Application under Regulation (EC) No 1829/2003 on genetically modified food and feed for authorization of 40-3-2 soybean for cultivation in the European Union

Part II

Summary

A. GENERAL INFORMATION

1. Details of application

a) Member State of application

The Netherlands

b) Notification number

Not available at the time of submission.

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

The product is 40-3-2 Roundup Ready® soybean.

The Monsanto development code for this genetically modified soybean is 40-3-2. 40-3-2 varieties will be marketed under the name of the variety, in association with the trademark Roundup Ready® soybean, indicating clearly to growers that 40-3-2 soybean[1] is tolerant to glyphosate, the active ingredient in Roundup® herbicides.

d) Date of acknowledgement of notification

Not available at the time of submission.

2. Applicant

a) Name of applicant

Monsanto Company, represented by Monsanto Europe S.A.

b) Address of applicant

Monsanto Europe S.A.	Monsanto Company
Avenue de Tervuren 270-272	800 N. Lindbergh Boulevard
B-1150 Brussels	St. Louis, Missouri 63167
BELGIUM	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))

40-3-2 soybean will be cultivated and used in the European Union in the same manner as commercial soybean and by the same growers and operators currently involved in the production, storage, transport, processing and use of soybean.

[1] Hereafter referred to as 40-3-2.

® Roundup and Roundup Ready are registered trademarks of Monsanto Technology LLC.

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)

(x) 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 (x)**
If *ye*s, specify	

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

Yes (x)	**No ( )**
If *n*o, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC	

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 (x)	**No ( )**
If *ye*s, specify 40-3-2 was authorized for import and processing according to Directive 90/220/EEC in April 1996 (Commission Decision 96/281/EC – Official Journal of the European Communities – L107/10 – 30.4.96). Foods and feeds containing, consisting of or produced from 40-3-2 were placed on the EU market in accordance with Part C of Directive 90/220/EEC before the entry into force of Regulation (EC) No 258/97.	

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

Yes (x)	No ( )

If *yes*, specify

40-3-2 has been notified to and evaluated by numerous international regulatory authorities, which granted its approval in 24 countries worldwide. Among those, the U.S.A., Canada, Argentina, Uruguay, Brazil, Romania, Republic of South Africa, Paraguay and Bolivia approved 40-3-2 for cultivation.

8. General description of the product

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

The original transformation was conducted on the soybean cultivar A5403 by the particle acceleration method. 40-3-2 produces the protein CP4 EPSPS, derived from *Agrobacterium* sp. strain CP4, which confers tolerance to glyphosate, the active ingredient in Roundup herbicides.

The use of 40-3-2 enables the farmer to use Roundup herbicides for effective control of weeds during the growing season and to take advantage of the favourable environmental and safety characteristics of its active ingredient glyphosate.

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

This application is for cultivation of 40-3-2 in the EU. The range of uses of this soybean for food and feed will be identical to the full range of equivalent uses of traditional soybean.

c) Intended use of the product and types of users

40-3-2 soybean will be cultivated and used in the European Union in the same manner as current commercial soybean and by the same growers and operators currently involved in the production, storage, transport, processing and use of soybean.

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

40-3-2 is substantially equivalent to traditional soybean, except for its tolerance to glyphosate, which is a trait of agronomic interest. This soybean was shown to be as safe and nutritious as traditional soybean. Therefore, 40-3-2 and its derived products will be stored, packaged, transported, used and handled in the same manner as for current commercial soybean. No specific conditions are warranted or required for the food and feed use of 40-3-2.

e) Any proposed packaging requirements

40-3-2 is substantially equivalent to traditional soybean, except for its tolerance to glyphosate. Therefore, 40-3-2 and derived products will be used in the same manner as other soybean and no specific packaging is required. (For labelling, *see* question 8.(f)).

f) A proposal for labelling in accordance with Articles 13 and 25 of Regulation (EC) 1829/2003. In the case of GMOs, food and/or feed containing, 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.

In accordance with Regulations (EC) No 1829/2003 and 1830/2003, the current labelling threshold of 0.9 % will continue to be applied for the marketing of 40-3-2 and derived products.

40-3-2 seeds will be marketed by Monsanto and its licensees under the name of the variety, in association with the trademark Roundup Ready® soybean. Seed bags and packages will be clearly marked with the following words "This product contains genetically modified organisms" or "This product contains genetically modified soybean" as well as the product's unique identifier MON-Ø4Ø32-6.

Operators are currently required to label products containing or consisting of 40-3-2 with the words "genetically modified soybean" or "contains genetically modified soybean" and shall continue to declare the unique identifier MON-Ø4Ø32-6 in the list of GMOs that have been used to constitute a mixture that contains or consists of this GMO.

Operators are currently required to label foods and feeds derived from 40-3-2 with the words "produced from genetically modified soybean". In the case of products for which no list of ingredients exists, operators shall continue to ensure that an indication that the food or feed product is produced from GMOs is transmitted in writing to the operator receiving the product.

Growers and operators handling or using 40-3-2 and derived foods and feeds in the EU are required to be aware of the legal obligations regarding traceability and labelling of these products. Given that explicit requirements for the traceability and labelling of GMOs and derived foods and feeds are laid down in Regulations (EC) No 1829/2003 and 1830/2003, and that authorized foods and feeds shall be entered in the Community Register, operators in the food/feed chain will be fully aware of the traceability and labelling requirements for 40-3-2.

Therefore, no further specific measures are to be taken by the applicant.

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)

MON-Ø4Ø32-6

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

40-3-2 is intended for cultivation in all soybean production regions 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

This application is for cultivation of 40-3-2 in the EU.

Cultivated soybean is not invasive, is weakly competitive outside cultivated areas and possess few weedy characteristics. 40-3-2 is shown to be substantially equivalent to traditional soybean, except for the introduced tolerance to glyphosate and, therefore, is unlikely to pose any threat to the EU environment or to require special measures for its containment. Furthermore, soybean volunteers can be easily controlled using currently available selective herbicides or by mechanical means. Therefore, no special measures are considered to be required in case of misuse or unintended release.

B. INFORMATION RELATING TO (A) THE RECIPIENT OR (B) (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

A5403

f) Common name

Soybean

2. a) Information concerning reproduction

(i) Mode(s) of reproduction

Soybean is a diploidized tetraploid (2n=40) and is a self-pollinated species, propagated by seed.

The papilionaceous flower consists of a tubular calyx of five sepals, a corolla of five petals, one pistil and nine fused stamens with a single separate posterior stamen. The stamens form a ring at the base of the stigma and elongate one day before pollination, at which time the elevated anthers form a ring around the stigma. 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 percentage of self-fertilisation and cross-pollination is usually less than one percent.

Pollination typically takes place on the day the flower opens. The pollen comes naturally in contact with the stigma during the process of anthesis. Anthesis normally occurs in late morning. The pollen usually remains viable for 2-4 hours, after which it germinates. No viable pollen can be detected by late afternoon. Natural or artificial cross-pollination can only take place during the short time of the day that the pollen is viable.

A soybean plant can produce as many as 400 pods, with two to twenty pods at a single node. Each pod contains one to five seeds.

(ii) Specific factors affecting reproduction

Soybean is a quantitative short day plant and hence flowers more quickly under short days. As a result, photoperiodism and temperature response are important in determining areas of cultivar adaptation.

During the reproductive stages of development, soybean plants are particularly sensitive to hydric and thermal (low temperature) stress which can cause significant flower abortion and yield loss. Soybeans do not yield well on acid soils and the addition of limestone may be required.

(iii) Generation time

Soybean is an annual crop which is planted in Europe in late spring (April to May). Pods develop in late summer (August) and harvesting is normally in September to October. The length of the cultural cycle is 100 to 160 days, depending on the variety and the region in which it is cultivated.

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

Glycine is the only genus in the tribe *Phaseoleae* where species have diploid chromosome numbers of 40 and 80, but not 20. The unique chromosome number of *Glycine* is probably derived from diploid ancestors with base number 11, which have undergone aneuploid loss

to base number 10. In the Family Leguminosae, only 10 of 71 genera are considered completely polyploid and *Glycine* is one of them. Soybean should be regarded as a stable tetraploid with diploidized genomes. Although soybean is a self-pollinated species, cross-pollination may occur.

Hybridization with cultivated soybean varieties

In studies with cultivated traditional soybeans, where conditions have been optimized to ensure close proximity and flowering synchrony, cross pollination has been found to be generally very low. Outcrossing has been reported to range from 0.03 to 3.62% between adjacent rows. At distances of more than 4.5 meters from the pollen source, cross-pollination in soybean is very rare (less than 0.02%) and most often not detectable. Recent data show cross pollination rates from 0.41% to 0.03% at distances of 0.9 m and 5.4 m from the pollen source, respectively. Cross-pollination frequencies may vary due to growing season, genotypes and location of male parent in relation to female parent. Insect activity does increase the outcrossing rate, but soybeans are generally not the preferred plant for pollinators.

Outcrossing with wild species

From a taxonomic standpoint, both the wild annual species of subgenus *Soja* and the wild perennial species of subgenus *Glycine* are candidates for gene exchange with the cultivated soybean. No other genus is closely enough related to soybean to allow for the possibility of outcrossing. Therefore, the discussion below will concentrate on species of subgenus *Glycine* and *Soja*.

Hybridization with wild perennial species of subgenus Glycine

There are no wild relatives of subgenus *Glycine* in Europe. Therefore, the only opportunities for inter-subgeneric hybridization would occur in Australia, South Pacific Islands, China, Papua New Guinea, Philippines and Taiwan, where those species are endemic. Nonetheless, there are no known reports of successful natural hybridization between cultivated soybean and these wild perennial species. All inter-subgeneric hybrids were obtained through *in vitro* seed culture. The F1 hybrids were generally sterile and further progeny has been obtained only in a few cases and with great difficulty. Consequently, the possibility of gene transfer between cultivated soybean and wild species of subgenus Glycine does not exist.

Hybridization with the wild annual species of subgenus Soja

The wild annual species *G. soja*, found in China, Taiwan, Japan, Korea and Russia can hybridize naturally with the cultivated soybean, *G. max*, since they are both members of the subgenus *Soja*. Frequency of spontaneous cross-pollination in reciprocal combinations of *G. max* and *G. soja* varied from 0.73 (♀ *G. soja* × ♂ *G. max*) to 12.8 % (♀ *G. max* × ♂ *G. soja*). Hybridization between female *G. soja* and male *G. max* was less successful than hybridization in the opposite direction. Species relationships in the subgenus *Soja* indicated that F1 hybrids of *G. max* (2n=40) and *G. soja* (2n=40) carry similar genomes and are completely fertile or differ by a single reciprocal translocation. *G. gracilis*, known only from Northeast China, is considered to be a weedy or semi-wild form of *G. max*, with some phenotypic characteristics intermediate to

those of *G. max* and *G. soja*. *G. gracilis* may be an intermediate in the speciation of *G. max* from *G. soja* or a hybrid between *G. soja* and *G. max*. Interspecific fertile hybrids between *G. max* and *G. soja* and between *G. max* and *G. gracilis* have been easily obtained.

It has however to be noted that the frequency of crop-to-wild introgression, which is defined as the permanent incorporation of genes from one population/species to another after hybridization, is thought to be exceedingly low in soybean.

To conclude, gene transfer between cultivated soybean and wild species of subgenus *Soja* may occur, but not in Europe, where the wild relatives of subgenus *Soja* are not present.

3. Survivability

a) Ability to form structures for survival or dormancy

Soybean reproduces solely by means of seeds. Soybean seeds have no innate dormancy and are sensitive to cold. Due to the lack of dormancy (which is selected for in commercial soybean seed), soybean seeds germinate quickly with adequate temperature and moisture. As a consequence, all seed that might shatter and fall to the ground will eventually germinate and grow as a volunteer in the year following cultivation. Volunteers are likely to be killed by frost during the autumn or early winter of the year they were produced. In case they should establish, volunteers do not compete well with the succeeding crop, and can easily be controlled mechanically or chemically.

b) Specific factors affecting survivability

See Section B.3.(a).

4. Dissemination

a) Ways and extent of dissemination

In theory, soybean dissemination may occur by means of seed dispersal or pollen dispersal.

However, during soybean harvesting, there are few seed lost due to the relatively large seed size. Furthermore, neither the soybean seedpod, nor the seed have morphological characteristics that would facilitate animal transportation.

Soybean pollen may also be considered as a vehicle for dissemination, but the pollen viability outside of the soybean flower is limited by the fact that soybean is a predominately self-pollinating plant with anthers enclosed within the keel of the corolla.

b) Specific factors affecting dissemination

See Section B.4.(a).

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

Soybean was domesticated in the eastern half of northern China around the 11th century BC or earlier and its cultivation subsequently extended throughout south-east Asia. Soybean cultivation was probably introduced in Europe and the United States of America (U.S.A.) in the 18th century. Today, soybean is grown as a commercial crop in over 35 countries. The major producers of soybeans are the U.S.A., Brazil, Argentina and China. Soybean is grown primarily for the production of beans, has a multitude of uses in the food and industrial sectors and represents one of the major sources of edible vegetable oil and of proteins for livestock feed use.

In Europe, soybean is grown mainly in Italy and in France. In Italy, the soybean production areas are located in the Po Valley, particularly in the Po Delta and on the coast line of the Veneto region. In France, soybean is predominantly grown in the south west and in the Loire Valley. Outside of the EU, Romania, one of the forthcoming accession countries, is also a large soybean producer.

There are no compatible species of cultivated soybean in Europe.

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

Not applicable, as soybean is grown in Europe.

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 is known to interact with other organisms in the agricultural environment. Soybean is sensitive to a number of economically important diseases and insect predators and is susceptible to competition from surrounding weeds, which commonly compete with soybean for light, water and nutrients.

Soybean seed is known to contain a number of natural anti-nutritional components, which are completely or partially inactivated during processing. Trypsin (proteinase) inhibitors are known to have anti-nutritive properties in animals fed unprocessed soybeans. Other anti-nutrients include lectins, stachyose and raffinose, phytoestrogens and phytate. Some of these anti-nutrients relate to their impact on human nutrition, while others relate to animal nutrition in general including livestock.

Soybeans have been shown to contain endogenous proteins that elicit an allergenic response when ingested. The prevalence of individuals with allergies to soybeans varies significantly between geographies. Allergenicity to soy proteins is generally a transient allergy of infancy or childhood, with allergenicity fairly rare in adults. Soy allergenic proteins have been identified and characterized. The number of allergenic proteins varies with sera obtained from individuals in different countries, probably reflecting the

extent of consumption of soybean products in the diet.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification

Plasmid vector PV-GMGT04 was used to produce 40-3-2 using the particle acceleration method. The original transformation was conducted on the soybean cultivar A5403.

2. Nature and source of the vector used

The vector used to generate 40-3-2 by particle acceleration method is coded PV-GMGT04. The genetic elements present in PV-GMGT04 are described in Table 1.

Table 1: Summary of DNA components of the plasmid vector PV-GMGT04

Genetic elements	Size (kb)	Function
P-E35S	0.61	The cauliflower mosaic virus (CaMV) 35S promoter with the duplicated enhancer region.
CTP4	0.22	The N-terminal chloroplast transit peptide sequence from the *Petunia hybrida epsps* gene.
cp4 epsps	1.36	The 5-enolpyruvylskikimate-3-phosphate synthase coding sequence (*cp4 epsps*) from *Agrobacterium* species strain CP4.
NOS 3'	0.26	The 3' non-translated region of the nopaline synthase gene, which directs polyadenylation of the mRNA.
nptII	1.32	The gene for the enzyme neomycin phosphotransferase type II from Tn5, a transposon isolated from *E. coli,* which allows selection of bacteria containing the plasmid.
ori-pUC	0.65	The origin of replication from the high copy *E. coli* plasmid pUC119, necessary for replicating the plasmid in *E. coli*.
P-MAS	0.42	The TR 2' mannopine synthase promoter region.
uidA	1.81	The *uidA* coding sequence from *E. coli* encoding a ß-D-glucuronidase (GUS) protein gene.
7S 3'	0.43	The 3' nontranslated region of the alpha subunit of the soybean 7S seed storage protein complex.
P-FMV	0.57	The 35S promoter from a modified figwort mosaic virus (FMV).
CTP4	0.22	The N-terminal chloroplast transit peptide sequence from the *Petunia hybrida epsps* gene.
cp4 epsps	1.36	The 5-enolpyruvylskikimate-3-phosphate synthase coding sequence (*cp4 epsps*) from *Agrobacterium* species strain CP4.
NOS 3'	0.26	The 3' non-translated region of the nopaline synthase gene, which directs polyadenylation of the mRNA.

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

Plasmid PV-GMGT04 contains three gene cassettes intended for insertion, of which two contain the *cp4 epsps* coding sequence and one contains the *uidA* coding sequence (*see* Table 1).

In both *cp4 epsps* gene cassettes, the *cp4 epsps* coding sequence is linked to a chloroplast transit peptide sequence designated CTP4, based on the CTP

sequence isolated from the *Petunia hybrida* 5-enolpyruvylshikimate-3-phosphate synthase (*epsps*) gene. CTP4 targets the CP4 EPSPS protein to the chloroplast, the location of EPSPS in plants and the site of aromatic amino acid biosynthesis.

In the first *cp4 epsps* gene cassette, the *ctp4-cp4 epsps* coding sequence is under the control of the enhanced 35S cauliflower mosaic virus promoter (P-E35S). The second cassette contains the *ctp4-cp4 epsps* coding sequence under the control of the 35S figwort mosaic virus promoter (P-FMV). Both promoters are constitutively active in plants.

In both *cp4 epsps* gene cassettes, the *cp4 epsps* coding sequence is joined to the nopaline synthase 3' non-translated sequence (NOS 3') from *Agrobacterium tumefaciens*, which provides the polyadenylation sites directing mRNA processing and multiple adenylate addition.

The *cp4 epsps* coding sequence, isolated from *Agrobacterium* sp. strain CP4, confers a high level of tolerance to glyphosate. It encodes the 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS), which unlike most native plant and microbial EPSPS enzymes, is naturally tolerant to glyphosate. EPSPS catalyzes the conversion of shikimate-3-phosphate (S3P) and phosphoenolpyruvate (PEP) into 5-enolpyruvylshikimate-3-phophate (EPSP), an intermediate required for the production of aromatic amino acids.

The *uidA* gene cassette contains the *uidA* coding sequence under the control of the TR 2' mannopine synthase promoter and is joined to the 7S 3' non-translated region of the alpha subunit of the soybean 7S seed storage protein complex. The GUS protein expressed by the *uidA* gene cassette is a 68 kD acid hydrolase that catalyzes the cleavage of several ß-glucuronides and has been used as a scoreable marker in the transformation and regeneration of 40-3-2.

D. INFORMATION RELATING TO THE GM PLANT

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

40-3-2 contains a fully functional intact gene encoding the CP4 EPSPS protein, which confers tolerance to glyphosate. Glyphosate has excellent weed control capabilities and well-known, favourable environmental and safety characteristics. However, the sensitivity of crop plants to glyphosate has prevented the in-season use of this herbicide over-the-top of crops. The extension of its use to allow in-season application in major crops such as soybean provides a novel weed control option for farmers.

2. Information on the sequences actually inserted or deleted

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

Molecular analysis was conducted to characterize the DNA inserted in 40-3-2. Genomic DNA was analyzed using Southern blot, PCR and genome walking analysis to determine the insert number (number of integration sites within the soybean genome), the copy number (number of DNA segments used for transformation integrated within one insertion site), the integrity of the inserted promoters, coding

sequences and polyadenylation signals and the presence or absence of any other elements of plasmid vector PV-GMGT04.

The data generated by molecular analyses support the following conclusions:

(1) The genome of 40-3-2 contains a single functional DNA insert comprised of a single copy of the *cp4 epsps* gene cassette under the control of the E35S promoter (*i.e.* primary, functional insert);

(2) At the 3' proximal region of the functional insert, a 250 bp segment of *cp4 epsps* DNA is located adjacent to the NOS 3' polyadenylation signal of the functional *cp4 epsps* gene cassette;

(3) In addition, a second co-segregating non-functional insert comprising a 72 bp *cp4 epsps* DNA segment was identified (*i.e.* secondary, non-functional insert);

(4) The *cp4 epsps* gene cassette within the primary, functional insert and its elements are functionally intact;

(5) No additional elements from vector PV-GMGT04 were detected in 40-3-2.

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

Not applicable

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

The presence of 40-3-2 in the nuclear genome is best shown by the Chi square (χ^2) analysis of the segregation data. The results of the χ^2 analysis indicate that a single functional DNA insert is integrated in the plant nuclear genome of 40-3-2 and is inherited as a single locus, following a Mendelian one-locus model, in a stable manner.

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

The primary, functional insert consists of a single cassette containing a portion of the E35S promoter, the CTP4 chloroplast transit peptide, the *cp4 epsps* coding sequence and the NOS 3' polyadenylation signal. There is an additional 250 bp segment of the *cp4 epsps* coding sequence immediately adjacent to the NOS 3' polyadenylation signal in the primary, functional insert. The secondary, non-functional, insert consists of 72 bp of the *cp4 epsps* sequence.

3. Information on the expression of the insert

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

40-3-2 contains one functional introduced protein, CP4 EPSPS, providing tolerance to glyphosate. CP4 EPSPS protein levels were measured in 40-3-2 leaf and seed tissues harvested in the 1992 and

1993 growing seasons from seven European locations.

CP4 EPSPS protein levels in seed and leaf extracts were estimated using ELISA. In soybean leaf tissue, the mean CP4 EPSPS protein level was 0.502 µg/mg fw. The mean CP4 EPSPS protein level in soybean seed tissue was 0.167 µg/mg fw.

Additional data, generated from samples collected during U.S.A. field trials in the 1992 and 1993 growing seasons, are consistent with the EU data reported here. The CP4 EPSPS protein level in soybean leaf tissue from the 1993 field trials ranged from 0.308 to 0.856 µg/mg fw (mean 0.489 µg/mg fw). The CP4 EPSPS protein level in soybean seed from the 1992 trials varied from 0.258 to 0.378 µg/mg fw (mean 0.301 µg/mg fw), while the CP4 EPSPS protein level in soybean seed from the 1993 trials ranged from 0.166 to 0.287 µg/mg fw (mean 0.218 µg/mg fw).

b) Parts of the plant where the insert is expressed

The expression of the CP4 EPSPS protein is expected to occur throughout the whole plant since the E35S promoter has been shown to drive constitutive expression of the encoded protein in genetically modified plants.

As seed and leaf are relevant tissues for the safety assessment of 40-3-2, protein levels in these tissues were estimated in the conducted European field trials.

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

a) Reproduction

Based on centuries of experience with traditional, domesticated soybean in the EU, there is no potential for soybean to be invasive of natural habitats or persist in the agronomic environment without the aid of human intervention. Soybean is known as a poor competitor, which outside of cultivation has no meaningful impact on the environment.

Comparative assessments of the phenotypic and agronomic characteristics of 40-3-2 and traditional soybean have been conducted, based on field trials in the EU at locations representative of the soybean cultivated area across several years. The phenotypic characteristics evaluated were: date of emergence, % of emergence, plant count, plant height, vigour and colour, morphological changes, date at 50% flowering, the difference in susceptibility to insects, nodes per plant, pods per plant, % lodging, % leaf drop, yield and % moisture.

On the basis of the studies described above, it is possible to conclude that no differences in the mode or rate of reproduction, dissemination, survivability or other agronomic or phenotypic characteristics are expected, when 40-3-2 will be grown in the EU and that 40-3-2 is equivalent to traditional soybean in its phenotypic and agronomic behaviour, except for the introduced glyphosate-tolerance trait.

The agronomic and phenotypic equivalence of 40-3-2 compared to traditional soybean is also supported by field tests conducted in the U.S.A. and Puerto Rico (1991-1994), in Argentina (1993-1994) and in

Canada (1993 and 1994) and by additional research after the commercial introduction of 40-3-2 in North America.

To conclude, 40-3-2 has been cultivated on over 225 million hectares globally since 1996 and demonstrated to possess expected agronomic and phenotypic characteristics. No unusual plant pest characteristics or unintended environmental effects have been observed, confirming the results of the extensive studies developed prior to, and subsequent to, approval and market introduction.

b) Dissemination

See Section D.4.(a).

c) Survivability

See Section D.4.(a).

d) Other differences

See Section D.4.(a).

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

The results of the χ^2 analysis show that a single functional DNA insert is integrated in the plant nuclear genome of 40-3-2 and is inherited as a single locus, following a Mendelian one-locus model, in a stable manner.

Additionally, on a phenotypic level, since the initial development and breeding of 40-3-2, the glyphosate-tolerance trait has been consistently inherited in a Mendelian fashion for at least 12 generations across diverse germplasm without reported instability.

The genetic stability of 40-3-2 has been further confirmed by Southern blot analyses.

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

a) Plant to bacteria gene transfer

No elements known to be involved in DNA mobility have been included in the inserted DNA. Therefore, in comparison to traditional soybean, no changes are to be expected in the ability of the GM plant to exchange genetic material with bacteria.

b) Plant to plant gene transfer

The natural hybridization between 40-3-2 and other cultivated soybean may occur at very low level, but, as wild relatives are not present in Europe, the possibility for out-crossing to wild species does not exist in the EU.

7. Information on any toxic, allergenic or other harmful effects on human or animal health arising from the GM food/feed

7.1 Comparative assessment

Choice of the comparator

40-3-2 was compared to a traditional soybean with the same genetic background.

7.2 Production of material for comparative assessment

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

Compositional analyses were conducted on 40-3-2 seed samples originating from 14 European field trials in the 1998 growing season. Seven non-replicated sites were located both in France and Italy in geographies representative of the soybean cultivated area. All plants were grown under normal agronomic field conditions for their respective geographic regions.

The results of these analyses establish that 40-3-2 is compositionally equivalent to traditional soybean.

Additional 40-3-2 compositional analyses have been conducted on soybeans grown in the U.S.A. in 1992 and 1993 at nine and four locations, respectively. The composition of 40-3-2 seeds and selected processing fractions was compared with that of a traditional soybean with the same background as 40-3-2 (*i.e.* the control). The results of these studies indicate that 40-3-2 and its processed fractions are compositionally equivalent to traditional soybean.

b) the baseline used for consideration of natural variations

40-3-2 was compared to eleven traditional soybean varieties grown in the same plots and was analyzed concurrently.

7.3 Selection of material and compounds for analysis

The components selected for 40-3-2 compositional analyses were chosen on the basis of industry accepted guidelines at the time the assessments were conducted in 1992, 1993 and 1998. Subsequently, the choice of key nutrients and other nutritionally important components that had been analyzed in 40-3-2 was confirmed by the OECD consensus document on compositional considerations for new varieties of soybean.

7.4 Agronomic traits

Field trials with 40-3-2 were conducted in the EU, as well as in several geographies, where the product was subsequently made available for wide-scale production. The agronomic observations made in these field trials and during the course of production supports the conclusion that from an agronomic and phenotypic (morphological) point of view, 40-3-2 is equivalent to traditional soybean, except for the introduced

glyphosate-tolerance trait (*see* Section D.4).

7.5 Product specification

40-3-2 contains a functionally intact gene cassette encoding the CP4 EPSPS protein, which confers tolerance to glyphosate.

40-3-2 and its derived products are currently imported into the EU and used as foods and feeds, as any other soybean. When 40-3-2 will be cultivated in the EU, it will be used by growers and operators that have traditionally been involved in the production, commerce, processing and use of soybean and soybean-derived products.

The presence of the glyphosate-tolerance trait in soybeans or soybean derived products can be identified by employing different techniques. Southern blot or PCR techniques can identify the inserted nucleotide sequences, while specific ELISAs have been developed to detect the presence of the CP4 EPSPS protein in individual 40-3-2 plants or in specific tissues. A 40-3-2-specific PCR assay allowing the identification and the quantification of 40-3-2 has been developed and provided to the Joint Research Centre (JRC), acting as the Community Reference Laboratory.

7.6 Effect of processing

As 40-3-2 is compositionally equivalent to traditional soybean, the use of 40-3-2 for the production of foods and feeds is not expected to be different from that of traditional soybean. Commercial experience since 1996 has confirmed that the production and processing of 40-3-2 does not differ from the production and processing of the equivalent foods and feeds, originating from traditional soybean.

7.7 Anticipated intake/extent of use

Anticipated dietary intake of soybean and soybean derived foods and feeds, is not expected to be altered upon authorization of 40-3-2 for cultivation and use in the EU. Since its authorization for import and processing under Directive 90/220/EC in 1996, 40-3-2 and derived products have been imported in the EU from other world areas and already make up a significant portion of the soybean products used in the EU. When 40-3-2 is approved for cultivation in the EU, it is expected to replace a portion of the locally produced soybeans, while not affecting the current uses and dietary intake.

7.8 Toxicology

7.8.1 Safety assessment of newly expressed proteins

The human and animal safety of the CP4 EPSPS protein is based upon the extensive characterization of CP4 EPSPS and its relatedness to EPSPS enzymes commonly found in a wide variety of food sources, which have a history of safe use. Furthermore, the CP4 EPSPS protein produced in 40-3-2 is identical to the full length, mature CP4 EPSPS protein found in other glyphosate-tolerant crops with an established history of safe human and animal consumption.

The safety of the CP4 EPSPS protein is supported by (1) the lack of acute toxicity as determined in a mouse acute gavage study, (2) the

rapid digestion in simulated gastric fluid, (3) the lack of homology with known protein toxins and (4) its long history of safe use.

7.8.2 Testing of new constituents other than proteins

Soybean has a long history of safe use and consumption around the world. 40-3-2 has been shown to be compositionally equivalent to traditional soybean. Therefore, no testing of any constituent other than the introduced protein is indicated.

7.8.3 Information on natural food and feed constituents

Soybean is known to contain a number of natural anti-nutritional components, such as trypsin inhibitors, lectins, isoflavones, stacchyose, raffinose and phytic acid, which are inactivated when the beans are toasted or heated during processing. Nonetheless, these antinutrients were evaluated in 40-3-2 compositional analyses and their levels were demonstrated to be comparable in 40-3-2 and in traditional soybean.

7.8.4 Testing of the whole GM food/feed

Compositional analyses and comparative phenotypic assessments have demonstrated that 40-3-2 is substantially equivalent to traditional soybean, with the exception of the introduced glyphosate-tolerance trait, which is conferred by the production of the CP4 EPSPS protein.

The CP4 EPSPS protein produced in 40-3-2 is shown to be safe for consumption by humans and animals. The safety of 40-3-2 has been confirmed by multiple rat feeding studies.

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

It is unlikely that the CP4 EPSPS protein will cause allergenic concerns due to the following considerations: (1) The CP4 EPSPS protein was not obtained from a source known to be allergenic; (2) The CP4 EPSPS protein shows no structurally significant amino acid sequence similarity to any known protein allergens; (3) The CP4 EPSPS protein is extremely labile to digestion in an *in vitro* pepsin digestion assay. Thus, using the best methodology available today, it can be concluded that the allergenic potential of the CP4 EPSPS protein is negligible.

7.9.2 Assessment of allergenicity of the whole GM plant or crop

Soybean is known to cause food allergies in certain individuals. Therefore, an assessment of the endogenous allergens in 40-3-2 and traditional soybean has been conducted. As expected, the analysis of the protein extracts prepared from 40-3-2 revealed that both the composition and the quantity of proteins detected by immunoblotting were indistinguishable from the results produced with traditional soybean varieties, demonstrating that the production of the CP4 EPSPS protein in 40-3-2 does not cause any change in the composition of the allergenic proteins endogenous to soybean.

7.10 Nutritional assessment of GM food/feed

7.10.1 Nutritional assessment of GM food

40-3-2 was shown to be compositionally equivalent to traditional soybean. The introduced glyphosate-tolerance trait is of agronomic interest, and is not intended to change any nutritional aspects of this soybean. Since the commercial introduction of 40-3-2 in the EU and in other world areas, soybean has not become less acceptable as a food ingredient. Therefore, anticipated dietary intake of soybean-derived foods is not expected to be altered upon cultivation of 40-3-2 in the EU, and no nutritional imbalances are expected as a result of the use of this soybean.

7.10.2 Nutritional assessment of GM feed

40-3-2 was demonstrated to be compositionally equivalent to traditional soybean. The safety assessment of 40-3-2 showed that this glyphosate-tolerant soybean does not pose any adverse effects for humans and animals. Animal feeding studies were nonetheless conducted with 40-3-2 and established the nutritional equivalence of this soybean to traditional soybean for use as feed. These studies further confirmed the absence of any pleiotropic or unanticipated effects resulting from the introduction of the glyphosate-tolerance trait into the soybean genome.

7.11 Post-market monitoring of GM food/feed

There are no intrinsic hazards related to 40-3-2 as no signs of adverse or unanticipated effects have been observed in a number of safety studies, including animal feeding studies using doses of administration that are orders of magnitude above expected consumption levels. The pre-market risk characterization for food and feed use of 40-3-2 demonstrates that the risks of consumption of 40-3-2 or its derived products are consistently negligible and no different from the risks associated with the consumption of traditional soybean. Commercial experience since 1996 has confirmed the conclusions of the pre-market risk characterization. As a consequence, specific risk management measures are not indicated, and post-market monitoring of the use of soybean for food and feed is not considered appropriate.

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

Not applicable. 40-3-2 is tolerant to glyphosate and, as such, does not have any target organisms.

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

9.1 Persistence and invasiveness

Based on centuries of experience with traditional, domesticated soybean in Europe, there is no potential for soybean to be invasive of natural habitats or persist in the agronomic environment without the aid of human intervention.

40-3-2 is substantially equivalent to traditional soybean, except for the introduced glyphosate-tolerance trait. Field trial data demonstrated that this soybean has not been altered in its phenotypic, agronomic, reproductive, survival and dissemination characteristics when compared to traditional soybean.

Therefore, the likelihood of unintended spreading of 40-3-2 into the environment is negligible.

9.2 Selective advantage or disadvantage

Within commercially grown fields, 40-3-2 plants theoretically have a selective advantage over glyphosate-susceptible weeds and over traditional soybean plants under specific conditions in the field (*i.e.* following treatment with glyphosate-containing herbicides). However, these conditions are predictable, spatially limited and short in duration. This 'selective advantage' is limited to the agricultural field and to the growing season of the 40-3-2 crop, and is considered of negligible risk to the agricultural environment. In addition, the risk of the glyphosate-tolerance trait in 40-3-2 to be the cause of any adverse effects resulting from a competitive advantage or disadvantage in natural environments is negligible. Therefore the only selective advantage of 40-3-2, which is associated with the introduced glyphosate-tolerance trait, is considered to be of negligible risk to the environment.

9.3 Potential for gene transfer

As soybean wild relatives are not present in Europe, the incidence of out-crossing of the introduced trait is discussed only for cultivated soybean. Soybean is, however, a self-pollinated crop. Therefore, the likelihood for gene transfer to traditional soybean is negligible.

In the unlikely event of out-crossing of the glyphosate-tolerance trait to a traditional soybean plant, this gene transfer would confer a selective advantage only upon conditions in which the soybean will be treated with a glyphosate-containing herbicide and this advantage would be spatially limited, short in duration and have no adverse consequences for agricultural or natural environments. In conclusion, the environmental risk posed by this transfer, and hence by the cultivation of 40-3-2 in the EU is negligible.

9.4 Interactions between the GM plant and target organisms

No characteristics could be identified which may cause an adverse environmental effect. 40-3-2 is tolerant to glyphosate and, as such, has no target organisms with which to interact, either directly or indirectly.

9.5 Interactions of the GM plant with non-target organisms

40-3-2 is substantially equivalent to traditional soybean, except for the introduced glyphosate-tolerance trait. Therefore, the interaction between 40-3-2 and non-target organisms in the receiving environment is not expected to be different from that of traditional soybean. Furthermore, the potential exposure of non-target organisms to the introduced CP4 EPSPS protein produced in 40-3-2 presents no conceivable mechanism for causing adverse effects because of its properties.

Based on the natural occurrence and history of exposure of non-target organisms to the CP4 EPSPS and related EPSPS enzymes, which are known as a class of safe proteins without any conceivable mechanism for biological activity toward other organisms, there is no *a priori* reason to suspect that the CP4 EPSPS protein could be harmful for non-target organisms. The non-hazardous nature of the CP4 EPSPS protein was confirmed by the analysis of a range of laboratory and field studies generated for various glyphosate-tolerant crops, including experiments on 40-3-2, which consistently showed that these crops and the CP4 EPSPS protein produced therein are unlikely to have adverse effects on non-target species in the environment.

In conclusion, the risk for any adverse effects to non-target organisms, through their ecological interactions with 40-3-2 or through contact with the produced CP4 EPSPS protein, is negligible.

9.6 Effects on human health

40-3-2 was shown to be substantially equivalent to traditional soybean, except for its introduced glyphosate-tolerance trait, imparted by production of the CP4 EPSPS protein, which has negligible potential to cause any toxic or allergenic effects. The safety of 40-3-2 was further confirmed by feeding studies in vertebrate animals using 40-3-2 containing diets. In conclusion, as has been shown in regions where 40-3-2 has been grown since 1996, the likelihood for any adverse effects occurring in humans as a result of their contact with this soybean is no different from traditional soybean. Therefore, the risk of any change in the occupational health aspects of this soybean is negligible.

9.7 Effects on animal health

Based on centuries of experience with traditional, domesticated soybean in Europe, there is a very low potential for soybean to cause any adverse health effects in livestock animals, especially considering that soybean is processed to deactivate antinutritional factors before feeding it to animals. 40-3-2 was shown to be substantially equivalent to traditional soybean, except for the introduced glyphosate-tolerance trait, imparted by production of the CP4 EPSPS protein, which has negligible potential to cause any toxic or allergenic effects. The safety of 40-3-2 was further confirmed by feeding studies in different vertebrate animals using 40-3-2-containing diets. In conclusion, as has been shown in regions where 40-3-2 has been fed to livestock animals since 1996, the likelihood of potential adverse effects in animals fed on 40-3-2 and in humans, consuming those animals, is negligible. Therefore, the risk of 40-3-2 for the feed/food chain is also negligible.

9.8 Effects on biogeochemical processes

Soybean production in general is known to have indirect impacts on biogeochemical processes through tillage and fertilizer application in a defined area. As 40-3-2 was shown to be compositionally equivalent to traditional soybean and has equivalent morphology, development, yield, dissemination, stress susceptibility, plant health and survival characteristics, there is no evidence that this soybean would be any different from traditional soybean regarding its direct influence on nutrient levels in the soil. Furthermore, it is highly unlikely that the

direct or indirect interaction between CP4 EPSPS-producing 40-3-2 and decomposers or detritivores in the receiving environment would cause any immediate or delayed adverse effects on the decomposition and nutrient recycling functions in the soil. The negligible potential to cause adverse effects on non-target organisms, involved in these biogeochemical processes, was confirmed by analysis of a range of laboratory and field data generated for various CP4 EPSPS-containing crops.

In conclusion, the environmental risk of adverse effects on biogeochemical processes, caused by the interaction of 40-3-2 and non-target organisms in the soil, is negligible.

9.9 Impacts of the specific cultivation, management and harvesting techniques

As 40-3-2 was shown to be substantially equivalent to traditional soybean (except for the introduced glyphosate-tolerance trait), all the agronomic practices currently used to grow soybean in the EU remain applicable for growing 40-3-2 and no new or specific techniques for cultivation, management and harvesting are necessary.

There is negligible potential for any direct or indirect, nor immediate or delayed adverse environmental effects from the recommended use of glyphosate (active ingredient in Roundup herbicides) in 40-3-2. In considering the potential effects of the use of plant protection products in crop management, such as the afore-mentioned usage of glyphosate in soybean or the use of any other plant protection product in 40-3-2, it is appropriate to refer to the prevailing regulatory framework of Council Directive 91/414/EEC of 15 July 1991, concerning the placing on the market of plant protection products.

To conclude, the environmental risks of the farming practices applied to grow 40-3-2 in the EU are considered no different from traditional soybean. It is actually expected that the production of 40-3-2 will positively impact current agronomic practices in soybean and provide benefits to farmers and the environment.

10. Potential interactions with the abiotic environment

40-3-2 was shown to be substantially equivalent to traditional soybean, except for the introduced glyphosate-tolerance trait, imparted by the production of the CP4 EPSPS protein. Although CP4 EPSPS is an introduced protein in soybean, it has a history of safe use and has no known negative interactions with the abiotic environment. The CP4 EPSPS protein in 40-3-2 is innocuous and belongs to a large class of EPSPS proteins that are ubiquitous in nature. The family of EPSPS proteins has no known negative interactions with the abiotic environment.

To conclude, no deleterious impact of 40-3-2 on the abiotic environment is expected to result from the cultivation of 40-3-2 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 the scope of this application under Regulation (EC) No 1829/2003 is for cultivation of 40-3-2 in the EU, a general surveillance plan in accordance with Annex VII of Directive 2001/18/EC was provided, as required by Articles 5(5) and 17(5) of the said Regulation.

11.2 Interplay between environmental risk assessment and monitoring

An environmental risk assessment (e.r.a.) of 40-3-2 was undertaken as required by Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003. Analysis of the characteristics of 40-3-2 has shown that the risk for potential adverse effects on human health and the receiving environment, resulting from the proposed use of 40-3-2 in the EU is consistently negligible. Therefore, the overall environmental risk posed by this genetically modified higher plant is negligible, and no specific strategies for risk management and no case-specific post-market monitoring actions are considered required.

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

As the overall environmental risk posed by this genetically modified higher plant is negligible, and as the conclusions of the environmental risk assessment are derived from the results of scientific studies, rather than major assumptions, no case-specific post-market monitoring actions, typically aimed at testing assumptions made in this assessment, would be warranted or required.

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

Any potential adverse effects of 40-3-2 on human health and the environment, which were not anticipated in the e.r.a., can be addressed under the general surveillance. General surveillance is largely based on routine observation and implies the collection, scientific evaluation and reporting of reliable scientific evidence, in order to be able to identify whether unanticipated, direct or indirect, immediate or delayed adverse effects have been caused by the placing on the market of a genetically modified (GM) crop in its receiving environment.

In order to allow detection of the broadest possible scope of unanticipated adverse effects, general surveillance is performed by either selected, existing networks, or by specific company stewardship programmes, or by a combination of both. The notifier will ensure that appropriate technical information on 40-3-2 and relevant legislation will be available for the relevant networks, in addition to further relevant information from a number of sources, including industry and government websites, official registers and government publications.

Following the approval of this soybean, Monsanto will approach key stakeholders and key networks of stakeholders of the product (including European farmers and their organisations, soybean traders and processors) and inform them that the product has been authorised under Regulation (EC) No 1829/2003 and may be present in European soybean production. Monsanto will request key stakeholders and networks for their participation in the general surveillance of the placing on the market of this soybean, in accordance with the provisions of Directive 2001/18/EC. Key stakeholders and networks will be requested to be aware of their use of this soybean and to inform Monsanto in case of potential occurrence of any unanticipated adverse effects to human and livestock health or the environment, which they might attribute to the use of this product. Appropriate technical and safety information on 40-3-2 will be provided to them. As growers are constantly present in the environments where the GM crop will be released, they are well placed to ensure good stewardship in the cultivation of the GM crop, as well as being a valuable source of surveillance information. Therefore, in addition to already existing stewardship programmes, a number of farmers who have experience with the cultivation of 40-3-2 will be contacted and requested to participate in regular environmental surveys by means of farmer questionnaires. Monsanto will examine the information revealed by these farmer questionnaires (including where possible by applying tools for statistical data analysis) and include this information in the annual general surveillance reports. In addition to the above-mentioned general surveillance actions directed to 40-3-2 growers, processors and users of soybean and other stakeholders, Monsanto experts will actively monitor existing information sources such as official websites and expert reports on GMOs in order to identify, collate and follow-up on potentially adverse observations made for this soybean or any other relevant information, in particular with respect to occupational health, animal feed safety or putative ecological effects of the release of this soybean.

Where there is scientifically valid evidence of a potential adverse effect (whether direct or indirect), linked to the genetic modification, then further evaluation of the consequence of that effect should be science-based and compared with available baseline information. Relevant baseline information will reflect prevalent use practices and the associated impact of these practices on the environment. Where scientific evaluation of the observation confirms the possibility of an unanticipated adverse effect, this would be investigated further to establish a correlation, if present, between the use of 40-3-2 and the observed effect. The evaluation should consider the consequence of the observed effect and remedial action, if necessary, should be proportionate to the significance of the observed effect.

11.5 Reporting the results of monitoring

Monsanto will submit an annual General Surveillance Report containing information obtained from participating networks, and/or in case of an effect that was confirmed. If information that confirms and adverse effect which alters the existing risk assessment becomes available, Monsanto will submit a Report, consisting of a scientific evaluation of the potential adverse effect and a conclusion on the safety of the product. The report will also include, where appropriate, the measures that were taken to ensure the safety of human or livestock health and/or the environment.

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

Southern blot or PCR techniques can be employed for the detection and identification of the inserted nucleotide sequences. Specific ELISAs have been developed and can be used to detect the CP4 EPSPS protein in individual plants. A 40-3-2-specific PCR-based assay allowing the identification and quantification of 40-3-2 has been provided to the Joint Research Centre (JRC), acting as the Community Reference Laboratory.

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

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

a) Notification number

Italy	B/IT/94-09-CON
	B/IT/95/18
	B/IT/96/23
	B/IT/99/04
France	B/FR/94/03/03
	B/FR/95/03/02
	B/FR/96/04/12
	B/FR/97/10/10
	B/FR/99/01/11
Spain	B/ES/97/25
	B/ES/98/11

b) Conclusions of post-release monitoring

The field trials, conducted with 40-3-2 in the EU, relate to the assessment of agronomic performance, growth and developmental, morphological and phenotypic characteristics, yield potential, residues determination, protein expression, compositional analysis and variety testing. Post-release surveillance provided no significant evidence that this soybean would likely cause any adverse effects to human or animal health or the environment.

c) Results of the release in respect to any risk to human health and the environment (submitted to the Competent Authority according to Article 10 of Directive 2001/18/EC)

Post-release surveillance provided no significant evidence that this soybean would likely cause any adverse effects to human health or the environment.

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

a) Release country

Table 2: History of previous releases

Country	Authority that granted the approval
U.S.A.	United States Department of Agriculture (May 1994)
Canada	Agriculture and Agri-food Canada (November, 1995)
Argentina	Agriculture, Fishing and Food, National Seed Institute (March, 1996)
Uruguay	Ministry of Livestock, Agriculture and Fisheries, General Direction of Agricultural Services/ Agriculture Protection division (October 1996)
Brazil	CTNBio (October, 1998)
Romania	National Biosafety Commission (March, 2000)
Republic of South Africa	Department of Agriculture (July, 2001)
Paraguay	Ministry for Agriculture and Livestock (October, 2004)
Bolivia	Vice Minister of Natural Resources and Environment (April 2005)

In addition, 40-3-2 and derived products are approved for import and consumption in 24 countries around the world, including the EU-25.

b) Authority overseeing the release

See Question E.2.(a).

c) Release site

All major soybean growing regions in North-America and in other countries around the world, listed under Section E.2.(a).

d) Aim of the release

Commercial release for all uses as traditional soybean.

e) Duration of the release

Commercial release. Please see Section E.2.(a).

f) Aim of post-releases monitoring

Extensive pre-market risk assessment did not provide evidence of adverse effects potentially associated with the cultivation, handling or use of 40-3-2, indicating that a requirement for post-release monitoring would not be appropriate.

In addition, 40-3-2 is commercialized alongside stewardship programmes, involving downstream stakeholders in the use of this

soybean, in order to ensure the implementation of good agricultural practice in its cultivation and to ensure a channel of communication in the unlikely event that unanticipated adverse effects might occur.

However, no such anticipated effects have been observed since the large-scale commercialization of 40-3-2 in 1996, nor during the field-testing programmes inside and outside the EU.

g) Duration of post-releases monitoring

Please see Section E.2.(f).

h) Conclusions of post-release monitoring

Please see Section E.2.(f).

i) Results of the release in respect to any risk to human health and the environment

Field-testing and post-marketing experience provided no significant evidence that 40-3-2 or derived products would be the cause of any adverse effects to human health or to the environment.

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.it/gmc_browse.asp and http://gmo-crl.jrc.it/statusofdoss.htm and the EFSA website http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html provide publicly accessible links to up-to-date databases on the regulatory progress of notifications under Directive 2001/18/EC and applications under Regulation (EC) No 1829/2003, including the Monsanto dossier for 40-3-2.

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

The ACNFP website http://www.food.gov.uk/science/ouradvisors/novelfood/ provides a link to the publicly accessible Initial Assessment Report from the UK Lead Member State for Monsanto notification C/UK/94/M3/1 on 40-3-2.

c) EFSA opinion

No EFSA opinion is available at the time of submission of this application.

d) Commission Register (Commission Decision 2004/204/EC)

http://europa.eu.int/comm/food/dyna/gm_register/index_en.cfm

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

Information on detection protocols is posted at http://gmo-crl.jrc.it/

f)	**Biosafety Clearing-House (Council Decision 2002/628/EC)** The publicly accessible portal site of the Biosafety Clearing-House (BCH) can be found at http://bch.biodiv.org/
g)	**Summary Notification Information Format (SNIF) (Council Decision 2002/812/EC)** EFSA provides a link to the publicly accessible summary of this application under Regulation (EC) No 1829/2003 at http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html.