Request for Authorization of genetically modified herbicide tolerant soybean

FG72 x A5547-127

for food and feed uses, and import and processing, in accordance with articles 5 and 17 of Regulation (EC) N° 1829/2003

EFSA-GMO-NL-2013-XX

Part VII – Summary

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EFSA-GMO-NL-2013-XX (FG72 x A5547-127)

1. GENERAL INFORMATION

1.1. Details of application

(a) Member State of application

The Netherlands

(b) Application number

Not available at the time of submission (EFSA-GMO-NL-2013-XXX)

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

FG72 x A5547-127. Currently, no commercial name has been attributed to this product.

(d) Date of acknowledgement of valid application

Not available at the time of submission

1.2. Applicant

(a) Name of applicant

Bayer CropScience LP and M.S. Technologies, LLC

(b) Address of applicant

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USA

Represented by: Bayer CropScience N.V.
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M.S. Technologies, LLC
103 Avenue D
West Point, Iowa 52656
USA

(c) Name and address of the representative of the applicant established in the Union (if the applicant is not established in the Union)

Bayer CropScience N.V. is the contact for this submission and all correspondence should be directed to:

Bayer CropScience N.V.
Seeds – Regulatory Affairs
Square de Meeûs 40
1000 Bruxelles
Belgium

1.3. Scope of the application

(a) GM food

☑ Food containing or consisting of GM plants

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

(b) GM feed

☑ Feed containing or consisting of GM plants

☑ Feed produced from GM plants

(c) GM plants for food or feed uses

☑ Products other than food and feed containing of consisting of GM plants with the exception of cultivation

☐ Seeds and plant propagating material for cultivation in the EU

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

No ☑

Yes ☐ (in that case, specify)

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

Yes ☐

No ☑ (in that case, provide risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC)

This application requests authorization for food and feed uses, and for import and processing and does not include cultivation in the EU.

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

No ☑

Yes ☐ (in that case, specify)

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

No ☑

Yes ☐ (in that case, specify the third country and provide a copy of the risk assessment conclusions, the date of the authorisation and the scope)

1.8. General description of the product

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

FG72 x A5547-127 soybean was developed by crossing the single parental lines FG72 and A5547-127 using traditional breeding methods. No new genetic modification was introduced in FG72 x A5547-127 soybean. FG72 x A5547-127 soybean (OECD code: MST-FGØ72-2 x ACS-GMØØ6-4) contains the stably integrated 2mepsps gene which confers tolerance to the herbicide glyphosate, the hppdPfW336 gene which confers tolerance to the herbicide isoxaflutole (IFT) and the pat gene which confers tolerance to glufosinate ammonium. The 2mepsps and hppdPfW336 genes were introduced into FG72 soybean genome and pat gene was introduced into A5547-127 soybean genome.

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

FG72 x A5547-127 soybean will enter the European Union (EU) by import as commodity soybean and derived products. Milling, processing and consumer packaging will be accomplished in the EU. The same production processes applied to conventional soybeans will be used for FG72 x A5547-127 soybean.

The scope of the application does not include cultivation in the EU.

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

The products, covered by this authorization, will be used as any other commercial soybean, with the exception of cultivation.

FG72 x A5547-127 soybean will enter the EU by import as commodity soybean and derived products and will be used for the same downstream purposes as conventional soybeans. There are three major food/feed products derived from soybeans – whole soybeans, oil and meal.

This application requests import and processing only and does not include cultivation of FG72 x A5547-127 soybean 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) Any specific instructions and/or recommendations for use, storage and handling, including mandatory restrictions proposed as a condition of the authorisation applied for.

Whole soybean, oil, cake and meal derived from FG72 x A5547-127 soybean will be imported from outside the EU and will be handled in the same way as other imported soybean and derived products produced within the EU. Therefore, no specific conditions for use or handling are foreseen for FG72 x A5547-127 soybean besides the labelling and traceability requirements according to Regulation (EC) N° 1829/2003 and Regulation (EC) N° 1830/2003.

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

No restrictions are necessary as FG72 x A5547-127 soybean is suitable for all uses in all regions of the European Union, the same as conventional soybeans. This application requests import and processing only and is not covering cultivation in the EU.

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

No restrictions are necessary as FG72 x A5547-127 soybean is suitable for all uses in all regions of the European Union, the same as conventional soybeans. This application requests import and processing only and is not covering cultivation in the EU.

(g) Any proposed packaging requirements.

FG72 x A5547-127 soybean will be handled in the same way as other imported soybean and derived products. No specific packaging is required.

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

FG72 x A5547-127 soybean 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.

(i) Estimated potential demand

(i) In the Union

There are no anticipated changes to the demand as a result of the introduction of FG72 x A5547-127 soybean in the soybean supply, the introduced traits have only an agronomical benefit. It is anticipated that the introduction of FG72 x A5547-127 soybean will replace some other soybean in existing food and feed products.

(ii) In export markets for EU supplies

There are no anticipated changes in the soybean production in export markets as a result of the introduction of FG72 x A5547-127 soybean. It is anticipated that the introduction of FG72 x A5547-127 soybean will replace some of the existing soybean-derived products.

(j) Unique identifier in accordance with Regulation (EC) No 65/2004

OECD code: MST-FGØ72-2 x ACS-GMØØ6-4

1.9. 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.

FG72 x A5547-127 soybean is tolerant to herbicide products having glyphosate, glufosinate and isoxaflutole as the active ingredients. FG72 x A5547-127 soybean remains 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.

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

2.1. Complete name

(a) **Family name:** *Leguminosae*

(b) Genus: *Glycine*

(c) Species: *max*

(d) **Subspecies:** not applicable

(e) **Cultivar/breeding line or strain:** FG72 and A5547-127

(f) **Common name:** soybean

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

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 90 countries, including Europe, throughout the world. *Glycine max* is not found as a wild species in Europe.

FAO data indicates soybean production in the following Member States during 2010: Austria, Bulgaria, Czech Republic, France, Germany, Greece, Hungary, Italy, Poland, Romania, Slovakia, Slovenia and Spain.

This application requests authorization for food and feed uses, and for import and processing and does not include cultivation in the EU.

2.3. Information concerning reproduction (for environmental safety aspects)

(a) 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.

(b) 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.

(c) Generation time

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

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

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 grac*ilis, an intermediate in form between *G. soja* and *G. m*ax, 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. latrob*eana 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.

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

This application requests authorization for food and feed uses, and for import and processing and does not include cultivation in the EU.

2.5. Survivability (for environmental safety aspects)

(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.

2.6. 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.

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

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

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

Not applicable, since soybean is grown in the EU.

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

Soybean has no major interactions with the environment other than as a crop. It is known to interact with other organisms including pollinators, fungi, animal browsers, birds, soil microbes and soil insects. As soybean is a legume, it can fix atmospheric nitrogen as a source of nitrogen for growth and development in a symbiotic relationship with *Bradyrhizobium japonicum*.

Soybean is widely cultivated and has a history of safe use. It is not considered harmful or pathogenic to humans; however there are a few compounds in legumes, and therefore also in soybeans, which are not favourable for human or animal nutrition.

3. MOLECULAR CHARACTERISATION

3.1. Information relating to the genetic modification

(a) Description of the methods used for the genetic modification

FG72 x A5547-127 soybean was developed by crossing the single parental lines FG72 and A5547-127 using traditional breeding methods. No new genetic modification was introduced in FG72 x A5547-127 soybean.

Genetic modification was used in the development of the parental lines FG72 and A5547-127. Direct gene transfer was used in the development of the single parental lines.

(b) Nature and source of the vector used

FG72 x A5547-127 soybean was developed by crossing the single parental lines FG72 and A5547-127 using traditional breeding methods. No new genetic modification was introduced in FG72 x A5547-127 soybean.

FG72 and A5547-127 were produced with the vectors pSF10 and pB2/35SAcK respectively.

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

FG72 x A5547-127 soybean was developed by crossing the single parental lines FG72 and A5547-127 using traditional breeding methods. No new genetic modification was introduced in FG72 x A5547-127 soybean. The DNA inserts in FG72 x A5547-127 soybean are inherited from FG72 and A5547-127. Information is provided below.

Information on the genetic elements in FG72

The genetic elements to be transferred into the plant have been isolated by a *Sal*I enzymatic digestion of the plasmid pSF10. Only the *Sal*I linear fragment containing genes of interest has been used for the transformation to obtain FG72 soybean.

Genetic elements located on *Sal*I insert

Nt Positions	Orientation	Origin
3262 - 3553	Counter clockwise	3´nos: sequence including the 3' untranslated region of the nopaline synthase gene from the T-DNA of pTiT37 (Depicker *et al.*, 1982)
3554 - 4630	Counter clockwise	*hppdPfW336*: the coding sequence of the 4-hydroxyphenylpyruvate dioxygenase of *Pseudomonas fluorescens* strain A32 modified by the replacement of the amino acid glycine with a tryptophane, as described by Boudec *et al*. (2001)
4631 - 5002	Counter clockwise	TPotp Y: coding sequence of an optimized transit peptide derivative (position 55 changed into tyrosine), containing sequence of the RuBisCO small subunit genes of *Z. mays* (corn) and *Helianthus annuus* (sunflower), as described by Lebrun *et al.* (1996)
5003 - 5143	Counter clockwise	5'tev: sequence including the leader sequence of the tobacco etch virus as described by Carrington and Freed (1990)
5144 - 6433	Counter clockwise	Ph4a748 ABBC: sequence including the promoter region of the histone H4 gene of *Arabidopsis thaliana*, containing an internal duplication (Chabouté *et al*., 1987)
6434 - 7448	Clockwise	Ph4a748: sequence including the promoter region of the histone H4 gene of *Arabidopsis thaliana* (Chabouté *et al*., 1987)
7449 - 7929	Clockwise	intron1 h3At: first intron of gene II of the histone H3.III variant of *Arabidopsis thaliana* (Chaubet *et a*l., 1992)
7930 - 8301	Clockwise	TPotp C: coding sequence of the optimized transit peptide, containing sequence of the RuBisCO small subunit genes of *Z. mays* (corn) and *Helianthus annuus* (sunflower), as described by Lebrun *et al.* (1996)
8302 - 9639	Clockwise	*2mepsps*: the coding sequence of the double-mutant 5-enol-pyruvylshikimate-3-phosphate synthase gene of *Z. mays* (corn) (Lebrun *et al*., 1997)
9640 - 10326	Clockwise	3´histonAt: sequence including the 3´ untranslated region of the histone H4 gene of *Arabidopsis thaliana* (Chabouté *et al*., 1987)

Information on the genetic elements in A5547-127

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.

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

3.2. Information relating to the GM plant

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

FG72 x A5547-127 soybean was developed by crossing the single parental lines FG72 and A5547-127 using traditional breeding methods. Therefore the inserted DNA fragments from both parental lines are inherited in FG72 x A5547-127 soybean.

Like FG72, FG72 x A5547-127 soybean contains the stably integrated *2mepsps* gene which confers tolerance to the herbicide glyphosate and the *hppdPfW336* gene which confers tolerance to the herbicide isoxaflutole (IFT).

Like A5547-127, FG72 x A5547-127 soybean contains the *pat* gene which confers tolerance to the herbicide glufosinate ammonium.

The *2mepsps* gene was generated by introducing mutations into the wild-type epsps (wt epsps) gene from maize, leading to a modified EPSPS protein with two amino acid substitutions (2mEPSPS). This modification confers a decreased binding affinity of the protein for glyphosate, allowing it to maintain sufficient enzymatic activity in the presence of the herbicide. Therefore, the plants expressing the 2mEPSPS protein (encoded by the *2mepsps* gene) are tolerant to glyphosate herbicides.

HPPD enzymes catalyze the second step in the pathway for the catabolism of tyrosine and are responsible for the transformation of p-hydroxyphenylpyruvate into homogentisic acid. In order to reduce the sensitivity of the HPPD enzyme to the herbicide isoxaflutole, a single amino acid substitution has been made in the wt *hppdPf* gene that resulted in introduction of a glycin at position 336. The modified protein HPPD W336 possesses greater than 99.5% homology to the native HPPD protein from *P. fluorescens* and is tolerant to isoxaflutole (IFT).

The *pat* gene is a phosphinothricin resistance gene, isolated from the soil micro-organism *Streptomyces viridochromogenes*. The *pat* gene, when expressed, enables the production of the enzyme, phosphinothricin acetyltransferase (PAT) that metabolizes glufosinate to an inactive, acetylated derivative, thereby conferring tolerance to glufosinate-ammonium herbicide.

Glufosinate ammonium herbicide is an inhibitor of glutamine synthetase, an enzyme in the nitrogen assimilation pathway.

No other new traits have been introduced into FG72 x A5547-127 soybean. The genetic modification is not intended to change any of the typical crop characteristics of soybean and the handling and use of imported FG72 x A5547-127 soybean for food, feed and processing will be the same as non-genetically modified soybean.

3.2.2. Information on the sequences actually inserted or deleted

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

Southern blot analysis of FG72 x A5547-127 confirmed the presence of the FG72 and A5537-127 DNA inserts in FG72 x A5547-127 soybean.

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

Not applicable. FG72 x A5547-127 soybean was developed by crossing the single parental lines FG72 and A5547-127 using traditional breeding methods

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

As supported by the Southern blot analysis of FG72 x A5547-127 soybean, the inserted DNA fragments from both parental lines, FG72 and A5547-127 are inherited in the FG72 x A5547-127 soybean.

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

Since the inserts in the single events FG72 and A5547-127 were retained in FG72 x A5547-127 soybean, the characteristics of the insertions and the 5' and 3' flanking sequences should be conserved in FG72 x A5547-127 soybean.

(e) In case of modifications other than insertion or deletion, describe function of the modified genetic material before and after the modification

Not applicable

3.2.3. Information on the expression of the insert

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

Expression levels of 2mEPSPS, HPPD W336 and PAT proteins were analysed in various plant tissues (root, leaf, forage and seed) at different growth stages for FG72 x A5547-127 soybean. As expected, the 2mEPSPS, HPPD W336 and PAT proteins were detected in the analysed FG72 x A5547-127 soybean tissues. In this application, the expression in seeds is considered, since is the part of the soybean plant relevant to the scope of this application.

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

The 2mEPSPS, HPPD W336 and PAT proteins content was determined in root, leaf, forage and seed. In this application, the expression in seeds is considered, since is the part of the soybean plant relevant to the scope of this application. The expression level of 2mEPSPS, HPPD W336 and PAT proteins was determined in FG72 x A5547-127 soybean seed harvested from field grown plants in Brazil and USA.

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

The results of the Southern blot analysis of FG72 x A5547-127 soybean demonstrated the stability of the inserted sequences of FG72 and A5547-127 in FG72 x A5547-127 soybean, and confirmed that no detectable rearrangements of these inserts occurred.

The results of the analysis of the newly expressed proteins in FG72 x A5547-127 soybean showing comparable levels to the expression in the single parental lines FG72 and A5547-127 confirmed the phenotypic stability of FG72 x A5547-127 soybean.

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

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

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

(b) Dissemination

The tolerance to the herbicides glyphosate, glufosinate and isoxaflutole has not affected agronomic characteristics. FG72 x A5547-127 soybean retains 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 mostly determined by seed characteristics. There is no indication of changes in the seed characteristics as a result of the genetic modification.

(d) Other differences

FG72 x A5547-127 soybean plants are tolerant to glyphosate, glufosinate and isoxaflutole herbicides.

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

(a) Plant to bacteria gene transfer

FG72 x A5547-127 soybean was developed by crossing the single parental lines FG72 and A5547-127 using traditional breeding methods. Therefore the inserted DNA fragments from both parental lines are inherited in FG72 x A5547-127 soybean. The newly inserted sequences in the single events are not providing different abilities to transfer genetic material compared to conventional soybean and no other elements in the inserts suggest that there could be an increase of the probability of homologous recombination. The combination of the single events using conventional breeding techniques has not resulted in any alteration on the inserts in FG72 x A5547-127 soybean. Therefore, the likelihood that plant to bacteria gene transfer occurs is highly unlikely.

(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.

The scope of this application is for authorization of FG72 x A5547-127 soybean for food and feed uses and import and processing and does not include cultivation of FG72 x A5547-127 soybean in the EU. As a consequence exposure to the environment will be very limited

4. COMPARATIVE ANALYSIS

4.1. Choice of the conventional counterpart and additional comparators

In each field site FG72 x A5547-127 soybean was compared to its conventional counterpart as well as to other non-GM reference varieties.

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

The production of material for the comparative assessment of FG72 x A5547-127 soybean took place in nine field trials planted in 2012 in the USA. The field locations were appropriate for production of Maturity Group 2-3 soybeans in the USA and the field trials were conducted following typical agricultural practices.

For the comparative assessment of FG72 x A5547-127 soybean, the experimental design included FG72 x A5547-127 soybean treated with the intended herbicides, FG72 x A5547-127 soybean with conventional herbicide management regimen and the conventional counterpart with conventional herbicide management regime. In addition, six non-GM reference varieties (conventional herbicide management regime) were included over the entire set of trials.

Each field location consisted of six soybean entries replicated four times resulting in 24 plots per trial planted in a randomized complete block design. In each field location 3 non-GM reference varieties were grown.

4.3. Selection of material and compounds for analysis

Soybean seed is the raw agricultural commodity and represents the main point of entry of the material into the food and feed production and processing chain. The key constituents included in the compositional analysis were selected according to OECD recommendations. Soybean seeds were analysed for proximates, fibre fractions, minerals, vitamins, anti-nutrients, isoflavones, total amino acids, and total fatty acids.

The results of the comparative assessment for compositional parameters support the conclusion of equivalence between FG72 x A5547-127 soybean and the set of non-GM reference varieties for any of the composition parameters. The comparative assessment of compositional parameters identified no biological relevant differences and/or lack of equivalence between FG72 x A5547-127 soybean and its comparator, taking into account natural variation.

4.4. Comparative analysis of agronomic and phenotypic characteristics

A comparative assessment of the phenotypic and agronomic characteristics of soybean FG72 x A5547-127 soybean and its conventional counterpart was performed, based on data collected at the nine field trials in the USA in 2012 (the same field study used to collect samples for compositional analysis).

The comparative assessment of phenotypic and agronomic characteristics identified no biological relevant differences and/or lack of equivalence between FG72 x A5547-127 soybean and its comparator, taking into account natural variation.

4.5. Effect of processing

The effects of processing on FG72 x A5547-127 soybean are not expected to be different from the effects on conventional soybean.

FG72 x A5547-127 soybean is not different from conventional soybean, except for the expressed 2mEPSPS, HPPD W336 and PAT proteins. During processing, proteins are subjected to harsh environmental conditions that drastically change the physical forces leading to denaturation and loss of protein function. These conditions include thermal processing, changes in pH, reducing agents, mechanical shearing etc. Thus, dietary exposure to functionally active proteins in processed food products can be negligible and below levels of any safety concerns. Therefore, it is highly likely that FG72 x A5547-127 soybean and its derived food and feed products are not different from the equivalent foods and feeds from conventional soybean and as a consequence, toxicological tests with FG72 x A5547-127 soybean processed products are not scientifically justified.

5. TOXICOLOGY

(a) Toxicological testing of the newly expressed proteins

FG72 x A5547-127 soybean expresses the proteins 2mEPSPS, HPPD W336 and PAT. These 3 enzymes have very specific enzymatic activities, with different substrates and different pathways in FG72 x A5547-127 soybean.

The available information for the assessment of the newly expressed proteins present in FG72 x A5547-127 soybean, indicates that no adverse effects on human or animal health are expected. Furthermore, in absence of indications of potential interactions between the 3 proteins as well as between the FG72 and A5547-127 events, as suggested in the molecular analysis and comparative assessment, the conclusions of the safety assessment for the individual 2mEPSPS, HPPD W336 and PAT proteins are not changed when their combined expression in FG72 x A5547-127 soybean is considered.

(b) Testing of new constituents other than proteins

No new constituents other than the 2mEPSPS, HPPD W336 and PAT proteins are expressed in FG72 x A5547-127 soybean. The comparative assessment of FG72 x A5547-127 soybean showed no biologically relevant differences between FG72 x A5547-127 soybean and its conventional counterpart and/or lack of equivalence, taking into account natural variation. Therefore, there is no need for further assessment.

(c) Information on natural food and feed constituents

No relevant changes in the composition of FG72 x A5547-127 soybean were identified, therefore the levels of food and feed constituents in FG72 x A5547-127 soybean have not been altered and there is no need for further assessment.

(d) Testing of the whole GM food/feed

The molecular characterization of FG72 x A5547-127 soybean demonstrated the integrity of the inserts in FG72 x A5547-127 soybean when compared to the single parental lines. The comparative assessment of FG72 x A5547-127 soybean showed no biologically relevant differences between FG72 x A5547-127 soybean and its conventional counterpart and/or lack of equivalence, taking into account natural variation. Therefore, there are not indications of possible interactions between FG72 and A5547-127 events in FG72 x A5547-127 soybean and whole food and/or feed testing with FG72 x A5547-127 soybean is not deemed necessary.

6. ALLERGENICITY

(a) Assessment of allergenicity of the newly expressed protein

The data provided lead to the conclusion that the 2mEPSPS, HPPD W336 and PAT proteins are unlikely to be allergenic. In addition, there is no evidence that there could be interactions between these 3 enzymes that would lead to additive, synergistic or antagonistic activities. Therefore, Bayer CropScience considers it to be unlikely that potential interactions could occur that would change the allergenicity of these proteins in FG72 x A5547-127 soybean.

(b) Assessment of allergenicity of the whole GM plant or crop

Equivalence of FG72 x A5547-127 soybean (with the exception of the introduced traits) to the conventional counterpart has been demonstrated on the basis of compositional analysis. The 2mEPSPS, HPPD W336 and PAT proteins expressed in FG72 x A5547-127 soybean are unlikely to be allergenic. The parental single events FG72 and A5547-127 showed no potential for increased allergenicity, therefore no increased allergenicity is anticipated for FG72 x A5547-127 soybean. To provide further evidence on the absence of alteration of the allergenicity profile of FG72 x A5547-127 soybean, a study was performed to define the presence or absence and to compare the expression level of known endogenous soybean allergens between the FG72 x A5547-127 soybean and its conventional counterpart.

The qualitative and quantitative analyses of expression of the FG72 x A5547-127 soybean endogenous allergens showed no biologically relevant differences from those expressed in the conventional counterpart. These results support the absence of evidence of interactions between FG72 and A5547-127 events.

7. NUTRITIONAL ASSESSMENT OF GM FOOD/FEED

(a) Nutritional assessment of GM food

The genetic modifications in FG72 x A5547-127 soybean are not intended to change nutritional characteristics of FG72 x A55471-27 compared to conventional soybean. Therefore, FG72 x A5547-127 soybean is not expected to be more or less attractive for use as food, so anticipated dietary intake of soybean-derived foods is not expected to be changed upon commercialization of FG72 x A5547-127 soybean.

Compositional analysis has demonstrated that FG72 x A5547-127 soybean is not different from its conventional counterpart, except for the introduced traits taking into account natural variation. Therefore, there is no need to carry out further nutritional studies with food derived from FG72 x A5547-127 soybean.

(b) Nutritional assessment of GM feed

The genetic modifications in FG72 x A5547-127 soybean are not intended to change nutritional characteristics of FG72 x A55471-27 soybean compared to conventional soybean. Therefore, FG72 x A5547-127 soybean is not expected be more or less attractive for use as feed.

Compositional analysis has demonstrated that FG72 x A5547-127 soybean is not different from its conventional counterpart, except for the introduced traits taking into account natural variation. Therefore, there is no need to carry out further nutritional studies with feed derived from FG72 x A5547-127 soybean.

8. EXPOSURE ASSESSMENT – ANTICIPATED INTAKE/EXTENT OF USE

FG72 x A5547-127 soybean was developed by crossing the single soybean parental lines FG72 and A5547-127 using traditional breeding methods. The intended traits in the soybean parental lines FG72 and A5547-127 were herbicide tolerance, therefore not intended to modify the nutritional parameters of FG72 x A5547-127 soybean. FG72 x A5547-127 soybean is not intended to be processed into products with enhanced functionality. The dietary role of FG72 x A5547-127 soybean will be the same as non-GM soybean. The use of the food and feed derived from FG72 x A5547-127 soybean will be the same as food and feed from non-GM soybean. It is expected that the introduction of FG72 x A5547-127 soybean will replace some of the existing commercial soybean-derived products. Therefore, no change is expected in the consumption of soybean and soybean-derived products.

The exposure assessment in humans and animals indicates that there is minimal dietary exposure to 2mEPSPS, HPPD W336 and PAT proteins from consumption of foods and feed derived from FG72 x A5547-127 soybean.

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

FG72 x A5547-127 soybean was developed by crossing the single parental lines FG72 and A5547-127 using traditional breeding methods. No new genetic modification was introduced in FG72 x A5547-127 soybean. FG72 and A5547-127 have been previously assessed in applications EFSA-GMO-BE-2011-98 and EFSA-GMO-NL-2008-52 respectively.

A comprehensive risk characterization of FG72 x A5547-127 soybean has been carried out by considering all available evidence from the analyses discussed through this application. The following conclusions from molecular characterisation, phenotypic and agronomic analyses, compositional analyses, toxicity assessment, allergenicity assessment and exposure assessment have been considered:

- The Southern analyses demonstrated that the structures of the inserts in the single events FG72 and A5547-127 were retained in FG72 x A5547-127 soybean. The molecular characterization of FG72 x A5547-127 soybean did not indicate safety concerns or potential interactions and there is no evidence of unintended changes in FG72 x A5547-127 soybean.

- The results of the comparative assessment conducted on FG72 x A5547-127 soybean support a conclusion that no differences were identified in the seed composition data obtained from FG72 x A5547-127 soybean or in its agronomics and phenotypic characteristics that would require further assessment with respect to their possible impact on food and feed safety and nutritional properties.

- The available information for the assessment of the newly expressed proteins (2mEPSPS, HPPD W336, PAT) present in FG72 x A5547-127 soybean indicates that no adverse effects on human or animal health are expected. Furthermore, there is no indication of potential interactions between the three newly expressed proteins as well as between the FG72 and A5547-127 events, as suggested by the absence of changes in the molecular analysis and comparative assessment.

- There are no indications of any potential adverse effect that could arise from natural constituents changes or from unintended effects. The results of the toxicological assessment indicate that consumption of FG72 x A5547-127 soybean food and feed products will be as safe as consumption of equivalent products from conventional soybean.

- The 2mEPSPS, HPPD W336 and PAT proteins expressed in FG72 x A5547-127 soybean have been evaluated previously and it was found unlikely that they are allergenic. There is no evidence to suggest that FG72 x A5547-127 soybean has greater allergenic potential compared

to conventional soybean varieties. It has been demonstrated previously that there is no change in the endogenous allergens in the FG72 and A5547-127 soybean parental lines and it has been demonstrated that there is no change in the endogenous allergens in the FG72 x A5547-127 soybean. This provides further evidence of the absence of interactions between the FG72 and A5547-127 events, or between the newly expressed proteins, which could lead to changes in the pattern of expression of endogenous proteins, including endogenous allergens.

- The genetic modifications in FG72 x A5547-127 soybean are not intended to change nutritional characteristics of FG72 x A55471-27 soybean compared to conventional soybean. Therefore, FG72 x A5547-127 soybean is not expected to be more or less attractive for use as food and/or feed, so anticipated dietary intake of soybean-derived foods and feeds is not expected to be changed upon commercialization of FG72 x A5547-127 soybean. The dietary role of FG72 x A5547-127 soybean will be the same as of non-GM soybean.

The evidences presented throughout this application demonstrate that:

a) the consumption of food and feed derived from FG72 x A5547-127 soybean is as safe as the respective comparators

b) the food derived from FG72 x A5547-127 soybean is not nutritionally disadvantageous for the consumer compared to the food which is intended to replace

c) the feed derived from FG72 x A5547-127 soybean is not nutritionally disadvantageous for animals compared to the feed which is intended to replace

d) the feed derived from FG72 x A5547-127 soybean does not harm or mislead the consumer by impairing distinctive features of the animal products compared to conventionally produced feed

10. POST-MARKET MONITORING ON GM FOOD/FEED

The risk characterization of FG72 x A5547-127 soybean has shown that the risk for potential adverse effects on human and animal health is negligible in the context of the intended uses of FG72 x A5547-127 soybean. It is therefore considered that there is no need for post marketing monitoring of food an feed derived from FG72 x A5547-127 soybean.

11. ENVIRONMENTAL ASSESSMENT

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

The scope of this application covers the import, processing and food and feed use of FG72 x A5547-127 soybean in the EU, no deliberate release of viable plant material in the EU environment is expected and no target organisms are associated with FG72 x A5547-127 soybean. Therefore an assessment of the potential resistance development in target organisms resulting from the import, processing and food and feed use of FG72 x A5547-127 soybean is not relevant for this application.

11.2. 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 FG72 x A5547-127 soybean during transportation and processing for food and feed.

(a) Persistence and invasiveness

The introduced traits in FG72 x A5547-127 soybean have been demonstrated to not affect the non-persistence and non-invasiveness of *Glycine max*. Volunteer plants, should they emerge in an area due to unintended spillage from transport, can be destroyed either mechanically or through the use of a herbicide other than HPPD inhibitor herbicide, glyphosate and glufosinate.

(b) Selective advantage or disadvantage

The scope of the application is for food and feed uses, import and processing and excludes cultivation.

FG72 x A5547-127 soybean has a seasonal advantage over weed competition only in concert with the use of a glyphosate, glufosinate and isoxaflutole herbicides to control weeds growing in the same field. FG72 x A5547-127 soybean, as all soybeans, are an annual, self-pollinating, cultivated crop without weedy characteristics and without wild relatives in the European Union. Except for tolerance to glyphosate, glufosinate and isoxaflutole and thus the opportunity to use these herbicides as part of the seasonal crop management, FG72 x A5547-127 soybean is similar in phenotypic, genotypic or reproductive biology to commercial soybean varieties developed solely through conventional breeding practices. Without the use of glyphosate, glufosinate and isoxaflutole, any plants that might germinate from an accidental spill during import or transport of FG72 x A5547-127 soybean, have no selective advantage over conventionally developed soybeans.

(c) Potential for gene transfer

The scope of this application is the authorization of the FG72 x A5547-127 soybean for food and feed uses, and for import and processing in accordance with articles 5 and 17 of Regulation (EC) No 1829/2003. The scope of this application does not include cultivation of FG72 x A5547-127 soybean in the EU.

Taking a conservative approach where a worst case scenario that considers that accidental spillage of viable plant material from FG72 x A5547-127 soybean during import, transportation, storage, handling or processing in the EU will occur, the likelihood that this could result in environmental harm is highly unlikely and the consequences would be marginal. The risk is therefore negligible.

Given the low levels of exposure that could arise from accidental spillage of FG72 x A5547-127 soybean imported into the EU, the lack of wild relatives that could take up the traits and the nature of the traits, which are unlikely to confer selective advantage, the uncertainty associated with this risk characterization can be considered very low. The probability of long-term environmental adverse effects is very low.

The background data collected on horizontal gene transfer, the molecular characterisation data gathered on FG72 x A5547-127 soybean and the results of the comparative safety assessment, allow to conclude that the *2mepsps*, *hppdPfW336* and *pat* genes expressed in FG72 x A5547-127 soybean are unlikely to be transferred to micro-organisms and, even if they were, this would not lead to human, animal or environmental harm. Thus, the likelihood that the import, processing or food and feed use of FG72 x A5547-127 soybean will result in harm to humans or animals or the environment is “highly unlikely”.

Given the probability that any of the genes would be transferred to micro-organisms and the fact that even if transfer occurred the consequences for humans or animals or the environment would be marginal, it can be concluded that the risk is negligible. The uncertainties associated with this risk characterisation and the possibility of long-term adverse environmental effect is low.

(d) Interactions between the GM plant and target organisms

The scope of this application covers the import, processing and food and feed use of FG72 x A5547-127 soybean in the EU, no deliberate release of viable plant material in the EU environment is expected and no target organisms are associated with FG72 x A5547-127 soybean. Therefore an assessment of the potential resistance development in target organisms resulting from the import, processing and food and feed use FG72 x A5547-127 soybean is not relevant for this application.

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

In this area of assessment, the main environmental concern, according to the EFSA ERA Guidance, is that the release of the GM plant into the environment will result in adverse effects on populations of non-target organisms (NTOs).

The scope of this application covers the import, processing and food and feed use of FG72 x A5547-127 soybean in the EU, no deliberate release of viable plant material in the EU environment is expected.

Given the reproductive biology of soybean, it is highly unlikely that accidental spillage of viable plant material would result in feral populations in the EU. Therefore an assessment of potential direct effects of FG72 x A5547-127 soybean on NTO populations is not relevant for this application. However, the assessment considers potential indirect adverse effects on NTO populations due to exposure through faeces of animals fed with FG72 x A5547-127 soybean.

Exposure to faeces of animals fed with FG72 x A5547-127 soybean would lead to very low levels of environmental exposure. The newly expressed proteins are expressed at low levels in grain and they are readily degraded by enzymatic activity in the gastro-intestinal tract of animals. Only minimal amounts of these proteins will be present in animal faeces. There would subsequently be further degradation of these proteins due to microbial processes. Exposure of soil and water environments to these proteins from disposal of animal wastes is likely to be very low and localized. Thus exposure of potentially sensitive NTOs to the FG72 x A5547-127 soybean is likely to be very low and of no ecological relevance.

(f) Effects on human health

The risks associated with the import, processing and food and feed use of FG72 x A5547-127 soybean in the EU on human and animal health have been assessed and summirized in point 9. No further risk characterization is considered necessary.

(g) Effects on animal health

The risks associated with the import, processing and food and feed use of FG72 x A5547-127 soybean in the EU on human and animal health have been assessed and summarized in point 9. No further risk characterization is considered necessary.

(h) Effects on biogeochemical processes

The scope of this application covers the import, processing and food and feed use of FG72 x A5547-127 soybean in the EU. Cultivation of FG72 x A5547-127 soybean in the EU is not included in the scope. Although environmental exposure could occur through the accidental spillage of FG72 x A5547-127 soybean, or through manure or faeces of animals fed on FG72 x A5547-127 soybean, or through organic matter or by-products from FG72 x A5547-127 soybean, these routes of exposure would represent very low levels of exposure that would be limited spatially and temporally. Therefore, it is highly unlikely that adverse effects on biogeochemical processes could occur.

An assessment of the impacts of FG72 x A5547-127 soybean on biogeochemical processes resulting from specific cultivation, management and harvesting techniques is not relevant given the scope of this application.

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

The scope of this application covers the import, processing and food and feed use of FG72 x A5547-127 soybean in the EU. Cultivation of FG72 x A5547-127 soybean in the EU is not included in the scope.

An assessment of the impacts of specific cultivation, management and harvesting techniques it is not relevant given the scope of this application.

11.3. Potential interactions with the abiotic environment

The scope of this application is the authorization of the FG72 x A5547-127 soybean for food and feed uses, and for import and processing in accordance with articles 5 and 17 of Regulation (EC) No 1829/2003. The scope of this application does not include cultivation of FG72 A5547-127 soybean in the EU.

12. ENVIRONMENTAL MONITORING PLAN

(a) General (risk assessment, background information)

As required by Article 5(5)(b) and 17(5)(b) of Regulation (EC) No 1829/2003 the proposed Post-Market Environmental Monitoring (PMEM) plan for FG72 X A5547-127 soybean has been developed according to the principles and objectives outlined in Annex VII of Directive 2001/18/EC and Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC. The PMEM plan also takes into account the Scientific Opinion on guidance on the Post-Market Environmental Monitoring of genetically modified plants[1].

(b) Interplay between environmental risk assessment and monitoring

The scope of this application is the authorisation of FG72 x A5547-127 soybean for import, processing, food and feed use in the European Union (EU) under Regulation (EC) No 1829/2003. The scope of the application does not include authorisation for the cultivation of FG72 x A5547-127 soybean seed products in the EU.

An environmental risk assessment (e.r.a.) was carried out for FG72 X A5547-127 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 and the EFSA guidance on the environmental risk assessment of genetically modified plants[2]. The scientific evaluation of the characteristics of FG72 x A5547-127 soybean in the e.r.a. (Section E of Part II – Scientific information) has shown that the risk for potential adverse effects on

[1] EFSA Panel on GMO; Scientific Opinion on guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants. EFSA Journal 2011;9(8):2316. [40 pp.] doi:10.2903/j.efsa.2011.2316. Available online: www.efsa.europa.eu/efsajournal.htm

[2] EFSA Panel on GMO; Guidance on the environmental risk assessment of genetically modified plants. EFSA Journal 2010;8(11):1879. [111 pp.]. doi:10.2903/j.efsa.2010.1879. Available online: www.efsa.europa.eu/efsajournal.htm

human and animal health or the environment is negligible in the context of the intended uses of FG72 x A5547-127 soybean relative to:

• Persistence and invasiveness

• Selective advantage or disadvantage

• Potential for gene transfer

• Interactions between the GM plant and target organisms

• Interactions of the GM plant with non-target organisms

• Effects on human health

• Effects on animal health

• Effects on biogeochemical processes

• Impacts of the specific cultivation, management and harvesting techniques

• Potential interactions with the abiotic environment.

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

The scientific evaluation of the characteristics of FG72 X A5547-127 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 of FG72 X A5547-127 soybean. It is therefore considered that there is no need for case-specific monitoring.

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

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.

The scope of this application is the authorisation of FG72 X A5547-127 soybean for import, processing, food and feed uses. The scope of the application does not include authorisation for the cultivation of FG72 X A5547-127 soybean seed products.

Therefore, exposure to the environment will be limited to unintended release of FG72 X A5547-127 soybean, which could occur for example via substantial losses during loading/unloading of the viable commodity including FG72 X A5547-127 soybean destined for processing into animal feed or human food products. Exposure can be 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 glyphosate, glufosinate and isoxaflutole).

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 FG72 X A5547-127 soybean 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 FG72 X A5547-127 soybean 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 FG72 X A5547-127 soybean. The operators will be provided with guidance to facilitate reporting of any unanticipated adverse effect from handling and use of viable FG72 X A5547-127 soybean.

(e) 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 FG72 X A5547-127 soybean 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 FG72 X A5547-127 soybean.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of FG72 X A5547-127 soybean 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 in accordance with Article 30 of Regulation (EC) No 1829/2003. Confidential parts of such report shall be submitted in separate documents.

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

The detection method for FG72 x A5547-127 soybean is based on the validated detection methods that are available for FG72 and A5547-127 (http://gmo-crl.jrc.ec.europa.eu/gmomethods/).

The method for detection, sampling and identification of FG72 x A5547-127 soybean has been submitted to the European Union Reference Laboratory (EURL) of the Joint Research Centre of the European Commission (EC-JRC) for the purpose of experimental testing and validation.

Appropriate control samples have also been made available to the EURL.

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

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

No field trials have been carried out with FG72 x A5547-127 soybean in EU

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

(a) Release country

Argentina, Brazil and USA

(b) Authority overseeing the release

Argentina: National Advisory Committee on Agricultural Biosafety (CONABIA)

Brazil: Comissão Técnica Nacional de Biossegurança (CTNBio)

USA: United States Department of Agriculture (USDA)

(c) Release site

Argentina: Information on the releases at

http://64.76.123.202/site/agregado_de_valor/biotecnologia/50-EVALUACIONES/index.php

Brazil: Information on the releases at www.ctnbio.gov.br

USA: Information on the releases at www.aphis.usda.gov/

(d) Aim of the release

Aim of field releases: breeding, seed increase, registration studies, herbicide efficacy

(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

Volunteer monitoring in subsequent 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.