PART II

SUMMARY

Request for Authorization of Herbicide Tolerant Genetically Modified Soybean

FG72

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

A. GENERAL INFORMATION

1. Details of application

a) Member State of application: Belgium
b) Application number: Not available at the date of application (EFSA-GMO-BE-2011-XX)
c) Name of the product (commercial and other names): Genetically modified soybean (*Glycine max*) with tolerance to glyphosate and isoxaflutole herbicides, transformation event FG72 (OECD code: MST-FGØ72-2).
d) Date of acknowledgement of valid application: Not available at the date of application

2. Applicant

a) Name of applicant: Bayer CropScience AG and M.S. Technologies, LLC represented by Bayer BioScience N.V.
b) Address of applicant: Bayer CropScience AG Alfred Nobelstrasse 50 D-40789 Monheim Germany Bayer BioScience N.V. Technologiepark 38, B-9052 Gent Belgium

M.S. Technologies, LLC 103 Avenue D West Point, Iowa 52656, U.S.A
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)): FG72 soybean will be imported and processed in the EU by the same groups who import, process and distribute soybean commodity 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 authorization for food and feed uses, and for import and processing and does not include cultivation 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:	

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

Yes ☒	No ☐

If *yes*, specify:

Country	Scope	Agency Name
United States	**Cultivation**	**FDA, USDA**
Canada	**Cultivation**	**CFIA, CaH**
Australia/ New Zealand	**Food / Feed import**	**FSANZ**
Korea	**Food / Feed import**	

FDA: Food and Drug Administration; **USDA**: United States Department of Agriculture; ; **CFIA**: Canadian Food Inspection Agency; **HC**: Health Canada,
FSANZ: Food Standards Australia New Zealand

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*. FG72 soybean has herbicide tolerance to glyphosate and isoxaflutole that will work together in a weed control system designed for soybean with favourable environmental and safety characteristics. The system combines tolerance to the broad spectrum, non-selective herbicide, glyphosate with tolerance to isoxaflutole to control glyphosate resistant weeds or to provide residual herbicide protection for FG72 soybean plants.

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

FG72 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 soybeans.

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

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

FG72 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 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) 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 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 soybean besides the labeling and traceability requirements according to Regulation (EC) N° 1829/2003 and Regulation (EC)

N° 1830/2003.
e) Any proposed packaging requirements: FG72 soybean will be handled in the same way as other imported soybean and derived products. No specific packaging is required.
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: FG72 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.
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): MST-FGØ72-2
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 FG72 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.

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 soybean is tolerant to herbicide products having glyphosate and isoxaflutole as the active ingredients. 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:	FG72
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

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.

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.

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 data indicates soybean production in the following Member States during 2009: Austria, Bulgaria, Czech Republic, France, Germany, Greece, Hungary, Italy, Poland, Romania, Slovakia, Slovenia and Spain

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.

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

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

Soybean is cultivated by the Member States of Austria, Bulgaria, Czech Republic, France, Germany, Greece, Hungary, Italy, Latvia, Poland, Romania, Slovakia, Slovenia and Spain. *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

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 favorable for human or animal nutrition.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification

A purified fragment from plasmid pSF10, containing the *hppdPfW336* and *2mepsps* genes, was introduced into Jack soybean cells via direct gene transfer.

2. Nature and source of the vector used

Plasmid pSF10 was constructed by inserting the *2mepsps* and *hppdPfW336* genes into an *E.coli* pBR322-derived cloning plasmid

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 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)

D. INFORMATION RELATING TO THE GM PLANT

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

FG72 soybean contains the stably integrated gene *2mepsps*, which encodes the 2mEPSPS protein and *hppdPfW336* gene, which encodes the HPPD W336 protein. The genes were introduced by direct gene transfer into Jack soybean. The resulting FG72 soybean plants are tolerant to IFT (isoxaflutole) and glyphosate herbicides by expressing the 2mEPSPS and HPPD W336 proteins.

FG72 soybean provides growers with new options for weed control using IFT herbicide in combination with a glyphosate herbicide. Glyphosate is widely used in herbicide-tolerant soybean and other agricultural production systems. IFT herbicide offers an alternative weed control option for the soybean grower. IFT controls weeds via a new herbicide mode of action for soybeans that is efficacious against many of the herbicide resistant weeds currently found in soybean fields. IFT has the flexibility to be applied pre-plant, pre-emergence, or post emergence to FG72 soybeans.

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 FG72 soybean insert consists of two partial 3'histonAt sequences in a head to head orientation, followed by two complete insert copies arranged in a head to tail orientation. Upon integration of the FG72 insert into the soybean genome, a genomic region translocated to a new position, which is joined at the 3' junction by 158 bases of the Ph4a748 promoter sequences.

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

Sequence determination of both the FG72 transgenic locus and corresponding sequences of *Glycine max* wild type regions (pre-insertion locus) and their alignments demonstrate that the translocation of genomic sequences resulted in the generation of two additional junctions, of which the 3' junction is joined by 158 bp of Ph4a748 promoter sequences. Twenty-five bases of the translocated sequence and 2 bases of the reintegration site of the translocated sequence are deleted upon transformation

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

Southern blot and full sequence analyses revealed that the FG72 transgenic locus consists of two partial 3′histonAt sequences in a head to head orientation, followed by two complete insert copies (the full FG72 insert) arranged in a head to tail orientation. Also, upon integration of the insert into the soybean genome, a non-transgenic region translocated to a new position, which is joined at the 3′ junction by 158 bases of Ph4a748 promoter sequences from the FG72 transfer DNA.

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 and HPPD W336 proteins were analysed in various plant tissues (leaf, stem, root and grain) at different growth stages for FG72 soybean. As expected, the 2mEPSPS and HPPD W336 proteins were detected in all FG72 soybean tissues and samples analysed.

b) Parts of the plant where the insert is expressed

The 2mEPSPS and HPPD W336 protein content was determined in leaves, stem and root tissues. The highest protein content was observed for both proteins in leaves, ranging from 4.69 to 6.48 µg/g fresh weight for HPPD W336 and from 79.1 to 115 µg/g fresh weight for 2mEPSPS. The amount of the 2mEPSPS and HPPD W336 proteins was also determined in FG72 soybean grain harvested from plants grown in 2008 and 2009 field trials.

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 tolerance to the herbicides glyphosate and isoxaflutole has not affected agronomic characteristics. Soybeans derived from event FG72 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 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

The only biologically significant difference observed in field evaluations is that FG72 soybean plants are tolerant to glyphosate and isoxaflutole herbicides.

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

The FG72 insert is integrated at chromosomal level and shows structural stability over multiple generations.

Phenotypic stability of FG72 soybeans was also demonstrated by evaluating the inheritance pattern of tolerance to glyphosate through succeeding generations. The inheritance of the introduced trait in soybean FG72 follows Mendelian pattern characteristics of a single locus.

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

a) Plant to bacteria gene transfer

It is not expected that the FG72 soybean would have different abilities to transfer genetic material compared to conventional soybean as FG72 soybean does not contain either an origin of replication from plasmid pSF10 or any sequences responsible for an enhanced frequency of recombination in bacteria.

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 soybean for food and feed uses and import and processing and does not include cultivation of FG72 soybean in the EU. As a consequence exposure to the environment will be very limited

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

Direct comparative assessments of FG72 soybean were made using the non-transgenic parental line Jack as the comparator.

7.2 Production of material for comparative assessment

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

Nutrient composition analysis was performed using the raw agricultural commodity, i.e. soybean grain harvested from field trials planted at ten locations in 2008 growing season and six locations during the 2009 growing season. The field trials were located in the typical soybean growing areas of north America. At each site three entries were planted:

1. the non-transgenic control isoline variety Jack (entry A), which was treated with conventional herbicides registered for use on soybean
2. the FG72 soybean treated with conventional herbicides (entry B), and
3. the FG72 soybean treated with the intended herbicides (isoxaflutole [IFT] and glyphosate [GLY]) (entry C).

Each of the three entries was planted in a randomized complete block design (RBC) with three replications per location. Three non-transgenic commercial soybean varieties were planted at the same locations.

Agronomic evaluations of the event FG72 soybean were conducted in the above mentioned field trials in 2008 and 2009.

b) The baseline used for consideration of natural variations

In all the comparative studies performed, FG72 soybeans were compared with the non-transgenic parental line Jack, a set of non-transgenic commercial soybean varieties and values for soybean as reported in available literature references.

7.3 Selection of material and compounds for analysis

Compositional analyses were conducted for the components as detailed in the OECD consensus document : 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.

Based on the statistical evaluation of the analytical data the soybean grain from the FG72 soybean are found to be nutritionally equivalent to grain from the non-transgenic comparator, the variety Jack.

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 FG72 to its appropriate counterpart Jack two years of field trials were conducted.

Genotypic traits including 1) flower color, 2) pubescence color, 3) pod color, 4) hilum color and shapes, 5) canopy architecture, 6) leaf shape, 7) growth habit, and 8) susceptibility to pests and diseases, were collected and analyzed. Agronomic traits including 1) emergence, 2) stand count, 3) plant vigor and health rating, 4) flowering date, 5) plant height, 6) days to maturity, 7) plant lodging, 8) pod shattering, and 9) yield were recorded and evaluated with analysis of variance statistical methods (ANOVA).

7.5 Product specification

The introduced traits in FG72 include glyphosate and isoxaflutole tolerance achieved by the in planta production of the 2mEPSPS and HPPD W336 proteins, respectively.

FG72 soybeans belong to the species *Glycine max* and are distinguished from conventional soybeans only by tolerance to the herbicides glyphosate and isoxaflutole.

7.6 Effect of processing

Soybeans harvested from FG72 plants will be produced and processed in the same manner as soybeans produced using conventional breeding methods, with one exception, FG72 plants can be sprayed with glyphosate and isoxaflutole herbicides during production. Processing will be handled in the same manner as conventional soybean.

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 FG72 soybean.

FG72 soybean and derived products are not different in quality or nutritional composition from the soybean products now consumed.

7.8 Toxicology

FG72 soybeans contain the stably integrated *2mepsps* gene which confers tolerance to the herbicide glyphosate and the *hppdPfW336* gene which confers tolerance to the herbicide isoxaflutole (IFT). The *2mepsps* and *hppdPfW336* genes were introduced into soybean genome in a single gene construct via direct-gene transfer.

Safety assessment of newly expressed proteins

The source organism for the 2mEPSPS protein, maize, is a safe crop plant widely used for food and feed. EPSPS proteins are ubiquitous in nature, being widely expressed in food and feed crops. 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. The 2mEPSPS protein has no amino acid sequence homology to known allergens and is rapidly degraded in simulated gastric fluid and simulated intestinal fluid assays. The 2mEPSPS protein has no amino acid sequence similarity to known toxins and exhibited no effects in an acute oral mouse toxicity test.

The wild-type (wt) *hppd* gene was isolated and cloned from *Pseudomonas fluorescens*. *Pseudomonas fluorescens* has a good history of safe use. It is ubiquitous in the environment, including soil, water and food. It has many beneficial uses in agriculture, human health and bioremediation. Despite this widespread presence, it is not described as allergenic, toxic or pathogenic to healthy humans and animals. A single amino acid substitution introduced in the wt *hppd* gene resulted in the modified *hppdPf W336* gene. This modification reduces the sensitivity of the HPPD enzyme to the herbicide isoxaflutole. 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 HPPD W336 protein has no amino acid sequence homology to known allergens and is rapidly degraded in simulated gastric fluid and simulated intestinal fluid assays. In the search for potential sequence homology with known toxins, the HPPD W336 protein showed similarities with other HPPD proteins from various origins that were not considered biologically relevant. The HPPD W336 protein exhibited no effects in an acute oral mouse toxicity test. In addition, the HPPD W336 was not toxic to mice in a repeated 28-day toxicity study. In conclusion, there is no concern regarding human food and animal feed safety with respect to the HPPD W336 protein.

7.8.2 Testing of new constituents other than proteins

Not required for FG72 soybean as no constituent other than the 2mEPSPS and HPPD W336 proteins is novel and no relevant changes were detected in the composition by the compositional analysis.

7.8.3 Information on natural food and feed constituents

Natural constituents of soybean have not been changed in FG72 soybean.

7.8.4 Testing of the whole GM food/feed

No further testing of the whole GM food / feed is necessary because;

a) Molecular analysis of FG72 soybean raised no concerns for unintended effects

b) Substantial equivalence between FG72 soybean and soybean currently in commerce is demonstrated

c) No concerns are raised in toxicology evaluations of the 2mEPSPS and HPPD W336 proteins

Although no further testing is necessary, a 42 day poultry feeding study was conducted to supplement the safety evaluation of FG72. The study confirms that FG72 soybeans derived from event FG72 are as wholesome for feed use as conventional soybeans. To further support the absence of unintended effects of the genetic modification in FG72 soybean also the 90-day toxicity study in rats was performed. The results of this study show that the FG72 toasted soybean meal is nutritionally equivalent to and as safe as its non-GM counterpart.

7.9 Allergenicity

Assessment of allergenicity of the newly expressed proteins

Zea mays from which the wild type EPSPS protein was isolated is common in nature, commonly consumed by animals and humans with an excellent history of safe use. It is not considered as an allergenic food or toxic food for humans and animals, despite its widespread consumption for centuries.

The potential amino acid sequence similarity of the 2mEPSPS protein with known allergens was

evaluated by using several *in silico* approaches. The results of the epitope homology search showed no identity for the 2mEPSPS protein with epitopes from known allergenic proteins. It has also been shown that the 2mEPSPS protein is very rapidly degraded in simulated gastric fluid. Furthermore, a complete digestion of the 2mEPSPS protein was observed within few seconds of incubation with SIF. This rapid degradation of the 2mEPSPS protein in the SGF and SIF indicates a minimal likelihood that the protein could survive and be absorbed through the gastrointestinal system

Pseudomonas fluorescens has a good history of safe use. It is ubiquitous in the environment, including soil, water and food. It has many beneficial uses in agriculture, human health and bioremediation. Despite this widespread presence, it is not described as allergenic, toxic or pathogenic to healthy humans and animals.

The potential amino acid sequence similarity of the HPPD W336 protein with known allergens was evaluated by using several *in silico* approaches. The results of the epitope homology search with the HPPD W336 protein showed no identity with epitopes from known allergenic proteins. It has also been shown that the HPPD W336 protein is very rapidly degraded in simulated gastric fluid and is completely digested within few seconds of incubation with SIF, indicating a minimal likelihood that the protein could survive and be absorbed through the gastrointestinal system

In conclusion, it is unlikely that the 2mEPSPS and HPPD W336 protein possesses allergenic properties.

7.9.2 Assessment of allergenicity of the whole GM plant or crop

Equivalence of FG72 soybean (with the exception of the introduced traits) to the conventional comparator Jack was demonstrated on the basis of compositional analysis. Therefore no increased allergenicity is anticipated for FG72 soybean. To provide further evidences on the safe allergenic profile of FG72 soybean, a study was performed to evaluate potential qualitative and quantitative differences in IgE binding to the transgenic soybean line FG72, the non-transgenic commercial counterpart (Jack) as well as three other commercial lines of soybeans.

Overall, for the soybean allergic subjects used in this study, the endogenous allergen profile of FG72 was equivalent to the endogenous allergen profile of Jack, its non-transgenic counterpart.

7.10 Nutritional assessment of GM food/feed

The trait introduced in FG72 is intended for agronomic benefits. FG72 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.

FG72 soybean products will be imported as any other commercial soybean in commingled commodities.

7.11 Post-market monitoring of GM food/feed

FG72 soybean is as safe as and as nutritious as any commercial soybean. It is therefore considered that there is no need for a post-market monitoring plan for GM food/feed for FG72 soybean.

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

FG72 soybean contains stably integrated *2mepsps* and *hppdPfW336* genes. The 2mEPSPS and HPPD W336 proteins expressed in FG72 soybean plants confer tolerance to the herbicides glyphosate and isoxaflutole, respectively. Therefore, there are no target organisms to consider for this herbicide tolerant soybean.

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 FG72 soybean during transportation and processing for food and feed.

9.1 Persistence and invasiveness

The introduced traits in FG72 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 and glyphosate.

9.2 Selective advantage or disadvantage

This application requests import and processing only and does not cover cultivation in the EU.

FG72 soybean has a seasonal advantage over weed competition only in concert with the use of a glyphosate and isoxaflutole herbicides to control weeds growing in the same field. FG72 soybeans, 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 and isoxaflutole and thus the opportunity to use these herbicides as part of the seasonal crop protection regime, FG72 is similar in phenotypic, genotypic or reproductive biology to commercial soybean varieties developed solely through conventional breeding practices. Without the use of glyphosate and isoxaflutole, any plants that might germinate from an accidental spill during import or transport of FG72 soybean, have no selective advantage over conventionally developed soybeans.

9.3 Potential for gene transfer

The scope of this application is the authorization of the FG72 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 soybean in the EU.

However, in theory cross pollination with other soybeans could occur if grain of FG72 was spilled and left in an area in which germination and soybean growth was possible. While possible, the likelihood of significant exposure of soybeans grown in the European Union to pollen from FG72 plants grown up as the result of spilled grain is extremely remote.

Soybean (*Glycine max*) is considered a self-pollinating species, with the amount of crosspollination to other soybean (*Glycine max*) generally considered to be less than 1%. This low probability of outcrossing is recognized in the planting guidelines for the production of certified seed. Those guidelines indicate that for such production practices, the only isolation considerations are that the soybeans of two different

cultivars be planted far enough apart to prevent inadvertent, mechanical mixing at harvest.

Gene flow 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, soybean exhibits a high level of self-fertilisation. Gene flow will not occur into wild related species because they are not present in the European Union.

Moreover, taking into account that this application does not include cultivation of soybean in the EU the likelihood of cross-pollination between GM soybean and cultivated soybean is extremely low. Volunteer plants if they would emerge in the area due to spillage from transport can be destroyed mechanically or through the use of herbicide other than HPPD inhibitor and glyphosate

9.4 Interactions between the GM plant and target organisms

The introduced traits confer tolerance to herbicides glyphosate and isoxaflutole, therefore there are no target organisms.

9.5 Interactions of the GM plant with non-target organisms

Soybeans are a commodity crop, generally co-mingled after harvest for export or processing. The likelihood that soybean spilled during transport from import locations or to transport facilities will germinate and establish itself is very low. Any FG72 plants that would germinate would only have a selective advantage in those cases where the herbicides glyphosate and isoxaflutole are used. In all other cases, the likelihood FG72 plants would establish itself is no greater than for soybeans developed through conventional breeding programs.

Observations of natural infestations were made at the trial sites for the occurrence and severity of the common pests and diseases of soybean. No pest or disease preference was noted for the plots of transgenic FG72 soybean, the non-transgenic counterpart Jack or the plots of conventional soybean varieties included at each location. No insect susceptibility was observed between the FG72 soybean plants and the variety Jack, the non-transgenic counterpart.

No adverse effect on non-target organisms from either the transgenic or non-transgenic plants was observed during any of the trials

9.6 Effects on human health

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 FG72 soybeans. Soybeans derived from transformation event FG72 have the same nutritional quality as soybeans in commerce, developed entirely through traditional breeding processes. The 2mEPSPS and HPPD W336 proteins, expressed in FG72 soybeans, are not a toxin or allergen and FG72 soybeans present no significant increased risk of an allergenic potential as compared to non-GM soybeans in soy-allergenic people.

9.7 Effects on animal health

No adverse effects on animal health are indicated when FG72 soybeans are used for feed purposes. Both whole soybean and processed fractions are used in animal feed. Soybean seeds can make up 15 to 25% of animal diets.

The nutritional composition of whole soybean and processed fractions of FG72 is substantially equivalent to that of soybean developed solely through traditional breeding practices.
The nutritional value was confirmed in a poultry feeding study conducted using diets containing meal derived from FG72 soybean.
There is no impact on the nutritional value of soybean grain or processed fractions caused by the genetic transformation.

9.8 Effects on biogeochemical processes

The scope of this application is the authorization of the FG72 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 soybean in the EU.

9.9 Impacts of the specific cultivation, management and harvesting techniques

Not applicable since the scope of this application is the authorization of FG72 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 soybean in the EU.

10. Potential interactions with the abiotic environment

The scope of this application is the authorization of the FG72 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 soybean in the EU.

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)

As required by Article 5(5)(b) and 17(5)(b) of Regulation (EC) No. 1829/2003 the proposed monitoring plan for MST-FGØ72-2 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 structure of the monitoring plan also takes into account the guidance on presentation of applications provided in the Guidance Document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed (The EFSA Journal (2006) 99, pp. 1-100).

11.2 Interplay between environmental risk assessment and monitoring

The scope of this application is the authorisation of MST-FGØ72-2 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 MST-FGØ72-2 seed products in the EU.

An environmental risk assessment (e.r.a.) was carried out for MST-FGØ72-2 according to the principles laid down in Annex II to Directive 2001/18/EC and Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC. The scientific evaluation of the characteristics of MST-FGØ72-2 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 MST-FGØ72-2 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.

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

As discussed in Section 2, the scientific evaluation of the characteristics of MST-FGØ72-2 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 MST-FGØ72-2. It is therefore considered that there is no need for case-specific monitoring.

11.4 General surveillance of the impact of the GM plant

11.4.1 Approach

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 MST-FGØ72-2, which could occur for example via substantial losses during loading/unloading of the viable commodity including MST-FGØ72-2 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 (other than HPPD inhibitor herbicides or glyphosate). Furthermore, unintended environmental effects due to the unintended release of MST-FGØ72-2 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 MST-FGØ72-2 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 MST-FGØ72-2 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 holders and operators handling and using viable MST-FGØ72-2. The operators will be provided with guidance to facilitate reporting of any unanticipated adverse effect from handling and use of viable MST-FGØ72-2.

A detailed description of the methodology proposed for general surveillance of MST-FGØ72-2 is

provided in Section 4.6.

11.4.2 Baselines

Since the intended use of MST-FGØ72-2 is the same as that of any other commercial soybean, the procedures for the import, handling and processing of MST-FGØ72-2 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.

11.4.3 Time-period

General surveillance of MST-FGØ72-2 will be undertaken for the duration of the authorisation period for MST-FGØ72-2 for import and processing.

11.4.4 Assigning responsibilities

The authorisation holders are 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 holders, who will immediately investigate and inform the European Commission in accordance with Regulation (EC) No 1829/2003, as described in Section 5.

11.4.5 Existing systems

Primary sources of information

The authorisation holders are not involved in commodity trade with MST-FGØ72-2. 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 MST-FGØ72-2. They are exposed to the imported viable MST-FGØ72-2 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 as outlined in Annex I.

Since traders may commingle MST-FGØ72-2 with other commercial soybeans, including authorised GM soybeans, the authorisation holders are working together with other members of the plant biotechnology industry within the European Association of Bioindustries (EuropaBio) and trade associations representing the relevant operators in order to implement a harmonised monitoring methodology. The following networks are currently involved:

⇒ *Importers / Traders*

COCERAL is the European association representing the cereals, rice, feedstuffs, oilseeds, oils and fats and agro-supply trade in the European Union. Its members are the national trade organisations that represent collectors, distributors, exporters, importers and agribulk storers of the above mentioned commodities in the majority of Member States. The main importers of cereals and feedstuffs into the EU are members of COCERAL.
Also see: http://www.coceral.com/cms/beitrag/10010169/227870.

⇒ *Silo Operators*

UNISTOCK is the European association representing professional storekeepers for agribulk commodities within the EU. It regroups representatives from 11 Member States and is itself a member of COCERAL. Commodity imports enter the EU by sea and transit through sea-port silos. The main storekeepers managing these silos are members of UNISTOCK.
Also see: http://www.coceral.com/cms/beitrag/10010260/232602

⇒ *Processors*

FEDIOL, the federation of the EU Oil and Protein Meal Industry, represents the interests of the European crushers of oilseeds meals producers and vegetable oils producers/processors. Its members

represent 80% of the EU industry and hold 147 oilseeds processing and vegetable oils and fats production facilities across Europe.
Also see: http://www.fediol.be/1/main1.php.

These associations represent the majority of European operators importing, handling and processing viable soybean commodity. They work closely together with a continuous and efficient flow of communication between them, particularly, through the documentation that needs to accompany any shipment containing GMOs in accordance with the labelling and traceability requirements of Regulation (EC) No 1830/2003, and are therefore best placed to observe and report any unanticipated adverse effects.

Other networks consisting of operators further down the food and feed chain have not been selected for the general surveillance of viable MST-FGØ72-2, because they focus on processed, non-viable material.

Additional sources of information

- In addition to the aforementioned existing monitoring systems, extensive independent research by scientists with a wide range of expertise is another valuable source of information on potential adverse effects arising from the use of GMOs. The applicant will actively screen peer-reviewed publications relevant to MST-FGØ72-2 by the scientific community.

11.4.6 Monitoring Methodology

The authorisation holders, together with other members of the plant biotechnology industry and EuropaBio, will implement general surveillance of viable GM soybeans, including MST-FGØ72-2, with the help of the selected networks described in Section 4.5.

The different parties agreed to collaborate on the following basis:

⇒ The authorisation holders 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.

Consequently, the European trade associations COCERAL, UNISTOCK and FEDIOL will notify EuropaBio of the results of the general surveillance on an annual basis. The report will cover all approved GM plant products subject to general surveillance. EuropaBio, will forward this report to the respective authorisation holders for inclusion in their annual report to the European Commission, as described in Section 5.

The current approach used for the collection of general surveillance information may still be adjusted in the future based on experience gained by the selected networks of operators with current and future GM plant products.

The general surveillance information reported to and collected by the authorisation holders from the European trade associations or other sources will be analysed for its relevance. Where information indicates the possibility of an unanticipated adverse effect, the authorisation holders will immediately investigate to determine and confirm whether a significant correlation between the effect and MST-FGØ72-2 can be established. If the investigation establishes that MST-FGØ72-2 was present when the adverse effect was identified, and confirms that MST-FGØ72-2 is the cause of the adverse effect, the authorisation holders will immediately inform the European Commission, as described in Section 5.

11.5 Reporting the results of monitoring

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

If information that confirms an adverse effect of MST-FGØ72-2 and that alters the existing risk assessment becomes available, the authorisation holders will immediately investigate and inform the European Commission. The authorisation holders, 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 holders 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 MST-FGØ72-2.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of MST-FGØ72-2 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.

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

The detection method for FG72 soybean has been sent to the European Union Reference Laboratory (EURL) (http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm) 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 JRC-EURL.

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

No field trials have been carried out with FG72 soybean in the EU.

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

a) Release country

FG72 soybean has been field tested in the USA and Argentina since 2001.

FG72 soybean has been field tested in Canada since 2008.

b) Authority overseeing the release

USA: United States Department of Agriculture (USDA)

Argentina: National Advisory Committee on Agricultural Biosafety (CONABIA).

Canada: Canadian Food Inspection Agency – Plant Biotechnology Office

c) Release site

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

Argentina: Information on the releases at http://www.sagpya.mecon.gov.ar/new/0-0/programas/conabia/bioseguridad_agropecuaria2.php

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.

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 websites http://gmoinfo.jrc.ec.europa.eu/gmp_browse.aspx and http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm provide 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.ec.europa.eu/
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.ec.europa.eu/