PART II: Summary
Application for amylopectin potato event AV43-6-G7 according to Regulation (EC) no 1829/2003

PART II: Summary

A GENERAL INFORMATION

1. Details of application

(a) Member State of application

The Netherlands

(b) Application number

[action CA]

(c) Name of the product (commercial and other names)

Genetically modified amylopectin potato, Modena (AV43-6-G7)

(d) Date of acknowledgement of valid application

[to be determined by CA]

2. Applicant

(a) Name of applicant

Verkoop- en Produktie Vereniging van Cooperatieve aardappelmeel en derivaten "AVEBE" U.A.

(b) Address of applicant

AVEBE-weg 1
9607 PT Foxhol
The Netherlands

(c) Name and address of the person established in the Community who is responsible for the placing on the market

Verkoop- en Produktie Vereniging van Coöperatieve aardappelmeel en derivaten "AVEBE" U.A.
AVEBEweg 1
9607 PT Foxhol
The Netherlands

3. Scope of the application

The scope of this application focuses on the main point of entry of the material in the processing chain and concerns the following categories:

1.1. GM plant for food use
1.3 Food produced from GM plants or containing ingredients produced from GM plants

2.1. GM plant for feed use
2.3 Feed produced from GM plants

3.2. Seeds and plant propagating material for cultivation in Europe

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

Yes X No □
If yes, specify
AVEBE applied for Plant Breeders rights for AV43-6-G7 in The Netherlands at Raad voor Plantenrassen under nr ARD1737 on 01-12-2005. PBR (nr 30805) was approved on 28-07-2008 and the name Modena was published.

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

Yes

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?

No

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

No

8. General description of the product

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

Potato (*Solanum tuberosum*) cultivar Karnico has been modified to prevent the formation of amylose

(b) Types of products planned to be placed on the market according to the authorisation applied for

Genetically modified potato cultivar Modena (AV43-6-G7) is placed on the market for the production of potato starch.

(c) Intended use of the product and types of users

AV43-6-G7 (Modena) is a starch potato variety. It is propagated and cultivated by specialized farmers. It is intended to be used for the isolation of starch by the starch industry and starch may undergo further processing by chemical, physical and biochemical derivation processes similar to present starch processing. The amylopectin starch from Modena is not intended for Food and/or Feed use. The starch is intended for non-food applications. Co products are intended for Feed and non-Food use similar to conventional co products of starch manufacturing.

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

No other instructions then legally required for GM traceability and labelling.

(e) **Any proposed packaging requirements**

None.

(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**

On accompanying documents of Modena potatoes according to the requirements of article 4, A (1) (2) of regulation 1830/2003/EC the following information will be given: "Modena, genetically modified potato (AVE-436G7-1)" and as a requirement of regulation 2001/18/EC Annex IV (8) the name and address of AVEBE U.A. will be given also. Article 4, B (6) of regulation 1830/2003/EC and article 13 of Regulation 1829/2003 are not applicable, Modena is not intended for direct use by consumers. Pre-packaged feed products from Modena will be labelled according to the requirements of article 25 of Regulation 1830/2003/EC with "produced from genetically modified potato following directly the name of the product", for bulk products this information is given on the accompanying documents.

(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)**

Unique identifier nr. AVE-436G7-1.

(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**

Not applicable. However, AV43-6-G7 will be cultivated and propagated similar to cultivar Karnico. Cultivar Karnico is phased out in agriculture from 2008 onwards.

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

This application concerns the full range of today's uses of the starch potato in agriculture and processing. Any product consisting of or derived from amylopectin potato AV43-6-G7 that during use, storage or handling found to be unintentionally present in the food chain, will be labelled and channeled according to applicable EU legislation, in particular Regulation (EC) No 1829/2003.

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

1. Complete name

Solanum tuberosum L

(a) **Family name,**

Solanaceae

(b) **genus,**

Solanum

(c) **species,**

Solanum tuberosum

(d) **subspecies,**

Tuberosum

(e) **cultivar/breeding line or strain,**

cv. Karnico

(f) **common name.**

Potato

2. Information concerning reproduction

(a) **mode(s) of reproduction,**

With respect to potato, two ways of reproduction are possible: sexual by cross- or self-fertilisation and non-sexual by tuber multiplication. Sexual propagation is only used in classical cross-fertilisation breeding programs. Multiplication via tubers ('cloning') is standard potato agricultural practice.

(i) **specific factors affecting reproduction (if any)**

No specific factors.

(ii) **generation time;**

Tuber multiplication takes place once a year in Europe

(b) **Sexual compatibility with other cultivated or wild plant species**

Solanum tuberosum ssp *tuberosum* belongs to the section *petota* subsection *potatoe*. The OECD concluded in 1997 that inter specific crosses both within subsection *potatoe* or with species from sections other then *petota* are not likely to occur. Crossing is possible with other cultivated potato varieties, all belonging to species *Solanum tuberosum*.

3. Survivability

Despite the longstanding use in agriculture, settlement of the potato in the wild flora in the Netherlands has never occurred. In general, the potato is not known as a coloniser of unmanaged ecosystems in Europe (OECD, 1997).

(a) Ability to form structures for survival or dormancy

Potato material can survive through seeds and tubers. In cultivation, development of seeds is possible after self and/or cross-pollination of plants in the field. Seeds can give rise to plants (volunteers) after germination in following years. Also small tubers left in the ground after harvest can act as volunteer weed.

(b) Specific factors affecting survivability

Volunteers will normally not survive due to frost, drought and normal agricultural practices such as ploughing, chemical weed management, and the competitive disadvantage in standard practices of crop rotation. Potato tuber cannot survive a temperature of -3°C and lower (OECD, 1997).The foliage dies at temperatures of -2 °C.

Botanical seeds of potato ('true potato seed') can survive frost periods. Standard agricultural practice with volunteer management and crop rotation will eliminate any potato seedlings from volunteer seed. Outside the field potato seedlings are in competitive disadvantage with other plants and without crop protection management subject to fatal potato diseases like *Phytophthora infestans*.

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4. Dissemination

(a) Ways and extent of dissemination

Dissemination can take place by seeds and tubers.
Pollen dissemination is limited and depends on weather conditions and the fertility of cultivars. Under field conditions 80 to 100% of the potato seed is formed after self-pollination. Dispersal by wind is possible but limited. Insects contribute to pollination. Bumble bees, a natural pollinator of potato, in general only travel short distances. In literature maximum pollen dissemination range varies from 10 to maximum 20 meter. However, one study indicated pollen dissemination over a distance of 1000 m. In this study a small beetle normally feeding on cruciferous plants including rape, cabbage and cauliflower, *Meligethes aeneus*, was the pollinator explaining the longer dissemination range. Survival of seedlings on or outside the field is not likely, see 3. In standard cultivation potatoes are vegetative propagated. Harvested tubers are not the result of cross fertilisation.

(b) Specific factors affecting dissemination

See 4(a).

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

Seed potatoes are general grown in the northern parts of the EU in countries connected to North sea and Baltic sea. Consumer potatoes are grown in all EU countries and starch potatoes (for the production of starch) are allowed in the following EU countries (alphabetic order) Austria, Czech Republic, Denmark, Finland, France, Germany, Netherlands, Poland, Sweden, and to a smaller

extend Estonia, Latvia, Lithuania, Slovakia and Spain in agreement with directive 94/1868/EEC as amended by regulation (EC) no. 941/2005.

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

Potato is a generally grown crop in the EU.

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

No other interactions, other then already valid for non-GMO starch potatoes, have been identified. AV43-6-G7 starch potato is free of antibiotic markers or any herbicide resistance, 95 % of all base pairs the inserted sequence stem from potato.
Well known toxic or anti-nutritional substances in potato are glycoalkaloids and trypsin inhibitor activity (OECD, 1997). In the composition analysis total glycoalkaloid content and trypsin inhibitor activity of AV43-6-G7 were measured and not elevated compared to the parent cultivar Karnico.

C INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification

DNA was introduced into potato cultivar Karnico by *Agrobacterium*-mediated gene transfer technology. Event AV43-6-G7 has been genetically modified without the use of any marker gene and contains a single insert to down regulate the enzyme granule bound starch synthase (GBSS) leading to the absence of amylose in potato starch and hence a pure amylopectin potato starch. AV43-6-G7 starch potato is free from marker genes such as antibiotic or herbicide resistance, 95 % of all base pairs of the inserted sequence originate from potato.

2. Nature and source of the vector used

Agrobacterium tumefaciens was used for transformation of potato. In the vector pTiBo542ΔT the T-DNA and the oncogenic traits are deleted. The binary vector, which functioned as a carrier of the trait that has been transferred to plant tissue, is derived from pBIN19 (Bevan 1984). pBIN19 was modified by removal of the *nptII* gene and can be propagated both in *Escherichia coli* as well as *A. tumefaciens.* It contains a T-DNA that is limited by the right and left border sequences from pTiT37. Outside the T-DNA border sequences there is a gene for kanamycin resistance (*nptIII)* to maintain the plasmid in a bacterial background.

3. Source of donor DNA, size and intended function of each constituent fragment of the region intended for insertion

Table 1 presents the size, the intended function and the origin of each constituent of the T-DNA of pKGBA50mf-IR1.1.

Table 1 : Summary of all elements of the T-DNA of pKGBA50mf-IR1.1

Size (bp)	Function	Origin
1-39	pTiT37 fragment (Zambryski et al, 1980) with right border sequence (RB), b. 1-25	*Agrobacterium tumefaciens*
40-220	M13mp19 fragment (Yanisch-Perron et al, 1985) from M13 phage genome	Phage M13 modified for laboratory use
222-451	M13mp19 fragment (Yanisch-Perron et al, 1985), part of Lac operon (lacI)	*Escherichia coli*
452-1302	Genomic GBSSI fragment (PGBSSI) functional as a promoter in plants (van der Leij et al, 1991)	*Solanum tuberosum*
1303-1335	Polylinker sequence	Artificial sequence
1336-2547	GBSSI cDNA fragment; 5' 1.1 kb part (Visser et al, 1991a), sense orientation in relation to the promoter sequence	*Solanum tuberosum*
2548-2574	Polylinker sequence	Artificial sequence
2575-3914	GBSSI cDNA fragment; 3' 1.3 kb part (Visser et al, 1991a), antisense orientation in relation to the promoter sequence	*Solanum tuberosum*
3915-5126	GBSSI cDNA fragment; 5' 1.1 kb part (Visser et al, 1991a), antisense orientation in relation to the promoter sequence	*Solanum tuberosum*
5127-5149	Polylinker sequence	Artificial sequence
5150-5403	pTiT37 fragment (Zambryski et al, 1980) containing the nopaline synthase gene terminator (TNOS), functional as a polyadenylation sequence in plants	*Agrobacterium tumefaciens*
5404-5410	Polylinker sequence	Artificial sequence
5411-5559	M13mp19 fragment (Yanisch-Perron et al, 1985), part of Lac operon (lacZ)	*Escherichia coli*
5560-5860	M13mp19 fragment (Yanisch-Perron et al, 1985), contains M13 ori	Phage M13 modified for laboratory use
5861-5991	M13mp19 fragment (Yanisch-Perron et al, 1985), part of Lac operon (LacI)	*Escherichia coli*
5992-6069	pTiT37 fragment (Zambryski et al, 1980) including left border sequence (LB), b. 6045-6069	*Agrobacterium tumefaciens*

D INFORMATION RELATING TO THE GM PLANT

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

By way of the inverted repeat of GBSSI cDNA sequences the transformant AV43-6-G7 has obtained an essentially amylose free starch in tuber tissue.

2. Information on the sequences actually inserted or deleted

AV43-6-G7 contains one insert of an inverted repeat construct of the potato GBSS gene. No marker genes e.g. antibiotic and herbicide resistance genes were inserted.

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

Southern blot analysis showed that one insert and one copy of the inverted repeat construct is present in AV43-6-G7.

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

The target site in the Karnico genome in which the T-DNA in event AV43-6-G7 had integrated was found to have a deletion of 1814 bp. *In silico* analysis of the insertion site did not reveal any known function. It was demonstrated that the corresponding sites present on the three other homologous chromosomes in event AV43-6-G7 are still intact.

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

Inserted sequence is present in the potato nuclear genome. Analysis of total DNA extracted resulted in one (1) single band. Crossings with non GM potatoes showed strict Mendelian inheritance confirming the nuclear organisation of the insert

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

No elements outside the left- and right border sequences of the T-DNA were inserted. Both border sequences of the T-DNA were truncated during the insertion event. The single insert in AV43-6-G7 consisted of potato DNA for 95 % of all base pairs. The non-potato DNA of the insert was a sequence originating form a (truncated) lac1 gene of *E. coli*.

3. Information on the expression of the insert

Insert is under the control of a potato GBSS promoter. The inverted repeat construct did not lead to any new protein. In fact no protein product is anticipated since the point of the inverted repeat construct is the down regulation of the GBSS gene.

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

GBSS promoter is expressed in tissues with high sugar content. Expression occurs in roots, leaves, stolons and tubers.

(b) **Parts of the plant where the insert is expressed**

The GBSS promoter leads to expression with high activity in stolons and tubers. Some expression in leaves and roots occurs but is very low as compared to stolons and tubers.

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

(a) **Reproduction**

The GM plants does not differ in reproduction compared to normal potato varieties. Crossings with non-Gm varieties demonstrated that the inserted trait is inherited in a Mendelian way indicating stable insertion of the single insert in the genome.

(b) **Dissemination**

See 4 (a). No differences were found which would anticipate any differences or deviation from normal potato dissemination.

(c) **Survivability**

Normally potatoes are cold sensitive. Frost temperatures just below zero degree Celsius are usually enough to kill any tubers remaining in the field after harvest. No indication was found in composition of macro- and micronutrients of AV43-6-G7 which may predict any differences in or deviation from normal potato survivability during frost periods.

(d) **Other differences**

AV43-6-G7 differs from potato starch varieties in its amylose content. No new proteins are expressed and no significant compositional differences were detected beyond what is known for normal starch potato varieties.

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

Insert of AV43-6-7 was stably integrated in the genome. Analysis of tissues for the period 2001 (date of transformation) until 2008 revealed the presence of a single insert. Crosses of AV43-6-G7 with non-GM varieties showed that the inserted trait is inherited in a Mendelian way indicating stable insertion of the single insert.

Compositional analysis demonstrated that the GM event AV43-6-G7 was similar in comparison to Karnico and other starch potato varieties. Starch content in AV43-6-G7 is statistically lower with a reciprocal increase in sugar precursors as compared to parent variety Karnico, however, this is related to the inserted trait.

Field trials in the period 2003-2007 did not reveal any significant phenotypic difference between parent variety Karnico and AV43-6-G7 for phenotype, development, maturity and disease resistances.

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

(a) **Plant to bacteria gene transfer**

No prokaryotic regulatory sequences and prokaryotic genes were inserted. The GM plants will not differ from wild type potatoes in ability to transfer any DNA.

(b) Plant to plant gene transfer

AV43-6-G7 contains one insert of which approximately 95 % of all base pairs originate from potato. No additional genes and or regulatory sequences are inserted. The tetraploid AV43-6-G7 contains three (3) intact insertion sites in its genome. The trait amylopectin does not confer any potential change in plant to plant gene transfer. Flowering characteristics of AV43-6-7 were identical to the parent cultivar Karnico.

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

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AV43-6-G7 was compared to its parent variety Karnico and other starch potato varieties.

7.2 Production of material for comparative assessment

(a) Number of locations, growing seasons, geographical spread and replicates

Field trails were conducted in The Netherlands in an area representative for the future use of the starch variety AV43-6-G7. Dataset comprise for consecutive growing seasons 2003-2007. Events were present in 3 replicates per location and were conducted on 3 (2003), 8(2004), 8 (2005), 10 (2006) and 10 (2007) locations.

(b) The baseline used for consideration of natural variations

Field trial results are compared to standard commercial practice in starch potato growing area in The Netherlands and Germany.

7.3 Selection of material and compounds for analysis

Standard set of analysis for all field trials are the so-called macro components:

- under water weight (UWW), starch content, total protein (tp), coagulable protein (cp), and sugar content.

These nutritionally important compounds normally represent 80-90% of dry matter in starch potatoes. For the seasons 2005 and 2006 a detailed analysis of the composition was performed and in addition to the above set of macro components, potatoes were analysed for;

- the ratio tp/cp, trypsin inhibitor activity, α–solanine, β-chaconine, α -chaconine, total glycoalkaloids (summation of chaconins and solanine), glucose, fructose, sucrose, total sugar (TS, summation of previous 3 sugars), nitrate, potassium, Cd, Pb, Zn, fat, fibre, chlorogenic acid, vitamin C, lactate, acetate, citrate, total amino acids (summation of all monomer amino acids in potato), aspartate, threonine, serine, asparagine, glutamine, glutamate, glycine, alanin, valine, methionine, isoleucin, leucine, tyrosine, phenylalanine, gamma-aminobuteric acid, ornithin, histidine, lysine, tryptophane and arginine.

Anti-nutrients in potatoes are glycoalkaloids and trypsin inhibitor activity.

7.4 Agronomic traits

Agronomic traits of AV43-6-G7 in comparison to its parent variety Karnico as well as other comparators were scored from 2003 until 2008. No significant phenotypic differences were detected between AV43-6-G7 and Karnico. The only (small) difference was the slightly lower starch content. It is concluded that this is linked to the intended trait which leads to the absence of the starch component amylose. This is accompanied with a small but statistic significant increase in sugar precursors. However, the differences in sugar content of AV43-6-G7 as compared to Karnico fall within the range as observed for other standard varieties.

7.5 Product specification

AV43-6-G7 was named Modena. An unique event code was assigned " AVE-436G7-1" and an unique identifier PCR test was developed. AV43-6-G7 potato starch does not contain quantifiable amylose. The remaining amylopectin is essentially amylose free.

7.6 Effect of processing

No new constituents are formed. AV43-6-G7 does not contain any marker genes. No effects on processing are expected as compared to other starch potato varieties.

7.7 Anticipated intake/extent of use

AV43-6-G7 potatoes are to be used for isolation of starch by the starch industry and like most other starch potatoes not intended for direct human consumption. Also the isolated amylopectin potato starch from AV43-6-G7 is not intended to be used as food. It will be used for non-Food industrial applications. For this purpose amylopectin potato starch from AV43-6-G7 may undergo further processing by chemical, physical and biochemical derivation processes similar to present starch processing.

Co products of starch processing such as fibres, protein and concentrated fruit juice will be placed on the market similar to conventional uses of these products. They may be used as Feed or fertilizer in agriculture.

7.8 Toxicology

No new constituent are formed. AV43-6-G7 does not contain any marker genes. No new proteins were detected and anticipated on the basis of *in silico* analysis of the inserted sequence. No effects on processing are expected as compared to standard potato starch varieties.
Known anti nutrients of potato such as glycoalkaloids and trypsin inhibitor activity were found to be unchanged and contents fall within the accepted range for potato. A 90 day rat toxicological trial with AV43-6-G7 in comparison with material derived from the parent Karnico and standard feed established no effects on growth, food and water consumption, haematology, clinical chemistry and organ weights.

7.8.1 Safety assessment of newly expressed proteins

No newly (expressed) proteins were found.

7.8.2 Testing of new constituents other than proteins

The inverted repeat used in the production of the GM potato plant prevents the formation of amylose (starch). No new constituents are intended nor expected.

7.8.3 Information on natural food and feed constituents

AV43-6-G7 was analysed on composition for macro- and micronutrients. Statistically significant differences were observed for the starch content (lower) and sugar content (higher), both differences are linked to the inserted trait. Some micronutrients showed small but statistical significant differences between AV43-6-G7 and Karnico. Total glycoalkaloid content in AV43-6-G7 was somewhat lower as compared to Karnico, however, this is beneficial.

It was concluded that found differences were only small, nutritionally not relevant and within the normal range for starch potatoes.

7.8.4 Testing of the whole GM food/feed

The possible toxicity of genetically modified potato (AV43-6-G7) was examined in a repeated-dose (13-week) oral toxicity study on rats. In the study an untreated control group receiving a diet without potato was compared to potato-fed groups with; a reference group receiving a diet containing 30% conventional potato Karnico, and two test groups receiving diets containing 15% and 30% AV43-6-G7 potato. Uncooked potato was freeze dried and incorporated into a rodent diet
It is concluded that dietary levels up to 30% genetically modified potato AV43-6-G7 did not induce any other changes than those observed with Karnico and that AV43-6-G7 is as safe as its traditional counterpart.

7.9 Allergenicity

The aim of the genetic modification of the potato plant is to prevent the formation of GBSS enzyme and the formation of amylose (starch). No marker has been used and no new enzymes or protein are formed. The allergenicity is not expected to be changed by the genetic modification.

7.9.1 Assessment of allergenicity of the newly expressed protein

Not applicable

7.9.2 Assessment of allergenicity of the whole GM plant or crop

Not applicable

7.10 Nutritional assessment of GM food/feed

The change of an amylose-amylopectin containing starch in to a pure amylose-free amylopectin starch is the only potential significant change in nutritional value. However, analyses showed that the energy content of amylopectin starches is not different from amylose/amylopectin starches. The composition of AV-43-6-G7 regarding other nutritional relevant substances does not show significant changes as compared to Karnico and is within the normal compositional range for starch potatoes.

7.10.1 Nutritional assessment of GM food

The composition of AV43-6-G7 potatoes is equivalent to its traditional counterpart. Also the nature of the genetic modification is such (see above) that it is assessed to have no nutritional implications.

7.10.2 Nutritional assessment of GM feed

The composition of AV43-6-G7 potatoes is equivalent to its traditional counterpart. Also the nature of the genetic modification is such (see above) that it is assessed to have no nutritional implications.
Compositional variation of co products due to processing, may have nutritional (and economical) implications. However, they are not GM related and will have no overall nutritional implications as feed always is nutritionally optimised based on the actual compositions by farmers and feed industry.

Any co product of potato starch manufacturing from AV43-6-G7 is nutritionally and toxicologically equivalent to standard co products.

7.11 Post-market monitoring of GM food/feed

AV43-6-G7 tubers are not intended to be used for direct Food consumption and will be used by the potato starch industry. The intended use for the isolated amylopectin starch will be for non-Food purposes. None of the characteristics in AV43-6-G7 will lead to relevant changes in processing and composition of co products and hence animal feed. All co products can be used according to standard practices. As is common practise, (co-)product compositional deviations from the standard are brought to attention of AVEBE Feed customers in normal business to business communications.

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

The aim of the genetic modification is a change in the starch composition. There is no trait like antibiotic or insect resistance, or herbicide tolerance and thus no target organism.

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

The aim of the genetic modification is a change in the starch composition. There are no target organisms and for non-target organisms no change is expected in their natural way of live and in their survival.

Point if interest could be the freezing properties of the potato plant resulting hypothetically in potential survival in frost periods. It has been shown that frost sensitivity is unchanged independent of the starch composition of the potato.
Crosses with other potatoes or other related species have never been found in nature (see elsewhere in the dossier).

9.1 Persistence and invasiveness

No marker genes were employed for the genetic modification. E.g. no herbicide markers were used. Field trails indicated no phenotypic difference of AV43-6-G7 in comparison with the parent

variety Karnico and other potatoes varieties. The introduced trait does not anticipate any change in persistence or invasiveness of AV43-6-G7.

9.2 Selective advantage or disadvantage

The essentially amylose-free starch of AV43-6-G7 does not lead to any selective advantage or disadvantage

9.3 Potential for gene transfer

No genes were inserted which potentially could influence pollen viability, any change in potential for gene transfer is not likely.

9.4 Interactions between the GM plant and target organisms

The genetic modification and intended trait do not involve any target organism.

9.5 Interactions of the GM plant with non-target organisms

The essentially amylose-free starch of AV43-6-G7 does not lead to any selective advantage or disadvantage. The compositional study, the *in silico* analysis of the inserted sequence, the nutritional calculations and the lack of any effect in the 90 day rat toxicological feeding study indicates that there are no hazards. No effects on non-target organisms are foreseen.

9.6 Effects on human health

See 7.10

9.7 Effects on animal health

See 7.10

9.8 Effects on biogeochemical processes

The compositional study and the *in silico* analysis of the inserted sequence demonstrates that AV43-6-G7 is equivalent to Karnico. The rat feeding study shows that nutritionally AV43-6-G7 is equivalent to Karnico. Without any apparent effect on the digestive system in this rodent study other than the effect of feeding potatoes we conclude that also natural and far more versatile mineralization processes in the environment will be not effected by the presence of AV43-6-G7 materials.

9.9 Impacts of the specific cultivation, management and harvesting techniques

The nature of the genetic modification does not lead to any change in the agronomic behaviour. The variety AV43-6-G7 will be grown just like any other (starch) potato variety.

10. Potential interactions with the abiotic environment

No interactions are targeted with the inserted trait. The absence of the amylose component in potato starch does not anticipate any change in interaction with the abiotic environment.

11. Environmental monitoring plan (not if application concerns only food and feed produced from GM plants, or containing ingredients produced from GM plants and if the applicant has clearly shown that environmental exposure is absent or will be at levels or in a form that does not present a risk to other living organisms or the abiotic environment)

The scope of the application of AV43-6-G7 is the non-Food use of the isolated starch and derivatives produced there from and the use of (rejected) tubers and co products of starch production as Feed or fertilizer.

No special effects are foreseen for AV43-6-G7.

Agronomic properties are unchanged in comparison with the parent Karnico and or other starch potatoes. Seed multiplication will be carried out under the responsibility of Averis Seeds BV (for The Netherlands) or Averis Saatzucht GmbH (for Germany) both fully owned subsidiaries of farmers cooperative AVEBE UA. Seed production will be according to standard seed multiplication procedures and under quality assurance of legally designated institutions and/or authorities. Seed multipliers are obliged to use the AVEBEs so-called Optimeel registration system. Optimeel will be extended with paragraphs to report any unforeseen effect of the GM plant.

End users/farmers of AV43-6-G7 are allowed -for captive use only- to further multiply AV43-6-G7 seeds one year (farm saved seed regulation for starch varieties). End user farmers will be forced to work under the so-called AVEBE Optimeel registration system. Optimeel will be extended with paragraphs to report any unforeseen effect of the GM plant.

The environmental monitoring plan focuses therefore on detection of any unforeseen and unexpected effect of cultivating AV43-6-G7. The essentially amylose-free starch of AV43-6-G7 does not lead to any selective advantage or disadvantage. The compositional study, the *in silico* analysis of the inserted sequence, the nutritional calculations and the lack of any effect in the 90 day rat toxicological feeding study indicates that there are no hazards. No effects on non-target organisms are foreseen.

A post marketing monitoring plan according to EU guidelines is part of this notification (**Annex** 8) .

11.1 General (risk assessment, background information)

See 11.

11.2 Interplay between environmental risk assessment and monitoring

See 11.1

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

See 11.1

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

See 11.1

11.5 Reporting the results of monitoring

See 11.1

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

A qualitative and quantitative event-specific detection method for AV43-6-G7 (cultivar name Modena) will be provided to DG Joint Research, Unit Biotechnology and GMOs .

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

AV43-6-G7 has been grown under part B notifications B/NL01/11, B/NL03/04 and B/NL04/004. Notification B/NL/07/04 and B/NL/07/05 are still pending

(b) Conclusions of post-release monitoring

No special potential environmental and human health impacts are expected nor detected. Reports of activities under notification mentioned under 1.(a) were yearly send to NL CA. B/NL03/04 can be found with link http://gmoinfo.jrc.it/gmp_report.aspx?CurNot=B/NL/03/04.

(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)

At http://gmoinfo.jrc.it the NL CA assessment report can be found under http://gmoinfo.jrc.it/gmp_report.aspx?CurNot=B/NL/03/04. No special potential environmental and human health impacts were detected.

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

None

(a) Release country

Not applicable

(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):

Notification B/NL/01/11can be found at http://gmoinfo.jrc.it, however, direct link is missing. B/NL/01/11 is abandoned for administrative reasons, plants are presently grown under the notification B/NL/04/04
Links:
http://gmoinfo.jrc.it/gmp_report.aspx?CurNot=B/NL/03/04
http://gmoinfo.jrc.it/gmp_report.aspx?CurNot=B/NL/04/04
http://gmoinfo.jrc.it/gmp_report.aspx?CurNot=B/NL/07/04

(a) **Status/process of approval**

No approval yet

(b) **Assessment Report of the Competent Authority (Directive 2001/18/EC)**

No approval yet

(c) **EFSA opinion**

No approval yet

(d) **Commission Register (Commission Decision 2004/204/EC21)**

No registration yet

(e) **Molecular Register of the Community Reference Laboratory/Joint Research Centre**

The information will be made available at http://gmo-crl.jrc.it

(f) **Biosafety Clearing-House (Council Decision 2002/628/EC22)**

The link to the biosafety clearing house is http://bch.biodiv.org

(g) **Summary Notification Information Format (SNIF) (Council Decision 2002/812/EC) 21 –Commission Decision of 23 February 2004 laying down detailed arrangements for the operation of the registers for recording information on genetic modifications in GMOs, provided for in Directive 2001/18/EC of the European Parliament and of the Council. Official Journal of the European Communities L 65: 20 – 22. 22 –Council Decision of 25 June 2002 concerning the conclusion, on behalf of the European Community, of the Cartagena Protocol on Biosafety. Official Journal of the European Communities L 201: 48 – 49.**

SNIFs for previous releases under are available at http://gmoinfo.jrc.it/gmp_browse.aspx (see 3.)
No SNIF for AV43-6-G7 at http://bch.biodiv.org.