing and all uses of the product for food, feed, non-food and non-feed purposes as applicable for any conventional starch potato variety.

c) Intended use of the product and types of users

Amylopectin potato AM04-1020 will be grown in the European Union. The intended use of the product and the types of users will be as for conventional starch potato varieties.

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

Amylopectin potato AM04-1020 will be used, stored, and handled as is currently done for any conventional starch potato variety. No mandatory restrictions during use, storage or handling are proposed as a condition of the authorisation.

e) Any proposed packaging requirements

Amylopectin potato AM04-1020 and products will be packaged as any other conventional starch potato product. See Point A.8.f below for labelling of amylopectin potato AM04-1020.

f) A proposal for labelling in accordance with Articles 13 and Articles 25 of Regulation ((EC) 1829/2003. In the case of GMOs, food and/or feed containing or consisting of GMOs, a proposal for labelling has to be included complying with the requirements of Article 4, B(6) of Regulation (EC) 1830/2003 and Annex IV of Directive 2001/18/EC

According to Regulations (EC) 1829/2003 and (EC) 1830/2003 operators handling or using foods and feeds produced from amylopectin potato AM04-1020 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 amylopectin potato AM04-1020 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.

g) Unique identifier for the GM plant (Regulation (EC) 65/2004; does not apply to applications concerning only food and feed produced from GM plants, or containing ingredients produced from GM plants)

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-A1Ø2Ø-5.

h) If applicable, geographical areas within the EU to which the product is intended to be confined under the terms of the authorisation applied for. Any type of environment to which the product is unsuited:

Amylopectin potato AM04-1020 is suitable for cultivation in all those geographical regions of the European Union that produce conventional starch potatoes.

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 amylopectin potato AM04-1020, mechanical means or selective use of herbicides can be employed to control amylopectin potato AM04-1020 like any other conventional potato.

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

1. Complete name

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

2. a. Information concerning reproduction

(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 is 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. The starch potato variety Kuras, which is the recipient variety for AM04-1020 potato, is known to be mainly male-sterile and described as forming no to hardly any berries.
(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. b. Sexual compatibility with other cultivated or wild plant species

Commercially cultivated potatoes are compatible with other cultivated potato varieties. Though the recipient potato variety Kuras is considered as mainly male-sterile and thereby rarely able to produce viable pollen for cross-pollination with cultivated potato varieties. The tetraploid *Solanum tuberosum* is not compatible with the wild related species *Solanum nigrum* and *Solanum dulcamara* occurring in Europe.

3. Survivability

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. The recipient potato variety Kuras is considered as mainly male-sterile and thereby rarely produces mature berries and seeds.

4. Dissemination

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. The starch potato variety Kuras, which is the recipient variety for AM04-1020 potato, is considered as mainly male-sterile and rarely able to produce either pollen or mature seed, which thereby affects and restricts its dissemination abilities. 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.

5. Geographical distribution and cultivation of the plant, including the distribution in Europe of the compatible species

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*.

6. 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

Potatoes are normally grown in all member states of the European Union, while the cultivation of starch potato varieties for the purpose of starch production within the EU starch quota system is limited to only a subset of member states. Those member states are in order of importance Germany, Netherlands, France, Denmark, Poland, Sweden, Finland, Austria, Czech Republic, Latvia, Spain, Lithuania, Slovakia, and Estonia.

7. 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

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.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification

Amylopectin potato AM04-1020 was produced via Agrobacterium-mediated transformation of potato leaf tissue.

2. Nature and source of the vector used

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

3. Size, source (name) of donor organism(s) and intended function of each constituent fragment of the region intended for insertion

The T-DNA fragment in plasmid pAP4 contains a granule bound starch synthase RNA interference cassette. The elements of this cassette are arranged in the following order: granule bound starch synthase (*gbss*) promoter from *Solanum tuberosum* (999 bp), *gbss* coding fragment in sense direction (457 bp), *gbss* spacer (66 bp), *gbss* coding fragment in antisense direction (457 bp), nopaline synthase polyadenylation sequence (253 bp) from *Agrobacterium tumefaciens*. 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 polyadenylation sequence (253 bp) from *Agrobacterium tumefaciens*. The T-DNA in pAP4 has a size of approximately 5500 bp and is delimited by pTiT37 right and left T-DNA border regions originating from *Agrobacterium tumefaciens.*

D. INFORMATION RELATING TO THE GM PLANT

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

Amylopectin potato AM04-1020 was developed by transformation of the starch potato variety Kuras with an RNA interference construct resulting in greatly reduced levels of granule bound starch synthase (GBSS). In the starch fraction, tubers of AM04-1020 potato contain more than 98% amylopectin, the branched-chain component, concomitant with much reduced levels of amylose. The *csr1-2* gene encoding acetohydroxyacid synthase (AHAS) from *Arabidopsis thaliana* was included in the transformation process as marker conferring tolerance to imidazolinone herbicides during selection in tissue culture.

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 pAP4 was integrated at a single locus and as a single copy in the potato genome. The complete AM04-1020 potato insert sequence is 5212 base pairs in length.

No DNA sequences other than those derived from the T-DNA of the plasmid pAP4 were integrated into the AM04-1020 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 AM04-1020 potato.

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

AM04-1020 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) Chromosomal location(s) of insert(s) (nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination

The insert of AM04-1020 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 AM04-1020 potato comprises a single functional copy of the *gbss* RNA interference cassette as well as the *csr1-2* gene as revealed by Southern blot and DNA sequence analyses of the insert and the flanking genomic potato DNA.

3. Information on the expression of the insert

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

Presence of the granule bound starch synthase (GBSS) protein at different growth stages of the AM04-1020 potato was determined via western blot analysis. Expression levels of the acetohydroxyacid synthase (AHAS) protein were determined by enzyme-linked immunosorbent assay using AHAS-specific antibodies. GBSS protein is absent in tubers, stolons and roots during potato plant

development at the growth stages analyzed. For all growth stages analyzed the expression of the AHAS protein is either below or just above the limit of quantitation.

b) Parts of the plant where the insert is expressed

The expression of the GBSS protein was determined in leaves, roots, stolons, tubers, and whole plants. The protein was not detectable in tubers, stolons or roots, whereas it was detected in all leaf and whole plant parts. The AHAS protein was detectable in leaves, roots, tubers, flowers and whole plants, however not quantifiable in most of the tissues. 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 AM04-1020 potato.

4. Information on how the GM plant differs from the recipient plant in

a) Reproduction

No changes in the reproduction characteristics compared to the mother variety Kuras have been observed in the agronomic and phenotypic assessments for AM04-1020 potato.

b) Dissemination

No changes in the dissemination characteristics compared to the mother variety Kuras have been observed in the agronomic and phenotypic assessments for AM04-1020 potato.

c) Survivability

No changes in the survival characteristics compared to the mother variety Kuras have been observed in the agronomic and phenotypic assessments for AM04-1020 potato.

d) Other differences

Throughout the field trials conducted over two growing seasons at multiple locations AM04-1020 potato did not show any biologically relevant changes in agronomic or phenotypic characteristics when compared to the mother potato variety Kuras or conventional potato varieties in the same trials.

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

The genetic stability of the insert in AM04-1020 potato was demonstrated across multiple generations of vegetatively propagated material by Southern blot analyses.

The phenotypic stability of AM04-1020 potato was confirmed by the stable absence of expression of the GBSS enzyme in tubers and the resultant change in the ratio of amylose and amylopectin starch.

6. Any change to the ability of the GM plant to transfer genetic material to other organisms

a) Plant to bacteria gene transfer

The horizontal gene transfer of intact genes from AM04-1020 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 pAP4 that could affect the mobility of DNA have been inserted into AM04-1020 potato. Therefore no changes, as compared to commercial potato varieties, are expected in the ability of AM04-1020 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. *Solanum tuberosum* is not compatible with the wild related species *Solanum nigrum* and *Solanum 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 AM04-1020 potato. Like its mother variety Kuras amylopectin potato AM04-1020 is considered male sterile and only rarely produces berries. Therefore no changes compared to conventional potatoes regarding the transfer of genetic material to other potatoes are expected.

7. Information on any toxic, allergenic or other harmful effects on human or animal health arising from the GM food/feed

7.1 Comparative assessment

Choice of the comparator

The mother potato variety Kuras 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.

7.2 Production of material for comparative assessment

a) Number of locations, growing seasons, geographical spreading and replicates

Field trials with AM04-1020 potato were conducted in the 2007 and 2008 growing seasons at locations in the European Union representative for areas of commercial starch potato production. At all trial locations, the plants were grown under standard agronomic practices in a complete randomized block design in four replicates.

b) The baseline used for consideration of natural variations

AM04-1020 potato was compared to the mother potato variety Kuras with a history of safe use. The baseline for natural variations was obtained from commercial potato varieties cultivated at the same field trial locations as part of the randomized block design.

7.3 Selection of compounds 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 51 components were analyzed in the tuber samples, including proximates, fiber, fructose, glucose, sucrose, starch, vitamin C, minerals, amino acids, fatty acids, and antinutrients.

7.4 Agronomic traits

Agronomic and phenotypic characteristics of AM04-1020 potato in comparison to the mother variety Kuras 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, tuber yield, and starch 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 *Phytophthora infestans*. In addition, the tubers were evaluated for resistance to wart and to potato cyst.

7.5 Product specification

AM04-1020 potato differs from its mother variety Kuras in an altered tuber starch composition with more than 98% amylopectin. An event-specific PCR-based detection method allows quantitative detection of AM04-1020 potato.

7.6 Effect of processing

Standard starch processing methods were applied to the production of starch from amylopectin potato AM04-1020. The compositional and physicochemical properties of the derived starch were analyzed. In addition the presence of the GBSS and AHAS proteins in the starch and pulp fraction derived from AM04-1020 potato was determined. The results of the analyses demonstrated that the AHAS protein, including both the *csr1-2* gene encoded and the endogenous potato AHAS protein, are either not detectable, or are present at or below the limit of quantification in both of the processed fractions starch and pulp produced from amylopectin potato AM04-1020.

7.7 Anticipated intake/extent of use

AM04-1020 potato is intended to be used as any other commercial starch potato variety. The amylopectin potato AM04-1020 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 commercial starch potatoes.

7.8 Toxicology

7.8.1 Safety evaluation of newly expressed proteins

The newly expressed protein in AM04-1020 potato, the *csr1-2* gene encoded Arabidopsis acetohydroxyacid synthase (AHAS) protein, which conferred tolerance to imidazolinone herbicides during selection in tissue culture, was assessed for its safety.

- The source organisms of the protein is *Arabidopsis thaliana* which is not known to be pathogenic to humans or animals nor is it known to be the source of toxins.
- The AHAS protein does not share sequence homology with known protein toxins.
- 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 AM04-1020 potato.

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

7.8.2 Testing of new constituents other than proteins

The traits introduced into AM04-1020 potato are a decrease in amylose content in tuber starch with a concomitant increase in amylopectin and the *csr1-2* gene encoded AHAS enzyme from Arabidopsis conferring tolerance to imidazolinone herbicides during selection in tissue culture. Thus no novel constituents are formed.

7.8.3 Information on natural food and feed constituents

The results of the comparative compositional analysis for amylopectin potato AM04-1020 revealed that though statistically significant differences were identified for some of the components, those remained well within the ranges of natural variation for conventional potato varieties. AM04-1020 potato only differs from conventional starch potatoes in its ratio of amylose and amylopectin in the tuber starch, which is the intended trait conferred to the potato.

7.8.4 Testing of the whole GM food/feed

In addition to the compositional analysis, and as supplemental evidence, the safety of amylopectin potato was confirmed in a 90-day feeding study in rats. The results of the study do not indicate adverse effects from the consumption of AM04-1020 potato.

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

The newly expressed protein in AM04-1020 potato, the *csr1-2* gene encoded Arabidopsis acetohydroxyacid synthase (AHAS) protein, was assessed for its allergenic potential.

- The source organisms of the AHAS protein is *Arabidopsis thaliana*, which is not known to have allergenicity potential.
- Bioinformatics analyses did not provide any indication of potential allergenicity. The AHAS protein does not share potentially immunologically relevant amino acid sequence segments or structure with know allergens.
- The AHAS protein is ubiquitous in plants and is not known to be allergenic.
- The AHAS protein is rapidly digested in simulated mammalian gastric (SGF) as well as intestinal fluids (SIF), similar to conventional dietary proteins in food products.
- At temperatures higher than 37 °C AHAS was found to be unstable. AHAS activity is rapidly inactivated at temperatures above 60 °C.
- No evidence of glycosylation was found associated with AHAS protein in AM04-1020 potato.

These results demonstrate that the AHAS protein lacks any characteristics of an allergenic protein and is as safe as other AHAS proteins present in conventional crops with a history of safe use.

7.9.2 Assessment of allergenicity of the whole GM plant or crop

Potatoes have a history of safe use in human food and animal feed, and in general, are not considered a source of allergens. AM04-1020 potato does not express any new proteins with allergenic characteristics.

7.10 Nutritional assessment of GM food/feed

7.10.1 Nutritional assessment of GM food

The compositional equivalence of AM04-1020 potato as compared to its mother potato variety Kuras and other conventional potato varieties was demonstrated by the analysis of key nutrients and antinutrients. In addition, a 42-day feeding study in broiler chicken confirmed the nutritional equivalence of amylopectin potato AM04-1020 in comparison to the mother and other conventional potato varieties.

7.10.2 Nutritional assessment of GM feed

Please refer to Point D.7.10.1.

7.11 Post-market monitoring of GM food/feed

Amylopectin potato is compositionally and nutritionally equivalent to conventional starch potato varieties except for the introduced trait. Since the starch component amylopectin is already present in the food supply as part of all starchy foods, it does not constitute a new component to the human diet, therefore post- market monitoring of the food and feed derived from AM04-1020 potato is considered not necessary.

8. Mechanism of interaction between the GM plant and target organisms (if applicable)

Neither the new trait of decreased amylose content in the tuber starch of AM04-1020 potato, nor the newly expressed Arabidopsis AHAS enzyme have target organisms. The point is not applicable.

9. Potential changes in the interactions of the GM plant with the biotic environment resulting from the genetic modification

In Points D.1. to D.7. the characteristics of the amylopectin potato AM04-1020 were described and it was shown that with regard to its compositional, agronomic, phenotypic, and nutritional characteristics AM04-1020 potato is equivalent to conventional starch potatoes, except for the amylopectin trait and expected associated characteristics, thereby suggesting that any interactions of this potato with the biotic environment have not been changed compared to conventional starch potatoes.

9.1 Persistence and invasiveness

As recorded in a series of field trials over two growing seasons, the survival, multiplication, or dissemination characteristics of AM04-1020 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 AM04-1020 potato would be any different to that of conventional starch potato varieties.

The risk for AM04-1020 potato therefore to become persistent and invasive or to have a selective advantage or disadvantage due to the introduced trait of altered starch composition or the expression of the *csr1-2* gene encoded AtAHAS enzyme is considered to be negligible.

9.2 Selective advantage or disadvantage

Please refer to Point D.9.1.

9.3 Potential for gene transfer

Plant to bacteria. Based on current scientific knowledge the probability of the transfer of any functional gene derived from AM04-1020 potato to bacteria under natural conditions is extremely low. The introduced traits in AM04-1020 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 AM04-1020 potato to microorganisms is considered negligible.

Plant to plant. *Solanum tuberosum* is sexually not compatible with the wild related species *Solanum nigrum* and *Solanum dulcamara*, therefore any cross pollination or gene flow, if at all possible, would only occur to commercial potato varieties. Like its mother variety Kuras, amylopectin potato AM04-1020 is considered male sterile and only rarely produces berries. Thus, the likelihood of AM04-1020 potato forming any fertile pollen is very low and therefore the frequency of any cross pollination to compatible conventional potato varieties would also be considered very low. Even if the unlikely event that vertical gene transfer would occur and fertile seeds would be formed, there are no reasons to assume that the resultant volunteer plants would have any selective advantage compared to conventional potato plants.

In conclusion, the potential for gene transfer from AM04-1020 potato to either bacteria or plants is considered negligible.

9.4 Interactions between the GM plant and target organisms

This point is not applicable, since neither the decreased amylose content nor the newly expressed Arabidopsis AHAS enzyme in amylopectin potato AM04-1020 are traits designed to interact with specific target organisms.

9.5 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. AM04-1020 potato is modified in its tuber starch composition resulting in an increase of the branched-chain amylopectin and expresses the *csr1-2* encoded AHAS protein from Arabidopsis. As described, none of the characteristics of AM04-1020 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 starch potato varieties. Neither the amylopectin, occurring naturally in all starchy plants and plant parts, nor the AHAS enzyme, which is ubiquitous in all plants and microbes, harbor any toxic properties. The risk for harmful effects of AM04-1020 potato on non-target organisms in the environment, either through direct or indirect interactions is therefore considered negligible.

9.6 Effects on human health

The safety of AM04-1020 potato to human and animal health as compared to the mother potato variety and conventional starch potato varieties was confirmed by several studies and is based on (i) the familiarity to the amylopectin trait, (ii) the extensive knowledge of the biological activity of the AHAS enzymes, (iii) the ubiquitous nature of the AHAS enzymes in the plant kingdom, (iv) the absence of sequence homology or similarities to known allergens or toxins, (v) the instability of the AtAHAS protein in simulated digestive environments and to high temperature, (vi) the compositional equivalence of tubers and processed fractions, except for the intended trait and the correlated characteristics, to either the comparator or conventional potato varieties, and the absence of any adverse

effects indicated in a 90-day rat feeding and a 42-day broiler feeding study. Taken together, these data support the conclusion that AM04-1020 potato is as safe to human and animal health as conventional starch potatoes. The risk for any adverse effects to human or animal health via exposure to and consumption of amylopectin potato AM04-1020 in food or feed products is considered negligible and comparable to that of commercial starch potato varieties.

9.7 Effects on animal health

Please refer to Point D.9.7.

9.8 Effects on biogeochemical processes

During cultivation, potato interacts directly or indirectly with soil organisms, and is susceptible to soil borne fungal or bacterial diseases. AM04-1020 potato is modified in its tuber starch composition resulting in an increase of the branched-chain amylopectin and expresses the *csr1-2* encoded AHAS protein from Arabidopsis. None of the characteristics of AM04-1020 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 starch potato varieties. Neither the amylopectin, occurring naturally in all starchy plants and plant parts, nor the AHAS enzyme, which is ubiquitous in all plants and microbes, harbor any toxic properties. Characteristics such as yield, susceptibility to fungal or bacterial diseases, survival or dissemination were determined to be comparable to the mother variety Kuras and conventional potato varieties. Based on this evidence, the risk for potential adverse effect on biogeochemical processes resulting from the interaction of AM04-1020 potato with soil dwelling non-target organisms is considered negligible and comparable to that of conventional starch potato varieties.

9.9 Impacts of the specific cultivation, management and harvesting techniques

The methods of cultivation, crop management, tuber production, and harvesting that will applied to AM04-1020 potato will not be different from those used for the cultivation and production of conventional starch potato varieties. Amylopectin potato AM04-1020 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 AM04-1020 potato on the environment due to specific cultivation, management, and harvesting techniques as compared to conventional practice in potato production is considered negligible.

10. Potential interactions with the abiotic environment

Considering the introduced traits in AM04-1020 potato, the comprehensive data confirming its compositional and agronomic equivalence to conventional starch potato varieties and the large variability of potato in responding to environmental abiotic factors, the risk of AM04-1020 potato to cause adverse effects on the biotic environment due to potential changes in its interaction with the abiotic environment is considered negligible.

11. Environmental monitoring plan (not if application concerns only food and feed produced from GM plants, or containing ingredients produced from GM plants)

11.1 General (risk assessment, background information)

The scope of this application according to Regulation (EC) No 1829/2003 includes the cultivation of amylopectin potato AM04-1020 in the European Union. An environmental monitoring plan for AM04-1020 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 (e.r.a.) 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 e.r.a. The structure of the monitoring plan also takes into account the guidance on presentation of applications provided in the Guidance Document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed.

Considering the biology of the recipient plant, the starch potato variety Kuras, the characteristics of the AM04-1020 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 AM04-1020 potato in the European Union for processing, food and feed use is negligible.

11.2 Interplay between environmental risk assessment and monitoring

An environmental risk assessment has been conducted to evaluate the potential adverse effects of amylopectin potato AM04-1020 on human and animal health and the environment. The conclusions of this e.r.a. confirm that the potential risks to human and animal health or the environment arising from placing on the market AM04-1020 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.

11.3 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 e.r.a. there is no scientific evidence of a potential adverse effect linked to genetic modification of AM04-1020 potato. It is therefore considered that no case-specific monitoring is required.

11.4 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 AM04-1020 will be undertaken for the duration of the authorization.

General surveillance will focus on those geographic regions within the European Union where AM04-1020 potato will be grown, and those environments that will be directly exposed to amylopectin potato AM04-1020. 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 AM04-1020 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 selected existing networks, and complemented by (iii) the Identity Preservation System installed by the authorization holder (company stewardship program), and (iv) the collated findings based on the monitoring of scientific publications, internet sites of official bodies and monitoring programs, as well as expert reports. The authorization holder will assume responsibility for general surveillance in the areas where AM04-1020 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 AM04-1020 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 applicable, the responsible competent authorities of the member states.

11.5 Reporting the results of monitoring

Reporting will be carried out according to the conditions specified in the authorization. Reports will be submitted to the Commission and, as applicable, to the respective competent authorities of the member states on an annual basis.

12. Detection and event-specific identification techniques for the GM plant

A quantitative event-specific detection for AM04-1020 potato and control materials are provided to DG Joint Research Centre, Community Reference Laboratory, according to Regulation (EC) No 1829/2003.

E. INFORMATION RELATING TO PREVIOUS RELEASES OF THE GM PLANT AND/OR DERIVED PRODUCTS

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 amylopectin potato AM04-1020 were carried out in the Czech Republic, Germany, The Netherlands, and Sweden.

Czech Republic: B/CZ/06/02

Germany: B/DE/05/173, B/DE/06/183, B/DE/07/191

The Netherlands: B/NL/05/05, B/NL/07/06

Sweden: B/SE/04/7943

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/

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 AM04-1020 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.

3. Links (some of these links may be accessible only to the competent authorities of the Member States, to the Commission and to EFSA):

a) Status/process of approval To be provided.
b) Assessment Report of the Competent Authority (Directive 2001/18/EC) To be provided.
c) EFSA opinion To be provided.
d) Commission Register (Commission Decision 2004/204/EC) To be provided.
e) Molecular Register of the Community Reference Laboratory/Joint Research Centre To be provided.
f) Biosafety Clearing-House (Council Decision 2002/628/EC) To be provided.
g) Summary Notification Information Format (SNIF) (Council Decision 2002/812/EC) To be provided.