Application for Authorisation of Imidazolinone-tolerant Soybean BPS-CV127-9 in the European Union 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** Not available at time of application.
c)	**Name of the product (commercial and other names)** The application is for genetically modified soybean event CV127. The unique identifier is BPS-CV127-9.
d)	**Date of acknowledgement of valid application** Not available at time of application.

2. Applicant

a)	**Name of applicant** BASF Plant Science GmbH representing BASF Agrochemical Products B.V.
b)	**Address of applicant** BASF Plant Science GmbH Carl-Bosch-Str. 38 67056 Ludwigshafen Germany representing: BASF Agrochemical Products B.V. Groningensingel 1 6835 EA Arnhem The Netherlands
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))** Refer to Point 2.a) and b) above. CV127 soybean will be produced outside the European Union (EU) and will be imported in the EU by operators that have traditionally been involved in the trade, processing, and distribution of commodity soybean and derived products.

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)
[ ] 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 CV127 soybean for the same uses as any other soybean.

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 [ ]	No [x]

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

As part of the application an environmental risk assessment for CV127 soybean has been carried out in accordance with Annex II of Directive 2001/18/EC and Commission Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC. The overall conclusion obtained from the risk analysis confirms that there are no identified adverse effects to human and animal health or the environment arising from the proposed uses of CV127 soybean.

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 [x]	No [ ]

An application for environmental release as well as food and feed use is being submitted simultaneously to Brazil where CV127 soybean is planned to be cultivated primarily.

In addition submissions for the approval of CV127 soybean will be made to the U.S.A., Canada, Japan, and other countries that import significant volumes of soybeans or soybean products.

8. General description of the product

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

The parental plant is soybean (*Glycine max* L. Merr.) which is extensively cultivated and has a long history of safe use.

The introduced *csr1-2* gene from *Arabidopsis thaliana* encodes an acetohydroxyacid synthase protein that confers tolerance to imidazolinone herbicides due to a point mutation that results in a single amino acid substitution in which the serine residue at position 653 is replaced by asparagine (S653N).

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

The scope of the application includes import, processing and distribution of CV127 soybean in the European Union for all food and feed and industrial uses, and for all food, feed and processed products derived from CV127 soybean excluding cultivation.

c) Intended use of the product and types of users

Soybeans derived from event CV127 will be grown primarily in Brazil and Argentina and will enter the EU by import as commodity soybean and derived products. CV127 soybean will be used for the same downstream purposes as non-GM soybeans and no novel method of manufacturing is envisaged. The CV127 soybean and all food, feed and processed products derived from CV127 soybean are expected to replace a portion of similar products from commercial soybean. The major food and feed products derived from soybeans are whole soybeans, oil and meal. The scope of this application includes import and processing only and is not intended for cultivation in the EU. The milling, processing and consumer packaging however will be accomplished in the EU. Therefore the users of CV127 soybean belong to the soybean crushing and packaging industry and their customers, to traders, and the consumers of soybean and soybean products.

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

CV127 soybean will be used, stored, and handled as is currently done for any commercial soybean. No mandatory restrictions during use, storage or handling are proposed as a condition of the authorisation.

Any product derived from CV127 soybean, including those unintentionally present in the food chain, will be labelled and handled according to applicable EU legislation, in particular Regulation (EC) No 1829/2003.

e) Any proposed packaging requirements

CV127 soybean and products will be packaged as any other commercial soybean product. See Point A.8.f below for labelling of CV127 soybean.

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 Regulation (EC) 1829/2003 and (EC) 1830/2003 operators handling or using foods and feeds produced from CV127 soybean are required to be aware of the legal obligations regarding traceability and labelling. The applicant will communicate such obligations to all parties involved in the processing. In processing the CV127 soybean, food and feed products will be obtained. These will be labelled according to Regulation (EC) 1829/2003 with "produced from genetically modified soybean" or "contains genetically modified soybean". 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-CV127-9.

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. This application relates to import and processing only and not for cultivation of CV127 soybean in the EU.

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 analysis, 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 CV127 soybean, mechanical removal or selective use of herbicides (with the exception of imidazolinone herbicides) can be employed to control CV127 soybean like any other commercially available soybean.

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

1. Complete name

a) Family name *Fabaceae*
b) Genus *Glycine* Willd.
c) Species *Glycine max* (L.) Merrill
d) Subspecies none
e) Cultivar/breeding line or strain Conquista
f) Common name Soybean, soy, soya bean, soya

2. a. Information concerning reproduction

(i) Mode(s) of reproduction
Soybean is a self-pollinating species that is solely propagated by seed. Pollen viability lasts for a short time of two to four hours. Natural or artificial cross-pollination is only possible during the short time when the pollen is viable. As a result, soybean exhibits a strong propensity for self-fertilization. The frequency of cross-pollination is usually less than one percent. There are no reports of vegetative propagation under field conditions.
(ii) Specific factors affecting reproduction
Soybean is not frost tolerant and does not survive freezing winter conditions. The seed will germinate when the soil temperature reaches 10 ℃ and will emerge in a 5 to 7 day period under favourable conditions. In areas where soybean has not been cultivated before an inoculation with *Bradyrhizobium japonicum* is necessary for optimum efficiency of the nodulated root system.
(iii) Generation time
Soybean is an annual food legume with a cultural cycle ranging from 3 to 5 months depending on the variety and the area of production.

2. b. Sexual compatibility with other cultivated or wild plant species

Due to the low level of genomic similarity among species of the genus *Glycine*, *G. max* can only cross with other members of *Glycine* subgenus *Soja* and so intergeneric hybridization does not occur. There are no wild plant species that are sexually compatible with soybean in the EU.

3. Survivability

a) Ability to form structures for survival or dormancy

The cultivated soybean plant has no weedy tendencies and is non-invasive in natural habitats; it has never been found outside of cultivated areas in unmanaged habitats. Soybeans are annuals that reproduce solely from seeds. Cultivated soybean rarely displays any dormancy characteristics and is sensitive to cold temperatures.

b) Specific factors affecting survivability

Soybean seed need adequate moisture and a soil temperature of at least 10 ℃ for germination. Cultivation is delimited by temperature as soybean plants are not frost-tolerant and plant growth is retarded by temperatures of below 20 ℃ and over 40 ℃. Moreover, soybeans do not yield well on acid soils.

4. Dissemination

a) Ways and extent of dissemination

Seed and pollen are potential sources of gene dispersal. Cultivated soybean is an annual almost completely self-pollinating crop which has a percentage of cross-pollination usually lower than 1 %.

Seed may disperse during transportation and handling, e. g. at sowing or during harvest. However, soybean is not an invasive crop and volunteer plants will usually not establish due to unfavourable environmental conditions.

b) Specific factors affecting dissemination

There are no special factors affecting dissemination. Spreading of seed is normally limited to the area of cultivation and is mainly due to human activity.

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

Historical and geographical evidence suggests that soybeans were first domesticated in eastern China, between the 17th and 11th century B.C.

Today soybean is grown as a commercial crop in more than 35 countries throughout the world. The major world producers of soybeans are the USA, Brazil, Argentina and China. In Europe, soybean is mainly cultivated in Italy, France and Romania.

Soybean is not found as a wild species and there are no wild plant species that are sexually compatible with soybean in the EU.

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

The cultivated soybean originates from eastern Asia but is grown in the following EU member States: Austria, Bulgaria, Czech Republic, France, Germany, Greece, Hungary, Italy, Poland, Romania, Slovakia, Slovenia, and Spain.

Soybean in Europe is only found in the agricultural environment. This application is not intended for cultivation of CV127 soybean 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

Soybean like every other plant is known to interact with other organisms in the environment including microorganisms, viruses, insects, birds, and mammals. Soybean is susceptible to a range of diseases and pests.

There are some compounds in soybeans which are not favourable for human or animal nutrition, such as lectins and trypsin inhibitors. In addition, soybean contains a number of protein allergens. However, the processing methods applied to soybean are well known and have a long history of safety.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification

A purified, linear DNA fragment derived from plasmid pAC321 was used to transform embryogenic axis tissue derived from the apical meristem of a single soybean seed of the commercial variety Conquista using particle bombardment. No carrier DNA was used in the process.

2. Nature and source of the vector used

Soybean tissues were transformed with an approximately 6.2 kb linear fragment PvuII fragment derived from plasmid pAC321 containing the *csr1-2* gene cassette.

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

The pAC321 fragment contains genomic Arabidopsis DNA including the mutant Arabidopsis acetohydroxyacid synthase large subunit (*ahasl*) coding sequence (also referred to in the literature as *csr1-2*) with transcription directed by the wild type Arabidopsis AHASL 5' and 3' untranslated regions (UTR) containing the putative promoter and terminator region. The *csr1-2* coding sequence is 2013 bp long and includes the S653N point mutation which confers tolerance to imidazolinone herbicides. In addition to the S653N mutation, a second mutation was discovered in the Arabidopsis *ahas* coding sequence integrated in the CV127 soybean genome. This second mutation, in which arginine at position 272 of the AtAHAS protein is replaced by lysine, does not impact the enzymatic function of the AHAS enzyme or its herbicide tolerance properties.

D. INFORMATION RELATING TO THE GM PLANT

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

CV127 soybean has been genetically modified to express an altered AtAHASL protein which is encoded by the *csr1-2* gene from *Arabidopsis thaliana* and confers tolerance to imidazolinone herbicides. The AtAHASL protein encoded by *csr1-2* is structurally and functionally identical to the native AtAHASL, except for substitution of a serine with an asparagine at residue 653 (S653N) which results in tolerance to imidazolinone herbicides. In addition, the *csr1-2* gene in CV127 contains a second mutation, in which arginine at position 272 is replaced by lysine (R272K).

2. Information on the sequences actually inserted or deleted

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

The PvuII fragment derived from plasmid pAC321 was integrated at a single locus and as one single copy in the soybean genome. The complete CV127 insert sequence is 4758 bp in length.

No DNA sequences other than those derived from the PvuII transformation fragment were integrated into the CV127 genome. Southern blot analyses clearly indicated that no elements derived from the backbone of the plasmid pAC321 either linked or unlinked to the insert were detected in the genome of CV127.

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

CV127 soybean was obtained via insertion of a plasmid-derived DNA fragment. Deletions of the genomic soybean 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 CV127 was integrated into the nuclear genome of soybean. The integration of the insert was confirmed by Southern blot analysis, PCR, and DNA sequence analysis.

The integration of one single insert into the nuclear soybean genome was confirmed by segregation data of the *csr1-2* gene which showed that tolerance to the herbicide is conferred by a single gene and that this trait is inherited according to classical Mendelian genetics.

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

The insert in CV127 comprises a single functional copy of the *csr1-2* gene as revealed by Southern blot analyses of and by cloning and sequencing of the insert, as well as genomic flanking DNA.

DNA sequence analysis revealed that the *csr1-2* gene cassette contains three point mutations relative to the PvuII linear DNA fragment of pAC321. One of the point mutations is a G to A mutation at position 272 in the *csr1-2* gene, which results in an amino acid change from arginine to lysine.

This is a conservative amino acid substitution and has no impact on the herbicide tolerance or enzymatic properties of the AtAHAS protein. The other two mutations

are genetically silent.

Sequence analysis revealed that parts of the PvuII transformation fragment are not contained within the transgene insert in CV127. Deletions of unannotated Arabidopsis genomic DNA occurred both at the 5' end and 3' end during insertion into the soybean genome.

3. Information on the expression of the insert

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

Expression levels of the AHAS protein in different tissues of CV127 soybean plants were determined by enzyme-linked immunosorbent assay using AHAS-specific antibodies. Generally, expression levels of the AtAHASL protein in CV127 soybean are extremely low, especially at later stages of plant growth and development.

AHAS enzyme activity is highest in young and growing plant tissues (leaves and whole plants at the V2 growth stage) where the need for branched chain and other amino acids is greatest due to the higher level of *de novo* protein synthesis and declines as tissues mature. Expression of AHAS decreased with age of the plant and AHAS was only barely detectable or undetectable in roots, older leaves, and grain.

b) Parts of the plant where the insert is expressed

The expression levels of the AtAHAS enzyme were determined in leaves, roots, flowers, grain, and whole plants. Highest levels of AHAS protein were detected in young leaves.

AHAS protein amounts in roots, flowers and grain were generally very low and either below or around the limit of quantification (LOQ).

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

a) Reproduction

No unexpected changes in pollen viability and germination characteristics or in seed production have been observed in field trials of CV127 soybean compared to the isogenic control. The tolerance to imidazolinone herbicides has no effect on the mode and rate of reproduction.

b) Dissemination

There is no indication that dissemination characteristics of CV127 soybean plants have changed compared to the isogenic control as a result of the genetic modification.

Spreading of seed is normally limited to the area of cultivation and is mainly due to human activity. In the EU, dissemination will be restricted to unintended release of CV127 soybeans due to accidental spillage of grain, e. g. during transportation.

c) Survivability

Agronomic data for CV127 soybean were collected in Brazil over two growing seasons. No biologically significant differences in survivability compared to the isogenic control were observed.

Also seed characteristics that most determine survival are not changed due to the genetic modification. There was no evidence of seed dormancy, which is a survival mechanism that is an important characteristic often associated with plants that are weeds.

d) Other differences

Except for the tolerance to imidazolinone herbicides, CV127 soybean did not show any biologically significant changes when compared to the isogenic control in field trials.

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

The genetic stability of the transgene insert in CV127 across multiple breeding generations was demonstrated by Southern blot analyses, as well as progeny segregation analysis using traditional breeding methods.

Phenotypic stability of CV127 soybean was confirmed by stable expression of the *csr1-2* gene and the production of the AtAHAS protein in two different generations of CV127 soybean.

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 CV127 soybean into bacteria and the expression of the genetic information encoded by them would involve complex processes that need several steps that all have an extremely low probability of occurrence.

As demonstrated by Southern blot analysis no genetic elements other than those derived from the PvuII transformation fragment that could affect the mobility of DNA have been inserted into CV127 soybean. Therefore no changes as compared to commercial soybean varieties are expected in the ability of CV127 soybean to transfer genetic material to bacteria.

b) Plant to plant gene transfer

Soybean is a self-pollinated species and there are no wild plant species that are sexually compatible with soybean in the EU. Both weedy relatives of *G. max*, *G. soja* and *G. gracilis,* are indigenous to Asia only.

Genetic material can only be transferred to other soybean varieties by pollen. No changes in flower morphology have been observed for CV127 soybean that could indicate a change in the ability to produce and release pollen. Therefore no changes compared to conventional soybeans regarding the transfer of genetic material to other soybeans are expected.

Additionally, it should be considered that this application is not for authorisation of the cultivation of CV127 soybean in the EU.

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

Either the parental variety Conquista with a history of safe use or an isogenic control line were used as comparators in the safety studies.

In addition, two commercial soybean varieties with a history of safe use were included as comparators in agronomic and compositional analyses to establish a range of natural variability.

7.2 Production of material for comparative assessment

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

Field trials of CV127 soybean were conducted at nine locations in total across Brazil during the growing seasons of 2006/2007, 2007, and 2007/2008. The sites were located in regions that are representative of areas of commercial soybean production. At the 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

CV127 soybean was compared either to the isogenic control or to the parental variety Conquista. In addition, the comparative assessment included two commercial soybean varieties with a history of safe use as comparators (see Point 7.1.).

The baseline for natural variations consisted of analytical data for soybean grain in the International Life Sciences Institute Crop Composition database and publicly available literature data about analyte levels in commercial soybeans.

7.3 Selection of compounds for analysis

The selection of components for analysis was based on the guidance contained in the OECD consensus document on Compositional Considerations for New Varieties of Soybean: Key Food and Feed Nutrients and Antinutrients.

Composition analyses were carried out on the raw agricultural commodities grain and forage and on processed soybean grain fractions.

A total of 70 components were analyzed in the grain samples. Components analyzed for grain included proximates, fiber, amino acids, fatty acids, minerals, vitamins, isoflavones, phospholipids, and antinutrients. Components analyzed in forage samples included proximates, fiber, and carbohydrates and calories by calculation.

In addition, grain was processed to produce toasted, defatted soybean meal, protein isolate and concentrate, and refined oil. Components analyzed in toasted soybean meal included proximates, fiber, antinutrients and isoflavones. Proximates only were analyzed for the protein isolate and concentrate fractions. The refined oil fractions were analyzed for fatty acid composition.

7.4 Agronomic traits

Agronomic and phenotypic characteristics of CV127 soybean in comparison to the isogenic control and two commercial soybean reference varieties were recorded over two seasons of replicated field trials in Brazil.

Quantitative characteristics that were evaluated included germination, final plant stand, seedling vigour, plant height, green stem, degree of lodging, days to full flower, days to full maturity, seed size and grain yield. In addition, data on susceptibility to pests and diseases, nitrogen fixation parameters were recorded.

The results of the comparative assessment confirmed that there are no biologically significant agronomic differences between CV127 soybean and the isogenic control with comparable genetic background and two commercial soybean reference varieties. The addition of the imidazolinone-tolerance trait has not altered the phenotypic or agronomic characteristics or interactions with the environment. There are no unexpected agronomic differences between CV127 soybean and its isogenic control and it can be concluded CV127 soybean and the isogenic control can be considered morphologically and agronomically equivalent.

7.5 Product specification

CV127 soybean is tolerant to the imidazolinone class of herbicides. An event-specific PCR-based detection method allows quantitative detection of CV127 soybean.

7.6 Effect of processing

Processing of CV127 soybean will essentially be the same as for commercial soybean. No novel method of processing is envisaged. Effects of the processing of CV127 soybean are not expected to be any different from any effects of the processing of commercial soybean.

Compositional analyses of processed soybean fractions produced from CV127 soybean, the isogenic control, and two commercial standard varieties support the conclusion that the nutrient and antinutrient composition of the processed fractions from CV127 soybean grain are within the same range or comparable to the composition of similar processed soybean fractions produced from grain of the isogenic control and two commercial standard soybean comparator varieties.

7.7 Anticipated intake/extent of use

The CV127 soybean is intended to be used as any other commercial soybean.

The CV127 soybean and all derived food, feed and processed products are expected to replace a portion of similar products from commercial soybean. Therefore, the total intake of soybean products derived from soybean is not anticipated to change with the introduction of CV127 soybean. CV127 soybean and all its derived products are not different in quality and are nutritionally equivalent to soybean products now consumed.

7.8 Toxicology

7.8.1 Safety evaluation of newly expressed proteins

CV127 soybean comprises an acetohydroxyacid synthase large subunit allele from *Arabidopsis thaliana*, which confers tolerance to the imidazolinone class of herbicides. The results obtained from the safety evaluation demonstrate that the AtAHAS enzyme can be regarded as safe:

- The AtAHASL protein does not share sequence homology with known protein toxins.
- The source 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 AtAHASL protein is ubiquitous in plants and is not known to be toxic.
- There has been a long history of safe production of crops containing an imidazolinone-tolerant AHAS with the same S653N amino acid substitution as that in the AtAHAS encoded by the *csr1-2* gene that has been used to produce imidazolinone-tolerant CV127 soybeans (commercialized under the Clearfield® brand name since 1992).
- There are no indications of acute toxicity for the AHAS protein in mammals based on acute oral administration in mice.

7.8.2 Testing of new constituents other than proteins

Not applicable. CV127 soybean does not contain any novel constituents other than the imidazolinone-tolerant AHAS enzyme and no changes in composition of the soybean were discovered by chemical analysis.

7.8.3 Information on natural food and feed constituents

Not applicable. The insertion of the *csr1-2* gene does not lead to a modification of CV127 soybean food and feed constituents beyond the natural variation.

7.8.4 Testing of the whole GM food/feed

The results of a 42-day feeding study with broiler chickens demonstrated that there were no statistically significant differences in body weight, weight gain, feed intake or feed conversion between animals fed feed containing soybean meal from CV127 soybeans and those fed feed containing soybean meal from the commercial varieties.

Therefore, it can be concluded that soybean meal derived from CV127 soybean is nutritionally comparable to soybean meals derived from conventional soybean varieties with a history of safe use.

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

The AHASL enzyme was assessed for its allergenic potential. Results demonstrate that the AtAHAS 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 in food and feed products:

- The source of the AHASL protein is *Arabidopsis thaliana* which is not known to have allergenicity potential.
- The AHASL protein is ubiquitous in plants and is not known to be allergenic.
- Bioinformatic analyses did not provide any indication of potential allergenicity. The AtAHASL protein does not share potentially immunologically relevant amino acid sequence segments or structure with known allergens.
- The AtAHASL protein is rapidly digested in simulated mammalian gastric fluid (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 the AtAHASL protein in CV127 soybean.

7.9.2 Assessment of allergenicity of the whole GM plant or crop

Soybean has a long history of safe use as food and feed. CV127 soybean does not express any new proteins with allergenic characteristics compared to its isogenic control and commercial comparator varieties. A comparative analysis focusing on the known endogenous allergens present in soybean grain has confirmed that CV127 soybean does not exhibit a significantly altered endogenous allergen content compared to parental variety Conquista. These results provide further support to the conclusion that the grain from CV127 soybean is as safe as grain from commercial soybean varieties.

7.10 Nutritional assessment of GM food/feed

7.10.1 Nutritional assessment of GM food

The composition and nutritional equivalence of CV127 soybean compared to commercial soybeans was demonstrated by analysis of key nutrients and antinutrients. It could be shown that introduction of the *csr1-2* gene into the soybean genome does not impact on the composition of CV127 soybean. The nutritional equivalence to commercial soybeans was further confirmed in a poultry feeding study. In conclusion, CV127 soybean can be considered compositionally and nutritionally equivalent to and as safe as food and feed produced from commercial soybean.

7.10.2 Nutritional assessment of GM feed

Please refer to Point 7.10.1.

7.11 Post-market monitoring of GM food/feed

Based on the food and feed risk assessment there is no indication that CV127 soybean is less safe than other commercial soybean varieties. In addition, from a compositional and nutritional point of view CV127 soybean is equivalent to its isogenic comparator except for the introduced imidazolinone tolerance trait.

Therefore, no post-market monitoring of the GM food and feed derived from CV127 soybean is required.

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

Not applicable. The introduced *csr1-2* gene confers tolerance to imidazolinone herbicides. The AHAS protein has no target organisms.

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

It should be noted that this application is for authorisation of CV127 soybean for all food and feed uses, and for all food, feed and processed products derived from CV127 soybean, and excludes cultivation of CV127 soybean in the EU. Therefore, any interactions of CV127 soybean with the biotic environment will be negligible and restricted to accidental and unintended release during transportation and processing.

9.1 Persistence and invasiveness

The CV127 soybean has been tested in field trials in Brazil, and results of the agronomic evaluation demonstrate that the introduced imidazolinone resistance trait in CV127 soybean does not result in differences regarding persistence or invasiveness compared to the isogenic control and commercial soybean. The *csr1-2* gene does not confer characteristics to CV127 soybean that result in altered survival, multiplication or dissemination characteristics compared to its conventional counterparts except in the presence of imidazolinone herbicides.

The cultivated soybean plant has no weedy tendencies; it has never been found outside of cultivated areas in unmanaged habitats. Furthermore, soybean is not frost tolerant and volunteers do not compete well with the succeeding crop.

In case of unintended grain spillage during handling, soybean volunteers can be controlled as other commercial soybean following conventional practices, e. g. mechanically or by selective use of herbicides (with the exception of imidazolinone herbicides).

In summary, there is negligible risk for the CV127 soybean to become persistent or invasive resulting in increased weediness.

9.2 Selective advantage or disadvantage

It should be taken into account that this application is for authorisation of CV127 soybean excluding cultivation in the EU.

Therefore, the likelihood of cross-pollination between cultivated soybeans and soybean plants resulting from accidental seed spillage can virtually be ruled out. Even in the unlikely event that transgene flow occurred to cultivated soybean plants, the introduced trait does not confer any selective advantage to the plants outside the agricultural environment.

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 CV127 soybean to bacteria under natural conditions is extremely low. The genetic modification in CV127 soybean does not change the inability of soybean to transfer genetic material to bacteria. There are no sequences inserted that could be involved in transfer of genetic material between soybean and bacteria.

The risk of a possible transfer of functional genes from CV127 soybean plants to microorganisms is considered negligible.

Plant to plant

There are no sexually compatible wild relatives of soybean known to exist in the EU. Potential for gene flow is therefore limited to other soybean plants resulting from accidental seed spillage. Even if the unlikely event of gene transfer would occur, there are no reasons to assume that the resulting hybrids would have any selective advantages compared to conventional soybean plants. It should be noted that this application excludes authorisation of cultivation of CV127 soybean in the EU.

In conclusion, the potential for gene transfer from CV127 soybean to either bacteria or plants is considered negligible.

9.4 Interactions between the GM plant and target organisms

The introduced AtAHAS protein confers tolerance to imidazolinone herbicides and has no target organisms.

9.5 Interactions of the GM plant with non-target organisms

Considering that the intended use of CV127 soybean in the EU excludes cultivation, there is negligible likelihood that the import and processing of CV127 soybean will lead to any unintended adverse effect on non-target organisms.

9.6 Effects on human health

Soybean has a long history of safe use for consumption as food or feed. Compositional analysis of grain, forage, and processed fraction produced from CV127 soybean demonstrated that CV127 soybeans have the same nutritional quality as commercial soybeans and the insertion of the imidazolinone herbicide resistance trait does not lead to a modification of CV127 soybean food and feed

constituents beyond the natural variation. A nutritional assessment, including a poultry feeding study, confirmed that CV127 soybeans or derived products are nutritionally equivalent to soybean varieties that are cultivated commercially.

On the basis of the data provided, consumption of or contact to CV127 soybeans or derived food and feed products will result in no adverse consequences to human or animal health. Food and feed products from CV127 soybean are as safe and wholesome as and substantially and nutritionally equivalent to food and feed products derived from commercially available soybean.

9.7 Effects on animal health

Please refer to Point 9.6.

9.8 Effects on biogeochemical processes

Considering the scope of the application of CV127 soybean which excludes cultivation, any effect on biogeochemical processes can be ruled out. Dispersal of CV127 soybean grain will be restricted to accidental release during transportation and processing.

In addition, data obtained from field trials did not indicate any effect on biogeochemical processes resulting from the cultivation of CV127 soybean.

9.9 Impacts of the specific cultivation, management and harvesting techniques

The scope of the application is excluding cultivation of CV127 soybean in the EU. Any exposure to the environment from the import of CV127 soybean will be limited to accidental seed dispersal during transportation and processing of the grain.

The results of various regulatory field trials of CV127 soybeans in Brazil demonstrate that other than tolerance to imidazolinone herbicides, the cultivation of CV127 soybeans will have no different agronomic or environmental consequences compared to the cultivation of commercial soybeans.

10. Potential interactions with the abiotic environment

CV127 soybean is compositionally equivalent to commercial soybeans except for the introduced trait of imidazolinone tolerance. No interaction with the abiotic environment is anticipated that would differ from commercial soybean. In addition, the scope of this application does not include authorisation for the cultivation of CV127 soybean, therefore interaction with the abiotic environment will be limited to unintended release of CV127 soybeans due to spillage during import, storage and processing of the grain.

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 relates to the authorisation of CV127 soybean for import, processing, food and feed use in the European Union and does not include cultivation of CV127 soybean seed products in the EU.

An environmental risk assessment (e.r.a.) was carried out for CV127 soybean according to the principles laid down in Annex II to Directive 2001/18/EC and Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC. The scientific evaluation of the characteristics of CV127 soybean in the e.r.a. has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses. Therefore, the overall environmental risk caused by the CV127 soybean plant is negligible. No specific strategies for risk management and no case-specific post-market monitoring actions are considered necessary.

11.2 Interplay between environmental risk assessment and monitoring

Please refer to Point 11.1.

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 result of the e.r.a. there is no scientific evidence of a potential adverse effect linked to the genetic modification of CV127 soybean. It is therefore considered that no case-specific post-market 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 general surveillance of CV127 will be undertaken for the duration of the authorisation.

Since the intended use of CV127 is the same as that of any other commercial soybean, the procedures for the import, handling and processing of CV127 will be the same and have been considered in the development of the monitoring plan.

Exposure to the environment will be limited to unintended release of CV127, which could occur for example via losses during loading/unloading of the viable commodity including CV127 destined for processing into animal feed or human food products.

As BASF Plant Science is not involved in commodity trade with CV127, the monitoring methodology is predominantly based on collaboration with third parties, such as operators involved in the import, handling and processing of viable CV127 in order to increase the possibility of detecting any unanticipated adverse effects. The operators will be provided with guidance to facilitate reporting of any unanticipated adverse effect from handling and use of viable CV127.

BASF Plant Science will implement general surveillance of CV127 soybean with the help of the selected networks (importers/traders, silo operators, and soybean processors) and will ensure that appropriate information on CV127 soybean will be available for the relevant networks.

The third parties involved in the general surveillance will report any potential unanticipated adverse effects to the authorisation holder. The baseline and controls for general surveillance will rely on the historical knowledge and experience with non-GM soybeans as comparable reference where necessary.

Where information indicates the possibility of an unanticipated adverse effect, BASF Plant Science will immediately investigate to determine and confirm whether a significant correlation between the effect and CV127 can be established. If the investigation establishes that CV127 was present when the adverse effect was identified, and confirms that CV127 is the cause of the adverse effect, BASF Plant Science will immediately inform the European Commission.

11.5 Reporting the results of monitoring

If information that confirms an adverse effect of CV127 and that alters the existing risk assessment becomes available, BASF Plant Science will immediately investigate and inform the European Commission.

BASF Plant Science will submit an annual monitoring report including results of the general surveillance in accordance with the conditions of the authorisation. The report will contain information on any unanticipated adverse effects that have arisen from handling and use of viable CV127.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of CV127 and, as appropriate, the measures that were taken to ensure the safety of human and animal health or the environment.

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

A quantitative event-specific detection method for CV127 soybean and control materials is 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 There have been no previous releases of CV127 soybean in the EU.
b) Conclusions of post-release monitoring Not applicable.
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) Not applicable.

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

a) Release country Environmental releases with CV127 were carried out in Brazil, Japan and Argentina.
b) Authority overseeing the release Brazil: Comissäo Técnica Nacional de Biossegurança (CTNBio) www.ctnbio.gov.br Japan: Ministry of Agriculture, Forestry and Fishery (MAFF) http://www.maff.go.jp/e/index.html Argentina: Secretaría de Agricultura, Ganadería, Pesca y Alimentos. http://www.sagpya.mecon.gov.ar/
c) Release site Brazil: Multiple sites across Brazil Japan: National Institute of Agriculture and Environmental Science, Tsukuba City, Japan. Argentina: Corientes, Argentina
d) Aim of the release Brazil: Regulatory and research trials. Field releases were performed to determine equivalence, for breeding, seed increase, and to produce reference material. Japan: Regulatory trial that is required by the Japanese regulatory agencies to determine equivalence to conventional soybean varieties in the Japanese environment. Argentina: Regulatory trial to determine equivalence to conventional soybean varieties in the Argentine environment.

e) Duration of the release Brazil: Multiple seasons (2006/2007, 2007, 2007/2008) Japan: One season (2008) Argentina: One season (2008/2009)
f) Aim of post-releases monitoring Control and destruction of potential volunteers.
g) Duration of post-releases monitoring One growing season.
h) Conclusions of post-release monitoring Occurrence of volunteers is no different from commercial soybeans.
i) Results of the release in respect to any risk to human health and the environment No adverse effects on human health or the environment were identified during the field releases.

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.