PART II

SUMMARY

REQUEST FOR AUTHORIZATION OF GM FOOD AND GM FEED IN ACCORDANCE WITH ATICLES 5 AND 17 OF REGULATION (EC) NO. 1829/2003

GLUFOSINATE AMMONIUM-TOLERANT SOYBEAN TRANSFORMATION EVENT A5547-127

A. GENERAL INFORMATION

1. Details of application

a) **Member State of application:** The Netherlands
b) **Application number:** Not available at the date of application (EFSA-GMO-NL-2008-XX)
c) **Name of the product (commercial and other names):** Genetically modified soybeans (*Glycine max*) with tolerance to glufosinate ammonium (GA) herbicide, derived by traditional breeding methods from crosses between GM soybean transformation event A5547-127 (OECD code ACS-GMØØ6-4) and non-GM soybean varieties.
d) **Date of acknowledgement of valid application:** Not available at the date of application

2. Applicant

a) **Name of applicant:** Bayer CropScience AG, represented by Bayer BioScience NV
b) **Address of applicant:** Bayer CropScience AG Alfred-Nobel-Strasse 50 D - 40789 Monheim am Rhein Bayer BioScience NV Technologiepark 38 B-9052 Gent **E-mail address:** info@bayercropscience.com
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)):** A5547-127 soybean derived seeds will be imported and processed in the EU by the same groups who import, process and distribute commodity soybean seed today.

3. Scope of the application

☒ GM plants for food use

☐ Food containing or consisting of GM plants

☐ Food produced from GM plants or containing ingredients produced from GM plants

☒ GM plants for feed use

☐ Feed containing or consisting of GM plants

☐ Feed produced from GM plants

☒ 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)

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

Yes ☐	No ☒
If *yes*, specify	

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

Yes ☐	No ☒
If *no*, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC This application requests import and processing only and is not intended for growing purposes in the EU.	

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 ☐
If *yes*, specify: Event A5547-127 has been notified according to Directive 90/220/EC in Belgium (C/B/98/01) and Portugal (C/PT/99/01) and according to Regulation 258/97 in Belgium. Due to the new regulations these notifications have been withdrawn and replaced by the current notification under Regulation (EC) No 1829/2003.	

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

Yes ☒	No ☐

If *yes*, specify:

COUNTRY	Type and Date of Approval – Event A5547-127 Food	Feed	Granted	**Agency Name**
Australia/ New Zealand	√		2004	**FSANZ**
Canada	√	√	2000	**CFIA, CaH**
Japan	√	√	2001	**MHLW, MAFF**
Mexico	√	√	2000	**SSA**
Russia	√	√	2002	**MHCSP, FGNKI**
United States	√	√	1998	**FDA, USDA**

FDA: Food and Drug Administration; **USDA**: United States Department of Agriculture; **MHLW**: Ministry of Health, Labour and Welfare; **MAFF**: Ministry of Agriculture, Forestry and Fisheries; **FSANZ**: Food Standards Australia New Zealand; **CFIA**: Canadian Food Inspection Agency; **CaH**: Canada Health, **MHCSP**: Ministry of Health Care and Social Progress; **SSA**; Health Ministry; **FGNKI:** Federal Service On Veterinary and Phytosanitary Surveillance (Rosselkhoznadzor)

Cultivation of A5547-127 is authorised in Canada (2006), and the United States (1995).

8. General description of the product

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

The recipient plant belongs to the species, *Glycine max*. The genetic modification confers tolerance to the herbicide glufosinate ammonium by virtue of recombinant DNA technologies used to create a new transgenic event in soybean, A5547-127. The inserted *pat* coding sequence codes for the specific enzyme, phosphinothricin acetyl-transferase (PAT). PAT acetylates glufosinate ammonium and thereby detoxifies the herbicide.

A5547-127 soybean and glufosinate ammonium herbicides work together in a weed control system with favourable environmental and safety characteristics. The system combines the broad spectrum, non-selective herbicide, GA with soybean varieties which have a genetically-based tolerance to this herbicide.

The use of glufosinate ammonium herbicides fits well with the new common agronomic practices for weed control in soybeans. These include less tillage, less herbicide combinations used pre-emergent and the targeted use of broad-spectrum post-emergence herbicides. The option to wait for crop establishment to assess weed infestations and the need for weed control allows the grower flexibility and avoids the often unspecific application of pre-plant and pre-emergence herbicides. Glufosinate ammonium allows the grower the option to delay herbicide application until the level of weed infestation is known. The unique mode of action of GA herbicides lends itself as an excellent herbicide rotational tool.

Advantages for US and Canadian agriculture provided by the GA tolerant soybeans include: 1) more options to rotate herbicides for resistance management programs; 2) control of less sensitive weeds (Morningglory); and 3) removal of difficult to control weeds (Ragweed). It thus provides more options for crop management, less environmental impact in soybean growing areas and potential implications for soil conservation through minimum tillage practices.

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

A5547-127 soybeans will be imported, processed and distributed in the European Union for the same uses as any other soybean (food, feed and industrial uses) excluding cultivation.

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

Soybeans derived from event A5547-127 will be grown in the United States of America (USA) and Canada (possibly Argentina and Brazil) and will enter the EU by import as commodity soybean and derived products and could be used for the same downstream purposes as non-GM soybeans. There are three major food/feed products derived from soybeans – whole soybeans, oil and meal.

This application requests import and processing only and is not intended for growing purposes in the EU. The milling, processing and consumer packaging however will be accomplished in the EU.

Therefore the intended categories of users belong to the soybean crushing and packaging industry and their customers, 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:

No mandatory restrictions for use, storage and handling are proposed as a condition of the authorisation. All standard practices applicable to soybean today remain adequate for the handling of glufosinate ammonium-tolerant, event A5547-127 varieties.

When genetically modified soybean is placed on the EU market (including co-mingled with non-genetically modified soybean during use, storage and handling), the corresponding batch will be labelled and handled according to the legislation in application in the EU, in particular the Regulation No. 1830/2003 (EC).

e) Any proposed packaging requirements:

Soybean derived from event A5547-127 will be packaged as any other conventional 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:

Event A5547-127 does not have characteristics that require specific labelling. Therefore, no additional labelling is proposed in addition to the GM labelling requirements foreseen in regulations (EC) 1829/2003 and 1830/2003.

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):

ACS-GMØØ6-4

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:

No restrictions are necessary as varieties derived from event A5547-127 are suitable for food, feed and industrial uses in all regions of the European Union. This application requests import and processing only and is not intended for growing purposes 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

Any unintended release or misuse will not have detrimental effects on the environment or on human and animal health as has been determined by the risk analysis. Therefore, no special measures are foreseen.

Soybeans derived from transformation event A5547-127 are tolerant to herbicide products having glufosinate ammonium as the active ingredient. They remain susceptible to a wide variety of other herbicides and plants can thus be easily eliminated. Besides chemical means, mechanical removal is also an option.

No additional specific measures are suggested in case of waste disposal and treatment.

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

1. Complete name

a) Family name:	*Leguminosae*
b) Genus:	*Glycine*
c) Species:	*max*
d) Subspecies:	Not applicable.
e) Cultivar/breeding line or strain:	A5547
f) Common name:	soybean

2 a. Information concerning reproduction

(i) Mode(s) of reproduction

Soybean is considered a self-pollinated species, propagated commercially by seed.

The soybean flower stigma is receptive to pollen approximately 24 hours before anthesis and remains receptive 48 hours after anthesis. The anthers mature in the bud and directly pollinate the stigma of the same flower. As a result, soybeans exhibit a high level of self-fertilisation and cross pollination is usually less than one percent.

(ii) Specific factors affecting reproduction

Soybeans are quantitative short day plants and thus flower more quickly under short days. As a result, photoperiodism and temperature response are important in determining areas of variety adaptation. Seed will germinate when the soil temperature reaches 10°C and will emerge in a 5-7 day period under favourable conditions. In new areas of soybean production an inoculation with *Bradyrhizobium japonicum* is necessary for optimum efficiency of the nodulated root system. Soybeans do not yield well on acid soils.

(iii) Generation time

Soybean is an annual crop. Generation time is 3 to 5 months in the primary areas of production.

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

There is no evidence of genetic transfer and exchange with organisms other than those with which soybean is able to produce fertile crosses through sexual reproduction.

In Europe, the cultivated soybean is *G. max*. No wild relatives have been reported and *G. max* itself is not a wild species.

The subgenus *Soja*, to which *G. max* belongs, also includes *G. soja* Sieb. and Zucc. (2n=40) and *G. gracilis* Skvortz. (2n=40), wild and semi-wild annual soybean relatives from Asia. *Glycine soja* is a wild viny annual with small and narrow trifoliate leaves, purple flowers and small round brown-black seeds. It grows wild in Korea, Taiwan, Japan, Yangtze Valley, N.E. China and areas around its western border. *Glycine gracilis*, an intermediate in form between *G. soja* and *G. max*, has been observed in Northeast China. Interspecific, fertile hybrids between *G. max* and *G. soja*, and between *G. max* and *G. gracilis* have been easily obtained.

In addition to the subgenus *Soja*, the genus *Glycine* contains also the subgenus *Glycine*. The subgenus *Glycine* consists of wild perennial species, including *G. clandestina* Wendl., *G. falcata* Benth, *G. latifolia* Benth., *G. latrobeana* Meissn. Benth., *G. canescens* F.J. Herm., *G. tabacina* Labill. Benth., and *G. tomentella* Hayata. These species are indigenous to Australia, South Pacific Islands, China, Papua New Guinea, Philippines, and Taiwan. Species of the subgenus *Glycine* have chromosome complements of 2n=40 or 2n=80.

Early attempts to hybridise annual (subgenus *Soja*) and perennial (subgenus *Glycine*) species were unsuccessful. Although pod development was initiated, these eventually aborted and abscised. Intersubgeneric hybrids were later obtained *in vitro* through embryo rescue, between *G. max* and *G. clandestina* Wendl; *G. max* and *G. tomentella* Hayata; and *G. max* and *G. canescens*, using transplanted endosperm as a nurse layer. In all cases, the progeny of such intersubgeneric hybrids was sterile and obtained with great difficulty.

This application requests import and processing only and is not intended for growing purposes in the EU.

3. Survivability

a) Ability to form structures for survival or dormancy

Soybean, *Glycine max*, is a cultivated, self-pollinating annual species, propagated commercially by seed. Soybean seeds rarely display any dormancy characteristics and only under certain environmental conditions will soybeans emerge as a volunteer in the year following cultivation. The soybean plant is not weedy in character and is not found outside of cultivation. Aside from seed, soybean has no other structures for survival or dormancy.

b) Specific factors affecting survivability

Soybeans are adapted to agricultural regions from equatorial to temperate zones. They grow most rapidly when air temperatures are between 25 and 30 °C. They are very susceptible to frost damage and somewhat susceptible to excessive drought and extended flooding. Seeds of cultivated soybean survive poorly in soil, normally less than one year, and generally do not overwinter.

4. Dissemination

a) Ways and extent of dissemination

Soybean is considered a self-pollinated species, propagated commercially by seed. It exhibits a high percentage of self-fertilisation and cross pollination is usually less than one percent.

Seed may be dispersed during transport, at sowing or during harvest. Pods may also shatter under some climatic conditions if harvest is delayed, resulting in seed dispersal. However, soybean is not an invasive crop and is seldom observed as a volunteer plant after soil cultivation.

b) Specific factors affecting dissemination

No special factors affect dissemination. Dissemination is due primarily 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 soybeans are grown as a commercial crop in more than 35 countries throughout the world. *G. max* is not found as a wild species.

FAO Agricultural Production Data indicates that during the year 2006, 221 million metric tons of soybean was harvested from 93 million hectares world-wide. Of that, almost 1.212.056 metric tons were produced on about 487.590 hectares in the European Union (EU27). FAO data indicates soybean production in the following Member States during 2006: Austria, Bulgaria, Czech Republic, France, Germany, Greece, Hungary, Italy, Latvia, Poland, Romania, Slovakia, Slovenia and Spain. Approximately 74% of all the soybeans produced in the EU were grown in Italy (45%) and Romania (28%) during that time period. France's production represented 10%, Hungary's 6.8% and Austria's about 5%.

During 2006, Canadian production amounted to about 3.5 million metric tons and USA production to about 87 million metric tons.

Wild relatives of soybean (*Glycine max*) are found only in Australia, China, Japan, Korea, Taiwan, the Philippines, Papua New Guinea and several South Pacific islands.

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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

Soybean is cultivated by the Member States of Austria, Czech Republic, France, Germany, Greece, Hungary, Italy, Slovakia, Slovenia, Spain, Romania and Bulgaria. *G. max* and its wild relatives are not indigenous to 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

As soybeans are legumes, they can fix atmospheric nitrogen as a source of nitrogen for growth and development in a symbiotic relationship with *Bradyrhizobium japonicum*. When soybeans are grown in new production areas, seeds are normally inoculated with *B. japonicum* prior to planting.

There are a few compounds in legumes, and therefore also in soybeans, which are not favourable for human or animal nutrition. However, their levels in soybeans derived from transformation event A5547-127 are not significantly different from those found in conventionally bred soybeans.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification

Soybean tissue for transformation was obtained from shoot apices derived from surface sterilized soybean seeds. The genetic modification was made through particle bombardment. No carrier DNA was used in the process.

2. Nature and source of the vector used

The plasmid, pB2/35SAcK, is a derivative of the vector pUC19. It contains a Right Border fragment from the *Agrobacterium tumefaciens* Ti plasmid pTiAch5 and the synthetic *pat* gene fused to 35S-promotor and 35S-terminator from Cauliflower Mosaic Virus

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

The genetic elements to be transferred into the plant are described in Table 1.

The pUC sequences in the plasmid include a *β-lactamase* gene (*bla*) and a bacterial origin of replication. The *bla* gene is however not functional in transgenic soybean cells because prior to transformation the vector was digested with a restriction enzyme (*Pvu*I) to disrupt the coding sequence of the *bla* gene and thereby remove the possibility of its expression.

Table 1 Genetic elements of the Plasmid pB2/35SacK to be inserted

Definition	Source	Size (bp)	Function
Sequence of the vector pUC19		188	Vector backbone
Right border repeat	Fragment of octopine plasmid TiAch5	55	*Cis*-acting element for T-DNA transfer
Sequence of the vector pUC19		217	Vector backbone
Promoter	Cauliflower mosaic virus from the vector PDH51	543	High level constitutive expression
Polylinker sequence	Synthetic	8	Plasmid cloning site
Synthetic *pat* gene	Synthetic (amino acid sequence from *Streptomyces viridochromogenes*)	552	Herbicide tolerance and selectable marker Stop signal
Polylinker sequence	Synthetic	18	Plasmid cloning site
Terminator	Cauliflower Mosaic Virus from the vector pDH51	203	Stop signal
Sequence of the vector pUC19, including the polylinker, the origin of replication and the ***β-lactamase* (*bla*) gene**		2292	Bacterial origin of replication and bacterial marker

D. INFORMATION RELATING TO THE GM PLANT

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

All LibertyLink® crops are tolerant to commercial herbicides containing glufosinate ammonium (active form is L-glufosinate). Their herbicide tolerance is based upon the naturally occurring *pat* gene, isolated from soil microbes that produce L-phosphinothricin, a bacterial metabolite with antimicrobial and herbicidal activity. Glufosinate ammonium is the synthetic salt of this natural herbicide. Activity of the *pat* gene protects the microbe as it makes L-phosphinothricin. In a similar manner, expression of the *pat* gene in plants allows survival after a foliar spray with glufosinate ammonium herbicide. The *pat* gene codes for the enzyme Phosphinothricin-Acetyl-Transferase (PAT) that acetylates L-phosphinothricin (also known as L-glufosinate) to an inactive form. The PAT protein is a highly specific enzyme with only this one function. If left in its L-isomer form, phosphinothricin disrupts the normal process of amino acid synthesis and results in a lethal build-up of ammonium in the microbe or plant cell. In a manner not unlike an inadvertent over-fertilisation of a plant, glufosinate ammonium herbicides cause sensitive plants to release internal ammonia, leading to rapid plant death.

LL Soybean varieties derived from event A5547-127 make the PAT protein mainly in their green leaf tissue. When sprayed with glufosinate ammonium herbicides, the A5547-127 plants can continue to grow while surrounding weeds rapidly die.

Several formulations of glufosinate ammonium are commercially used in many regions of the world. Registered trade/brand names include Liberty®, Ignite®, Finale® and Basta®. Registered uses in Europe include non-selective weed control in the floor of orchards and vineyards and desiccation of potatoes and oilseed rape prior to harvesting. LibertyLink® crops currently on the market in certain countries include varieties of GM corn, cotton and canola. None of them are currently cultivated in the European Union.

2. Information on the sequences actually inserted or deleted

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

Southern blot, PCR and sequence analysis demonstrated that the glufosinate ammonium-tolerant, soybean event A5547-127 contains one copy of the *pat* gene cassette and truncated parts of the *bla* gene at the 5' and 3' ends of the insert.

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

No deletion occurred.

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

Based upon Southern blot and genetic segregation analysis, it was demonstrated that the DNA has integrated in a single genetic locus in the soybean nuclear genome (chromosome).

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

The inserts were completely sequenced and compared to the vector sequence.

The DNA sequences of event A5547-127 are completely identical to the corresponding transforming plasmid DNA sequences. The *β-lactamase* gene was disrupted into non-functional fragments. The characterization of the inserted sequences in event A5547-127 confirmed the presence of one copy of the *pat* gene cassette and truncated parts of the *bla* gene at the 5' and 3' ends of the insert (Figure 1).

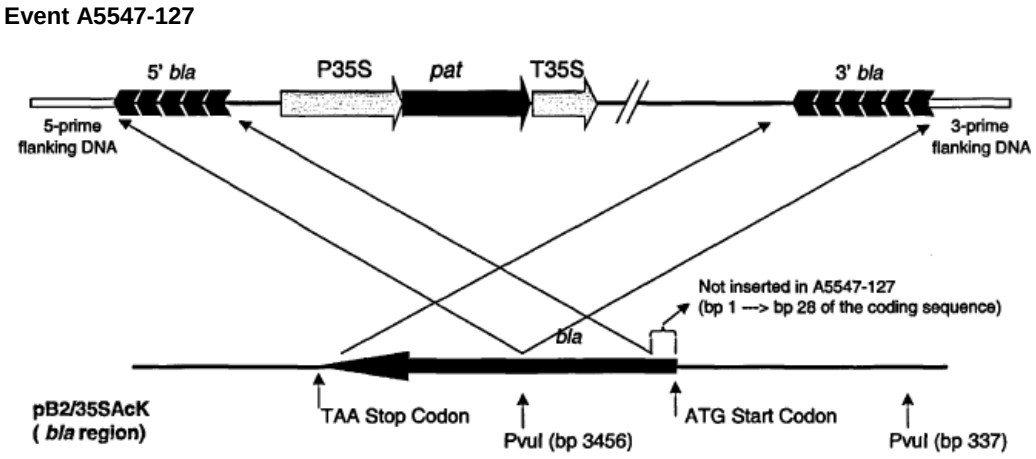

Figure 1. Organization of the inserted *bla* sequences in event A5547-127 (Not drawn to scale)

3. Information on the expression of the insert

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

The type of promoter linked to the inserted plasmid DNA can predict the pattern of expression. Tissue specific promoters can be used to limit the expression to certain tissues of the plant, while constitutive promoters will cause expression of the inserted gene throughout the plant in all tissues. For transformation events A5547-127, the expression of the *pat* gene is regulated by the 35S promoter, a constitutive promoter isolated from the Cauliflower Mosaic Virus. Therefore expression of the PAT protein in all tissues was expected. The partial *bla* sequences are under control of bacterial transcription regulatory sequences and are not expressed in the plant.

Expression level was measured by PAT protein specific ELISA. The amount of PAT protein in the leaves of A5547-127 during the vegetative life cycle of the plant is determined in the range of 18µg to 26µg PAT protein per gram fresh weight.

In order to determine whether the *bla* sequences present in soybean event A5547-127 are expressed, a Northern blot analysis was performed on different tissues. This analysis confirmed that the *bla* sequences are not expressed in the tested plant tissues.

b) Parts of the plant where the insert is expressed

Linked to the plant promoter, 35S, the expression of the *pat* gene is targeted to green tissue of the plant. PAT levels measured in root and stems ranged from 3,6 – 8,2 µg/g, and 13,8 – 39,2 µg/g respectively in samples taken from greenhouse conditions and sampled at two growth stage. The PAT levels found represent only a minor part of the total crude protein in roots and stems of soybean

derived from transformation event A5547-127.

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

a) Reproduction

The herbicide tolerance trait has no effect on the mode and rate of reproduction.

b) Dissemination

The introduction of tolerance to the herbicide glufosinate ammonium has not affected agronomic characteristics. Soybeans derived from event A5547-127 retain the same growth rate and growth habit as non-transgenic soybeans, continue to be self-pollinating plants and disperse their seed in the same way as non-transgenic soybean.

c) Survivability

For cultivated soybean, survival is most determined by seed characteristics. There is no indication of changes in the seed characteristics as a result of the genetic modification.

d) Other differences

The only biologically significant difference observed in field evaluations is that soybean varieties derived from transformation event A5547-127 are tolerant to glufosinate ammonium herbicides.

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

The trait is stably integrated and inherited as a single locus (shown by Southern analysis and Mendelian inheritance patterns).

Stability has been demonstrated by Southern analysis of the molecular structure of three consecutive generations (R3, R4, and R5) of plants derived from Soybean event A5547-127. The hybridization data revealed that all of the analyzed offspring had integration patterns identical to that observed for the primary transformation event.

Phenotypic stability of soybeans derived from event A5547-127 was also demonstrated by evaluating the inheritance pattern of tolerance to glufosinate ammonium through succeeding generations. The inheritance of the introduced trait in soybean A5547-127 follows a Mendelian pattern characteristics of a single dominant gene.

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

a) Plant to bacteria gene transfer

The likelihood of the transfer of a functional *pat* or *bla* gene from soybeans derived from event A5547-127 to bacteria is extremely remote. (Addressed in more details in Section 9.3)

b) Plant to plant gene transfer

There is no evidence of genetic transfer and exchange under natural conditions with organisms other than those with which soybean is able to produce fertile crosses through sexual reproduction. There are no indications that the potential for successful exchange of genetic material has changed due to the genetic modification.

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

Event A5547-127 was created by the transformation of Asgrow Soybean cultivar A5547. Throughout the comparative assessment studies the parent variety, A5547 was used as a comparator.

7.2 Production of material for comparative assessment

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

Soybean plants containing the glufosinate tolerant event A5547-127 and soybean plants representing the non-transgenic counterpart, A5547, were field tested throughout the growing seasons 1999, 2000, 2006 and 2007 in the USA in North Carolina, Florida, Georgia, Mississippi, Arkansas, Louisiana and Texas (EPA Regions II, III, IV, and VI), which are typical growing regions for group 5 soybeans.

At each site three plots for the non-transgenic control (A5547) and six plots for the transgenic soybean event A5547-127 were planted and grown under the same conditions except for the glufosinate ammonium treatment. Three of the transgenic plots were sprayed two times with the glufosinate herbicide. The plots were arranged in a complete randomized trial design.

Soybean for compositional analysis of the unprocessed oilseeds was produced in 16 locations (4 locations in 1999, 5 locations in 2000, 7 locations in 2006).

The agronomic trait data were collected from 16 sites in the years 2006 and 2007 (8 locations/year).

b) The baseline used for consideration of natural variations

In all the comparative studies, the soybeans derived from event A5547-127 were compared with non-transgenic comparator A5547. In addition, the results of the composition study were also compared with information available in the literature about constituent levels in soybeans.

7.3 Selection of material and compounds for analysis

Analyses were conducted for the components suggested by OECD Consensus Document on Compositional Considerations for New Varieties of Soybean: Key Food and Feed Nutrients and Anti-nutrients. Proximate and fibre compounds, the micro-nutrients, such as minerals and vitamins, the isoflavones, the anti-nutrients raffinose, stachyose, phytic acid, trypsin inhibitors, and lectins, the total amino acids, and the total fatty acids were analysed.

Statistically significant differences based on ANOVA statistics were only detected for raffinose and oleic acid (C18:1). These findings were not confirmed however by the overall analyses including the year effects and were inside the ranges for both compounds reported in the literature.

The conclusion drawn from the comparative analyses is that LL Soybean event A5547-127 is found to be compositionally and nutritionally equivalent to its traditional non-transgenic counterpart and to other current commercial soybean varieties. There is no impact on the nutritional value of the soybean caused by the genetic transformation.

7.4 Agronomic traits

The analysis of the agronomic and morphological characteristics represents a key component of the comparative approach for identifying unintended effects during the risk assessment process. In order to demonstrate the morphological and agronomic equivalence of event A5547-127 to its appropriate counterpart A5547 two years of field trials were conducted.

Data on qualitative traits including flower colour, pubescence colour, pod colour, hilum colour, canopy architecture, leaf shape, as well as susceptibility to pests and diseases were collected and analyzed. Quantitative traits including: emergence, stand count, plant vigor and health rating, flowering date, plant height, days to maturity, and yield were recorded and analyzed with analysis of variance statistical methods (ANOVA).

Based on the comparative assessment of seven qualitative and seven quantitative soybean characteristics transgenic event A5547-127 and the non-transgenic A5547 soybeans are considered to be morphologically and agronomically equivalent.

7.5 Product specification

The imported commodity is A5527-127 soybean and derived food, feed and industrial products. A5547-127 is a candidate to be the commercial successor event of A2704-12 soybean.

Event A5547-127 was created by the transformation of Asgrow Soybean cultivar A5547.

The test material used in the different studies submitted within this application has been produced from the homozygous, self pollinated A5547-127 line.

The LibertyLink® soybean varieties containing event A5547-127 belong to the species Glycine max and are distinguished from conventional soybeans only by tolerance to the herbicide glufosinate ammonium.

7.6 Effect of processing

Soybeans harvested from A5547-127 plants will be produced and processed in the same manner as soybeans produced using conventional breeding methods, with one exception, A5547-127 plants can be sprayed with glufosinate ammonium herbicides during production.

The effect of processing was studied in seven different feed and food materials: (1) hulls, (2) non toasted meal, (3) toasted meal, (4) crude oil, (5) refined food grade oil and in food additives: (6) soybean protein isolate, (7) lecithin on the i.) general composition of the food feed material and specifically on the ii.) PAT protein content of these processed fractions.

The effect of processing resulted in the same general composition of soybean A5547-127 as its non-transgenic comparator A5547. Processing steps including the application of high temperature regimes, pressure of the screw pressing, separation by extraction with a non-polar solvent and heating during the solvent recovery resulted in no detectable level of PAT protein in (4) refined oil, (5) food grade (refined, bleached and deodorized) oil and (7)crude lecithin produced from A5547-127 soybean seeds. The last traces of protein in the crude oil are removed in the alkali treatment and deodorization steps of the oil refining

Long term storage freezing conditions indicated that the PAT protein is essentially stable in raw soybean commodities.

7.7 Anticipated intake/extent of use

The intake of soybean or derived products in the diet of the European Union is not anticipated to change with the introduction of A5547-127 varieties. Soybean and soybean products derived from A5547-127 varieties are not different in quality or nutritional composition from the Soybean products now consumed. No change in the use patterns for soybean is anticipated.

7.8 Toxicology

7.8.1 Safety assessment of newly expressed proteins

-The coding sequence of the pat gene is derived from a common soil microbe not known to be a pathogen,
-The acetyltransferase proteins have not been described as allergenic or toxic for humans or animals and are likely to occur frequently in nature. No adverse health effects have been related to these compounds,
-The PAT protein has no homology with any known allergens, toxins or antinutrients,
-The PAT protein has no glycosylation sites present on certain food allergens,
-The PAT protein is quickly degraded and denatured in gastric and intestinal fluids of domestic animals and humans,
-The PAT protein is not degraded or modified in a way that would affect its migration in SDS-PAGE by heat; however the PAT protein is completely thermo-inactivated after 10 minutes at 55°C and higher temperatures ,
-The PAT enzyme is highly substrate-specific. It acts on its target, glufosinate ammonium, but it does not act on glutamate, the closest structural analogue of L-glufosinate ammonium,
-There were no adverse effects found in mice, even at a high dose level of the PAT protein, via intravenous administration,
-A sub-chronic oral toxicological study with pure PAT protein has also shown the absence of adverse

effects of the PAT protein.

Due to the low expression of PAT in A5547-127 soybean plants, the PAT protein used for the sub-chronic study was produced in *E.coli*. The PAT protein generated in *E.coli* was not distinguishable by means of biochemical and immunological methods from the protein expressed in plants of Soybean event A5547-127.

7.8.2 Testing of new constituents other than proteins

No constituent other than the PAT protein is novel and no changes in composition of the soybean were discovered by chemical analysis.

7.8.3 Information on natural food and feed constituents

Natural constituents of soybean have not been changed in A5547-127 soybeans. Extensive compositional analysis was undertaken and the conclusion drawn from the comparative analyses is that LL Soybean event A5547-127 is found to be compositionally and nutritionally equivalent to its traditional non-transgenic counterpart and to other current commercial soybean varieties. There is no impact on the nutritional value of the soybean seeds caused by the genetic transformation.

7.8.4 Testing of the whole GM food/feed

In addition to the comparative assessment studies, the nutritional value of feed derived from A5547-127 was assessed in a 42-days poultry feeding study.

The broiler chicken (*Gallus gallus domesticus*) is an economically significant and widely distributed food animal. The species used is based upon commercial practice and is very sensitive to detect differences in nutrient quality because of its rapid growth (15-fold increase in body weight during the first 18 days). This study showed there were no differences between groups of broiler chickens fed with A5547-127 soybean meal diet or fed with an equivalent non-transgenic parental soybean meal diet.

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

The PAT protein does not possess any of the characteristics associated with food allergens.

The PAT protein has no sequence homology with any known allergens, toxins or antinutrients.

The PAT protein has no glycosylation sites present on certain food allergens.

The PAT protein forms only a minor part of the crude protein fraction in A5547-127 event, making it unlikely to become a food allergen.

7.9.2 Assessment of allergenicity of the whole GM plant or crop

An *in vitro* human allergenicity study was carried out to determine if genetically modified Soybean event A5547-127 has any increased activity as compared to non-genetically modified parental soybeans A5547. There was no significant difference observed in the endogenous soybean allergen content of the extract obtained from the genetically modified soybean event A5547-127 as compared to the extract obtained from traditional soybean variety A5547. Thus, there is no significant increased risk of allergenic potential of the transgenic soybean event A5547-127 as compared to the non-transgenic soybean variety A5547 in soy-allergenic subjects.

7.10 Nutritional assessment of GM food/feed

The trait introduced in A5547-127 is intended for agronomic benefits. A5547-127 soybeans have no specific novel role in the diet therefore it is very unlikely that it would be consumed in an altered way to how other soybeans are consumed. The product is not intended to improve the nutritional status of consumers nor does it have the potential to introduce nutritional imbalances.

A5547-127 soybean products will be imported as any other commercial soybean in commingled commodities. The actual A5527-127 content of the shipment will depend on many factors and will vary from vessel to vessel.

7.11 Post-market monitoring of GM food/feed

No post-market monitoring plan is required for food and feed derived from A5547-127 soybeans. Traditional comparators were used in the comparative analysis. The intent of the genetic modification was for agronomic benefit, no change in the nutritional composition or value was intended. No health claims are intended. Food derived from A5547-127 will not be marketed as an alternative to or replacement for traditional soybean food products. A5547-127 has no specific properties that might increase the dietary intake compared to conventional soybeans. There is no evidence that the long term nutritional and health status of some individuals of the European population could be impacted by the marketing of A5547-127 derived food products.

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

The trait introduced in event A5547-127 is herbicide tolerance. Therefore, there are no target organisms to consider.

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

The scope of the application is for food and feed uses, import and processing and excludes cultivation. The environmental exposure is limited to accidental release of A5547-127 soybean during transportation and processing for food and feed.

9.1 Persistence and invasiveness

The data of the reproductive and vegetative fitness indicate that soybean A5547-127 compares to its parent variety A5547 in all aspects except the tolerance to glufosinate ammonium herbicide. The introduced trait in event A5547-127 does not affect the non-persistence and non-invasiveness of *Glycine max*.

9.2 Selective advantage or disadvantage

This application requests import and processing only and is not intended for growing purposes in the EU.

Soybeans derived from event A5547-127 have a seasonal advantage over weed competition only in concert with the use of a glufosinate ammonium herbicide to control weeds growing in the same field.

A5547-127 soybeans, as all soybeans, are an annual, self-pollinating, cultivated crop without weedy characteristics and without wild relatives in the European Union.

There is no known scientific report of increased spread and establishment of soybean A5547-127 and any change in survival capacity, including overwintering. Except for tolerance to glufosinate ammonium and thus the opportunity offered to use glufosinate ammonium herbicides as part of the seasonal crop protection regime, there are no significant phenotypic, genotypic, including reproductive biology differences between event A5547-127 and commercial soybean varieties developed solely through conventional breeding practices. Absent the use of glufosinate ammonium, any plants that might germinate from an accidental spill during import or transport of A5547-127 have no selective advantage over conventionally developed soybeans.

In addition the herbicide glufosinate ammonium is not likely to be used in the vicinity of seed storage facilities, processing plants or roadways, areas where an accidental spill might occur.

9.3 Potential for gene transfer

A prerequisite for any gene transfer is the availability of pathways for the transfer of genetic material, either through (a) horizontal plant to bacteria gene transfer, or (b) vertical plant to plant gene flow via seed dispersal or cross-pollination.

(a) Plant to bacteria gene transfer: In order for any horizontal gene transfer to lead to a new type of micro-organism and, therefore, to introduce a significant impact, some of the following conditions would have to be fulfilled**:**

- The uptake would need to result in the incorporation of complete un-degraded DNA
- The plant targeted genes would need to result in significant expression in a prokaryotic background
- The expression would need to represent a significant increase over the background level
- The trait would need to convey a competitive advantage to the strain in which it is incorporated.

Sequence analysis of event A5547-127 confirmed the presence of one copy of the *pat* gene cassette and truncated parts of the *bla* gene at the 5' and 3' ends of the insert. The likelihood of the transfer of any functional gene from soybeans derived from event A5547-127 to bacteria is extremely remote.

(b) Plant to Plant gene transfer: As discussed under section D6(b), while this request does not cover cultivation of soybeans derived from event A5547-127, in theory cross pollination with other soybeans could occur if grain of A5547-127 was spilled and left in an area in which germination and soybean growth was possible and the opportunity for cross pollination presented itself. While possible, the likelihood of significant exposure of soybeans grown in the European Union to pollen from A5547-127 plants grown up as the result of spilled grain is extremely remote.

The likelihood of gene flow: Gene flow from A5547-127 soybean can occur into an adjacent soybean crop, however, the amount of cross-pollination to other soybean is generally considered to be less than 1%. Soybean anthers mature in the bud and directly pollinate the stigma of the same flower. As a result, soybeans exhibit a high level of self-fertilisation. Gene flow will not occur into wild related species because they are not present in the European Union.

The consequence of gene flow: In the improbable event it did occur, transfer of the *pat* gene into cultivated soybean will not exacerbate problems of weed control or adversely impact agriculture. Glufosinate ammonium is used mainly in agricultural areas in Europe, and the weed management of roadsides and the yards of processing facilities based on the use of glufosinate ammonium is not in practice.

This application requests import and processing only and is not intended for growing purposes in the EU and thus, this risk is only hypothetical. No adverse impact to biodiversity was identified.

9.4 Interactions between the GM plant and target organisms

The introduced trait is not a pesticidal trait. There are no target organisms.

9.5 Interactions of the GM plant with non-target organisms

There are no non-target organisms specific to A5547-127 compared to non-genetically modified soybeans. There are no observed effects of the herbicide-tolerant soybean on beneficial or pest organisms. Field observations found no differences in insect populations, or reactions to natural infestation of soybean pathogens (D.7.4). A survey of beneficial and pest populations conducted at the final maturity stage during a soybean trial in Brazil found no difference in the presence or preference of pests or beneficials, which might be attributed to the genetic modification, when comparing soybeans derived from event A5547-127 with the non-genetically modified counterpart. Considering the intended use of soybean A5547-127 excludes cultivation and consequently the low level of exposure to the environment; the interaction of the GM plant with non-target organism in Europe is very limited.

9.6 Effects on human health

Related to event A5547-127 no adverse effects on human health are indicated for people working with, coming into contact with or in the vicinity of an environmental release of A5547-127 soybeans. Soybeans derived from transformation event A5547-127 have the same nutritional quality as soybeans in commerce, developed entirely through traditional breeding processes. The PAT protein, expressed in A5547-127 soybeans, is neither a toxin nor an allergen and A5547-127 soybeans present no significant increased risk of an allergenic potential as compared to non-transgenic soybeans in soy-allergenic people.

9.7 Effects on animal health

No adverse effects on animal health are indicated when A5547-127 soybeans are used for feed purposes. Both seed and processed fractions are used in animal feed. Soybean hulls can make up to 20% of cattle and poultry diet and seed can make up 15 to 25% of animal diets. Soybean seed is typically heated to 100 °C before use to destroy proteinase inhibitors and the temperatures used are high enough to inactivate the PAT protein.

The nutritional composition of seed and processed fractions of A5547-127 is substantially equivalent to that of soybeans developed solely through traditional breeding practices. The similar nutritional value was confirmed in a poultry conducted using diets containing meal derived from A5547-127. There is no impact on the nutritional value of soybean seeds or processed fractions caused by the genetic transformation.

9.8 Effects on biogeochemical processes

Throughout the field testing history of transformation event A5547-127, no differences were noted that could be attributed to pleiotropic effects of the insertion. No differences were observed that would indicate an effect on biogeochemical processes resulting from the cultivation of A5547-127.

Chemical analysis of the components in soybeans found no significant differences in mineral composition and thus no reason to consider mineral utilization from the soil to be different than for conventional soybeans.

Considering the intended use of soybean A5547-127 excludes cultivation in Europe and consequently the low level of exposure to the environment; the effect on biogeochemical cycles is not an issue.

9.9 Impacts of the specific cultivation, management and harvesting techniques

A5547-127 varieties will be grown in the United States of America (USA), Canada and possibly Argentina and Brazil. Soybean seed and derived products produced in the USA enter the European Union (EU) by import as commodity soybean, meal, flakes or oil. Further processing and consumer packaging are accomplished in the EU. A5547-127 soybeans once approved and once commercialized, will be included in EU commodity soybean imports.

Soybeans in agricultural production require weed control and successful weed control depends upon combinations of management practices. For soybean production, farmers use the planting of weed-free seed, crop rotation to break weed cycles, precision land levelling to aid irrigation, seed-bed preparation, conservation tillage programs, irrigation and the application of one or more herbicides insecticides, and sometimes fungicides, seed-dressing and inoculation with soil bacteria.

Compared to previous LibertyLink Soybean event A2704-12, the event A5547-127 provides a useful alternative to seed companies and farmers. The soybean event A5547-127 has a different insertion site in a different genetic background that provides more freedom and flexibility in variety breeding for seed companies. The transformation using the Soybean maturity group V facilitates and speeds up the introgression in geographical adapted varieties for additional agricultural markets/regions. The LibertyLink system represents the only practical alternative for those markets that can deliver complete weed control and for which there is no known resistant weeds worldwide.

10. Potential interactions with the abiotic environment

No interaction with the abiotic environment is foreseen that would differ from soybean now in cultivation and in commerce. Less soil erosion may be a benefit of the cultivation of A5547-127 as farmers growing it will be able to practice minimum tillage and conservation tillage systems. Considering that the intended use of soybean A5547-127 in the EU excludes cultivation, and consequently the levels of exposure to the environment will be low; the interaction with the abiotic environment in Europe is not an issue.

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)

11.1 General (risk assessment, background information)

The scope of this application is the import of soybean derived from event A5547-127 (ACS-GMØØ6-4) for food, feed and industrial uses. No authorisation for growing is requested in the Member States of the European Union.

Environmental risk assessment for the import of A5547-127 into the European Union identified no potential risk.

11.2 Interplay between environmental risk assessment and monitoring

Because there are no adverse effects identified relating to import of herbicide-tolerant A5547-127, the resulting monitoring to perform is limited to a general surveillance of potential adverse effects, immediate or delayed, direct or indirect, of the GMO on human health and/or the environment which are not covered in the environmental risk assessment (e.r.a.).

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

The scientific evaluation of the characteristics of A5547-127 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 of A5547-127. It is therefore considered that there is no need for case-specific monitoring.

11.4 General surveillance of the impact of the GM plant

Approach and strategy. In accordance with Council Decision 2002/811/EC, general surveillance is not based on a particular hypothesis and it should be used to identify the occurrence of unanticipated adverse effects of the viable GMO or its use for human and animal health or the environment that were not predicted in the e.r.a. Exposure to the environment will be limited to unintended release of A5547-127, which could occur for example via substantial losses during loading/unloading of the viable commodity including A5547-127 destined for processing into animal feed or human food products. However, such exposure is highly unlikely to give rise to an adverse effect and can be easily controlled by clean up measures and the application of current practices used for the control of any adventitious soybean plants, such as manual or mechanical removal and the application of herbicides (with the exception of glufosinate ammonium herbicides). Furthermore, unintended environmental effects due to the unintended release of A5547-127 will be no different than that of other commercial soybeans. However and in order to safeguard against any adverse effects on human and animal health or the environment that were not anticipated in the e.r.a., general surveillance on A5547-127 will be undertaken for the duration of the authorisation. The general surveillance will take into consideration, and be proportionate to, the extent of imports of A5547-127 and use thereof in the Member States. In

order to increase the possibility of detecting any unanticipated adverse effects, a monitoring system will be used, which involves the authorisation holder and operators handling and using viable A5547-127. The operators will be provided with guidance to facilitate reporting of any unanticipated adverse effect from handling and use of viable A5547-127.

Since the intended use of A5547-127.is the same as that of any other commercial soybean, the procedures for the import, handling and processing of A5547-127.will be the same and have been considered in the development of the monitoring plan. The baseline and controls for general surveillance will rely on the historical knowledge and experience with non-GM soybean as comparable reference where necessary.

General surveillance will be undertaken for the duration of the authorisation period for A5547-127.for import and processing.

The authorisation holder is responsible for ensuring that the monitoring plan included in the application is put in place and properly implemented in accordance with the conditions of the authorisation. The third parties involved in the general surveillance will report any potential unanticipated adverse effects to the authorisation holder, who will immediately investigate and inform the European Commission in accordance with Regulation (EC) No 1829/2003.

The authorisation holder is not involved in commodity trade with A5547-127. The monitoring methodology hence needs to be predominantly based on collaboration with third parties, such as operators involved in the import, handling and processing of viable A5547-127. They are exposed to the imported viable A5547-127 and therefore are the best placed to observe and report any unanticipated adverse effects in the framework of their routine surveillance of the commodities they handle and use. The routine surveillance is based on the HACCP principles.

Method and analysis. The authorisation holder, together with other members of the plant biotechnology industry and EuropaBio, will implement general surveillance of viable GM soybeans, including A5547-127, with the help of the selected networks. The different parties agreed to collaborate on the following basis:
The authorisation holder represented by EuropaBio will:
-Agree with the operators before adding or amending activities that fall under their responsibility in accordance with the proposed monitoring plan.
-Inform the operators in a timely fashion of any newly approved GM plant products for import and processing under Regulation (EC) No 1829/2003 or Directive 2001/18/EC subject to general surveillance
-Set up and maintain a website dedicated to operators that provide an overview and detailed information on approved GM plant products subject to general surveillance. The website, hosted on the EuropaBio website under www.europabio.org/InfoOperators, contains the following information:

- An introduction to the purpose of the website
- A table giving an overview of all currently approved GM plant products subject to general surveillance
- A profile for every approved GM plant product providing documentation on characteristics and safety, positive EFSA opinion(s) and Commission Decision(s) authorising the GM plant product in the EU
- A contact point at EuropaBio for information exchange on any of the GM plant products. The website will be regularly updated in order to further facilitate and ensure a transparent process for general surveillance and easy access to relevant information for operators.

-Contact the selected networks of operators annually, providing them with an update on the approved GM plant products subject to general surveillance and reminding them of their agreement to report on any unanticipated adverse effects (or absence thereof).

The selected networks of operators (European trade associations) will:
-Inform and remind their member organisations and companies on an annual basis
- to monitor for potential unanticipated adverse effects
- to inform and remind their own member companies of this requirement
- to report back any adverse effect reported to them to the European trade associations

-Report to the authorisation holders directly or via EuropaBio
- at least annually, regardless whether an adverse effect was observed or not
- immediately any adverse effects reported to them.

11.5 Reporting the results of monitoring

In accordance with Regulation (EC) No 1829/2003, the authorisation holder is responsible to inform the European Commission of the results of the general surveillance.

If information that confirms an adverse effect of A5547-127 and that alters the existing risk assessment becomes available, the authorisation holder will immediately investigate and inform the European Commission. The authorisation holder, in collaboration with the European Commission and based on a scientific evaluation of the potential consequences of the observed adverse effect, will define and implement management measures to protect human and animal health or the environment, as necessary. It is important that the remedial action is proportionate to the significance of the observed effect.

The authorisation holder 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 A5547-127.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of A5547-127 and, as appropriate, the measures that were taken to ensure the safety of human and animal health or the environment.

The report will also clearly state which parts of the provided information are considered to be confidential, together with a verifiable justification for confidentiality.

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

A discriminating PCR (dPCR) method and control materials have been provided to the DG Joint Research Centre – Community Reference Laboratory – as defined by EU Regulation 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 B/ES/04/10
b) Conclusions of post-release monitoring Nothing to report.
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) Nothing to report.

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

1) USA

On January 14, 1998, APHIS received a request for an extension of a determination of nonregulated status (APHIS No. 98-014-01p) from AgrEvo USA Company (AgrEvo) of Wilmington, DE, for a soybean line designated as transformation event A5547-127, which has been genetically engineered tolerance to the herbicide glufosinate. The AgrEvo request sought an extension of a determination of non-regulated status that was issued for certain lines of glufosinate tolerant soybean (antecedent organisms) in response to APHIS petition number 96-068-01p (61 FR 42581-42582, August 16, 1996, Docket No. 96- 019-2). Based on the similarity of event A5547-127 to the antecedent organisms, AgrEvo requested a determination that glufosinate tolerant soybean event A5547-127 does not present a plant pest risk and, therefore, is not a regulated article under APHIS' regulations in 7 CFR part 340.

Key findings of the USDA environmental assessment of transformation event A5547-127 includes:

Based on an analysis of the data submitted by AgrEvo and a review of other scientific data and field tests of the subject soybean line, APHIS has determined that event A5547-127 soybean: (1) Exhibits no plant pathogenic properties; (2) is no more likely to become a weed than soybean lines developed by traditional breeding techniques; (3) is unlikely to increase the weediness potential for any other cultivated or wild species with which it can interbreed; (4) will not cause damage to raw or processed agricultural commodities; and (5) will not harm threatened or endangered species or other organisms, such as bees, that are beneficial to agriculture. Therefore, APHIS has concluded that the subject soybean line and any progeny derived from crosses with other soybean varieties will be as safe to grow as soybeans in traditional breeding programs that are not subject to regulation under 7 CFR part 340.

The effect of this determination was that AgrEvo's event A5547-127 soybean is no longer considered a regulated article under APHIS' regulations in 7 CFR part 340. Therefore, the requirements pertaining to regulated articles under those regulations no longer apply to the field testing, importation, or interstate movement of the subject soybean line or its progeny. However, importation of the subject soybean line or seeds capable of propagation are still subject to the restrictions found in APHIS' foreign quarantine notices in 7 CFR part 319.

2) Japan MAFF environmental assessment for import of grain

In the isolated field tests conducted in 1999 at the National Institute for Agro-Environmental Sciences, comparison were made for differences between the recombinant soybean A5547-127 (R5 generation) and the non-recombinant soybean. Following review of the data, the Ministry of Agriculture, Forestry and Fishery (MAFF) of Japan granted an environmental clearance for importing grain of soybean varieties based upon transformation event A5547-127 In 1999, based on the "Guideline for the use of recombinant in agriculture forestry and fisheries", the conducting of isolated field tests was approved by the Ministry of Agriculture, Forestry and Fisheries. In addition, in November 2001, based on the "Guideline for the use of recombinant in agriculture, forestry and fisheries", the conformance with the guideline regarding recombinants being imported into Japan (used for processing and feed) was confirmed by the Ministry of Agriculture, Forestry and Fisheries. (http://www.s.affrc.go.jp/docs/sentan/).

a) **Release country**

USA (field release since 1996, not regulated since 1998)
Authority overseeing the releases: United States Department of Agriculture (USDA) under notifications: 96-032-03N, 96-071-14N, 96-099-07N, 96-338-01N, 97-20-09N, 97-077-07N, 97-077-08N, 97-077-09N, 97-077-10N, 97-077-11N, 97-077-12N, 97-077-13N, 97-080-06N, 97-098-02N, 97-098-05N, 97-111-05N and 97-120-01N.
http://www.aphis.usda.gov

Argentina (field releases in 1996-2008)
Authority overseeing the releases: Comisión Nacional Asesora de Biotecnología Agropecuaria (CONABIA). Environmental approval in 2001.
http://www.sagpya.mecon.gov.ar/new/0-0/programas/conabia/liberaciones_ogm.php

Brazil (field release in 2000)
Authority overseeing the releases: Comissäo Técnica Nacional de Biossegurança (CTNBio) www.ctnbio.gov.br

Chile (field release in 2000)
Department of Agricultural Protection

b) **Authority overseeing the release**

See E.2.a

c) **Release site**

See E.2.a.

d) **Aim of the release**

See E.2.a. Field releases were performed to establish substantial equivalence, for breeding, seed increase, reference material production and variety development.

e) **Duration of the release**

The generation time for soybean from planting to harvest, is 3 to 5 months in the primary growing areas.

f) **Aim of post-releases monitoring**

No post release monitoring is required or conducted in countries with approval for commercial cultivation of soybeans derived from event A5547-127 (the U.S. and Canada.) In countries in which the event is still regulated, fields are monitored for volunteer plants in at least one subsequent growing season.
g) Duration of post-releases monitoring Generally one season.
h) Conclusions of post-release monitoring Occurrence of volunteers is very infrequent and no different from soybean derived through conventional breeding practices.
i) Results of the release in respect to any risk to human health and the environment No risk to human health or the environment has been indicated by the field release experience.

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 The JRC website http://gmoinfo.jrc.it/gmc_browse.asp provides publicly accessible links to up-to-date databases on the regulatory progress of notifications under Directive 2001/18/EC and Regulation (EC) No 1829/2003.
b) Assessment Report of the Competent Authority (Directive 2001/18/EC) Not applicable.
c) EFSA opinion Not yet available
d) Commission Register (Commission Decision 2004/204/EC) Not yet available
e) Molecular Register of the Community Reference Laboratory/Joint Research Centre Information on detection protocols will be posted at http://gmo-crl.jrc.it/
f) Biosafety Clearing-House (Council Decision 2002/628/EC http://bch.biodiv.org/
g) Summary Notification Information Format (SNIF) (Council Decision 2002/812/EC) http://gmoinfo.jrc.it/gmc_browse.asp