Application for authorization to place on the market MON 89788 soybean in the European Union, according to Regulation (EC) No 1829/2003 on genetically modified food and feed

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 name of the product is Roundup RReady2Yield™ soybean.

The Monsanto development code for this genetically modified soybean is MON 89788. MON 89788 varieties will be marketed under the name of the variety, in association with the trademark Roundup RReady2Yield™ soybean.

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))

MON 89788 will be produced in other world areas and will be imported and used in the European Union by operators that have traditionally been involved in the commerce, transport, processing and use of soybean and soybean-derived products in the EU.

™ Roundup RReady2Yield is a trademark of Monsanto Technology LLC.

3. Scope of the application

(x) GM plants for food use

(x) Food containing or consisting of GM plants

(x) Food produced from GM plants or containing ingredients produced from GM plants

(x) GM plants for feed use

(x) Feed containing or consisting of GM plants

(x) Feed produced from GM plants

(x) Import and processing (Part C of Directive 2001/18/EC)

( ) Seeds and plant propagating material for cultivation in Europe (Part C of Directive 2001/18/EC)

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

Yes ( )	**No (x)**
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 (x)**
If *no*, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC The protein expression, the composition, the safety, the agronomic and the phenotypic characteristics of MON 89788 have been studied at multiple locations in North and South America that cover a range of environmental conditions. The data collected from these field releases have been used in the risk assessment presented in the MON 89788 application. A summary of the conclusions of the risk analysis that demonstrate the safety of MON 89788 to humans, animals and to the environment, have been presented in the respective sections throughout this summary.	

6. Has the GM plant or derived products been previously notified for marketing in the Community under Part C of Directive 2001/18/EC or Regulation (EC) 258/97?

Yes ( )	**No (x)**
If *yes*, specify	

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

Yes (x)	No ( )

If *yes*, specify

MON 89788 has been notified in the U.S.A. for the full range of uses as traditional soybean, including the cultivation of varieties. In addition, applications for the import and use of MON 89788 are currently under review in other countries around the world. The scope and the status of these pending regulatory reviews typically depend on the country and its local regulatory framework.

8. General description of the product

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

The first genetically modified soybean authorized for import and use in the EU was Roundup Ready® soybean 40-3-2. Roundup Ready soybean 40-3-2 was developed by Monsanto Company by incorporating the *cp4 epsps* coding sequence derived from the common soil bacterium *Agrobacterium* sp. strain CP4 into the soybean genome using the particle acceleration method. Roundup Ready soybean 40-3-2 produces the 5-enolpyruvyl shikimate-3-phosphate synthase (EPSPS) from *Agrobacterium* sp. strain CP4 (CP4 EPSPS) that is less sensitive to inhibition by glyphosate[1] compared to plant endogenous EPSPS. The CP4 EPSPS protein renders Roundup Ready soybean 40-3-2 tolerant to glyphosate, which is the active ingredient of Roundup® herbicides. The utilization of Roundup herbicides plus Roundup Ready soybean 40-3-2, collectively referred to as the Roundup Ready soybean system, has provided significant convenience in weed control, encouraged the use of conservation-tillage and provided positive economic impact to the farmers. In 2005, Roundup Ready soybean 40-3-2 was planted on approximately 87% of the U.S.A. and 60% of the global soybean areas, which makes it the most cultivated biotechnology product to date.

Developments in biotechnology and molecular-assisted breeding have enabled Monsanto to generate a second-generation glyphosate-tolerant soybean product, Roundup RReady2Yield™ or MON 89788. MON 89788 produces the same CP4 EPSPS protein as Roundup Ready soybean 40-3-2. MON 89788 was produced by introducing the *cp4 epsps* gene cassette driven by a chimeric constitutive promoter into the soybean genome. The transformation was based on a new technique of *Agrobacterium*-mediated gene delivery to the soybean meristem, where cells were induced directly to form shoots and give rise to genetically modified plants. This technique allowed the direct transformation of the

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

[1] N-phosphonomethyl-glycine is the active ingredient in the non-selective, foliar-applied, broad-spectrum, post-emergent Roundup herbicides.

cp4 epsps gene cassette into elite soybean germplasm such as the Asgrow soybean variety A3244, which is known for its superior agronomic characteristics and high yielding property. Using elite germplasm as the base genetics, the superior agronomic characteristic of A3244 can be introgressed to other soybean varieties through crosses with MON 89788. In general, MON 89788 has been found to have a 4 to 7% yield advantage compared to Roundup Ready soybean 40-3-2 in the same elite genetic background (A3244). MON 89788 will continue to provide growers flexibility, simplicity and cost effective weed control options of the Roundup Ready soybean system. In addition, MON 89788 and the varieties containing this trait have the potential to enhance yield and thereby further benefit farmers and the soybean industry.

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

This application is for authorization of MON 89788 for import, food and feed use according to Articles 5 and 17 of Regulation (EC) No 1829/2003 on genetically modified food and feed. The scope of this application does not include the cultivation of MON 89788 varieties in the EU.

c) Intended use of the product and types of users

MON 89788 soybean will be used in the EU in the same manner as current commercial soybean and by the same operators currently involved in the trade 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

MON 89788 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, MON 89788 and its derived products will be stored, packaged, transported, used and handled in the same manner as current commercial soybean. No specific conditions are warranted or required for the food and feed use of MON 89788.

e) Any proposed packaging requirements

MON 89788 is substantially equivalent to traditional soybean, except for its tolerance to glyphosate. Therefore, MON 89788 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 MON 89788 and derived products.

Operators shall be required to label products containing or consisting of MON 89788 with the words "genetically modified soybean" or "contains genetically modified soybean" and shall continue to declare the unique identifier MON-89788-1 in the list of GMOs that have been used to constitute a mixture that contains or consists of this GMO.

Operators shall be required to label foods and feeds derived from MON 89788 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.

Operators handling or using MON 89788 and derived foods and feeds in the EU shall be 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 MON 89788. 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-89788-1

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

MON 89788 is suitable for use throughout 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

Because this application is for consent to import and use MON 89788 as any other soybean, not including the cultivation of varieties of MON 89788 in the EU, environmental release would be more likely to occur during import, storage and processing of MON 89788. However, modern methods of soybean handling minimize losses of seed, so there is little chance of germination of spilt soybeans resulting in the development of mature MON 89788 plants in the EU. Moreover, in the event of incidental spillage, the establishment of volunteer plants would be unlikely, since soybean cannot survive without human assistance and is not capable of surviving as a weed due to selection over centuries of cultivation. Soybean is not documented as a source of volunteer plants in rotational crops, which results from the combination of absence of seed dormancy, poor seed survivability in soils, frost sensitivity of soybean seedlings and soil preparations prior to the planting of a subsequent crop (which includes destruction of any existing vegetation and soil cultivation). MON 89788 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

A3244

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 (usually between 10.00 and 11.00 am, depending on the environmental conditions). 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. Neither the seedpod, nor the seed, has morphological characteristics that would facilitate animal transportation.

(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, natural cross-pollination may occur.

<u>Outcrossing with cultivated soybean species</u>

Natural cross-pollination in soybean has been found to be generally very low. Cross-pollination frequencies vary with growing conditions, genotypes and location of the male parent in relation to the female parent. Insect activity does increase the outcrossing rate, but soybeans are generally not the preferred plant for pollinators.

Numerous studies on soybean cross-pollination have been conducted (with and without supplemental pollinators). Under natural conditions, cross-pollination among adjacent plants in a row or among plants in adjacent rows ranged from 0.03 to 3.62%. In experiments where supplemental pollinators (usually bees) were added to the experimental area, cross-pollination ranged from 0.5 to 7.74% in adjacent plants or adjacent rows. However, cross-pollination does not occur at these levels over long distances. Cross-pollination rates decrease to less than 1.5%

beyond one meter from the pollen source and decreases further with greater distances from the source. For example, the following outcrossing rates at extended distances have been reported: 0.05% at 5.4 m, 0% at 6.5 m and 0.02% at 8.2 m.

It has however to be noted that the scope of the current application does not include the cultivation of MON 89788 varieties in the EU. Therefore, any outcrossing between MON 89788 and cultivated *Glycine* varieties is highly unlikely.

Outcrossing with wild soybean 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, West, Central and South Pacific Islands, China, Russia, Japan, Indonesia, Korea, 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 F_1 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 F_1 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. Mature 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. However, 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. However, natural cross-pollination may occur to a certain extent as discussed in B.2.a.

b) Specific factors affecting dissemination

See Section B.4.b.

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 B.C. or earlier and its cultivation subsequently extended throughout south-east Asia. Soybean cultivation was probably introduced in Europe starting in the late 16th and throughout the 17th century and in 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. In Europe, soybean is grown mainly in Italy and France. Outside of the EU, Romania, one of the accession countries, is also a large soybean producer.

Soybean is grown primarily for the production of seed, 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.

There are no compatible species for 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, raffinose and phytic acid. 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 in humans. 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. However, allergenic reactions to soy proteins are mostly manifested in atopic symptoms and are rarely life-threatening.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification

Plasmid vector PV-GMGOX20 was used to produce MON 89788 by *Agrobacterium*-mediated tranformation. This transformation was conducted on the soybean cultivar A3244.

2. Nature and source of the vector used

The vector used to generate MON 89788 by *Agrobacterium*-mediated transformation is PV-GMGOX20. The genetic elements present in PV-GMGOX20 are described in Table 1.

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

The genetic elements of PV-GMGOX20 intended for insertion into the soybean genome comprised between the T-DNA borders are *FMV/Tsf1*, a chimeric promoter containing enhancer sequences to regulate constitutive expression; the *Tsf1* leader and intron sequence to enhance the expression of the *CTP2*/*cp4 epsps* coding sequence; the *CTP2* transit peptide to direct the transport of the CP4 EPSPS protein to the chloroplast; the *cp4 epsps* coding sequence encoding the CP4 EPSPS protein that confers tolerance to glyphosate and the *E9* 3' nontranslated sequence that directs transcriptional termination and polyadenylation of the *CTP2*/*cp4 epsps* mRNA.

A detailed description of each element can be found in Table 1.

Table 1. Summary of genetic elements in plasmid vector PV-GMGOX20

Genetic element	Position in plasmid	Function
		T-DNA
Intervening sequence	1-51	Sequences used in DNA cloning
P–*FMV/Tsf1*	52-1091	Chimeric promoter consisting of enhancer sequences from the *35S* promoter of the Figwort Mosaic Virus and the promoter from the *Tsf1* gene of *Arabidopsis thaliana* encoding the elongation factor EF-1 alpha
L–*Tsf1*	1092-1137	5' nontranslated leader (exon 1) from the *Tsf1* gene of *Arabidopsis thaliana* encoding the elongation factor EF-1 alpha
I–*Tsf1*	1138-1759	Intron from the *Tsf1* gene of *Arabidopsis thaliana* encoding the elongation factor EF-1 alpha
Intervening sequence	1760-1768	Sequences used in DNA cloning
TS–*CTP2*	1769-1996	Sequences encoding the chloroplast transit peptide from the *ShkG* gene of *Arabidopsis thaliana* encoding EPSPS
CS–*cp4 epsps*	1997-3364	Codon optimized coding sequence of the *aroA* (*epsps*) gene from the *Agrobacterium* sp. strain CP4 encoding the CP4 EPSPS protein
Intervening sequence	3365-3406	Sequences used in DNA cloning
T–*E9*	3407-4049	3' nontranslated sequence from the ribulose-1,5-bisphosphate carboxylase small subunit (*RbcS2*) *E9* gene of pea (*Pisum sativum*)
Intervening sequence	4050-4092	Sequences used in DNA cloning
B–Left border	4093-4534	DNA region from *Agrobacterium tumefaciens* containing the left border sequence used for transfer of the T-DNA
		Vector backbone
Intervening Sequence	4535-4620	Sequences used in DNA cloning
OR–*ori V*	4621-5017	Origin of replication from the broad host range plasmid RK2 for plasmid maintenance in *Agrobacterium*
Intervening Sequence	5018-6525	Sequences used in DNA cloning
CS–*rop*	6526-6717	Coding sequence for the repressor of primer protein for maintenance of plasmid copy number in *E. coli*
Intervening Sequence	6718-7134	Sequences used in DNA cloning
OR–*ori-PBR322*	7135-7763	Origin of replication from pBR322 for plasmid maintenance in *E. coli*
Intervening sequence	7764-8263	Sequences used in DNA cloning
aadA	8264-9152	Bacterial gene encoding an aminoglycoside-modifying enzyme, 3' (9)-O-nucleotidyl-transferase from the transposon Tn*7*
Intervening sequence	9153-9288	Sequences used in DNA cloning
		T-DNA
B–Right border	9289-9645	DNA region from *Agrobacterium tumefaciens* containing the right border sequence used for transfer of the T-DNA
Intervening sequence	9646-9664	Sequences used in DNA cloning

D. INFORMATION RELATING TO THE GM PLANT

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

MON 89788 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 insert in MON 89788. Genomic DNA was analyzed using Southern blot to determine the insert number (number of insertions of the integrated DNA within the soybean genome), the copy number (the number of copies of the integrated DNA within one locus), the integrity and organization of the inserted promoters, coding sequences and 3' nontranslated sequence and the presence or absence of any other elements of plasmid vector PV-GMGOX20.

The molecular analysis shows that one intact copy of the *cp4 epsps* expression cassette is integrated at a single integration locus. No additional elements from the transformation vector PV-GMGOX20, linked or unlinked to the T-DNA, were detected in the genome of MON 89788. Additionally, no element of the PV-GMGOX20 backbone sequence was detected in MON 89788.

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 the MON 89788 insert in the soybean 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 insert is integrated in the plant nuclear genome and is stably inherited as a single locus, following a Mendelian one-locus model.

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

The MON 89788 insert consists of the *cp4 epsps* gene cassette containing the *FMV/Tsf1* promoter, the *Tsf1* leader and *Tsf1* intron sequences, the *CTP2* chloroplast transit peptide sequence, the *cp4 epsps* coding sequence and the *E9* 3' nontranslated sequence.

3. Information on the expression of the insert

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

MON 89788 produces one functional protein, CP4 EPSPS, providing tolerance to glyphosate. CP4 EPSPS protein levels were determined in over-season leaf (OSL), seed, root and forage tissues derived from MON 89788 plants produced in replicated field trials across five Argentinean and five U.S.A. locations during the 2004-2005 and 2005 growing seasons, respectively.

For MON 89788, the mean CP4 EPSPS protein levels across Argentinean sites for OSL1, OSL2, OSL3, OSL4, seed, root and forage were 280, 340, 310, 460, 170, 100 and 290 µg/g dw, respectively. The mean CP4 EPSPS protein levels across U.S.A. sites for OSL1, OSL2, OSL3, OSL4, seed, root and forage were 300, 340, 330, 290, 150, 74 and 220 µg/g dw, respectively. It is therefore concluded that the CP4 EPSPS protein expression levels measured in each tissue are comparable across both growing seasons and geographies.

b) Parts of the plant where the insert is expressed

The expression of the CP4 EPSPS protein occurs throughout the plant since the *FMV/Tsf1* promoter has been shown to drive constitutive expression of the encoded protein in genetically modified plants.

As seed and forage are the most relevant tissues for the safety assessment of MON 89788, protein levels in these tissues were estimated in field trials conducted in U.S.A. and Argentina. However, protein levels in overseason leaves and roots were also determined, as described in 3(a).

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.

Agronomic data collected from trials conducted with MON 89788 in 2005 at 17 sites in the U.S.A. in the major soybean producing geographies have demonstrated that MON 89788 has not been altered in survival,

multiplication and dissemination characteristics when compared to traditional soybean.

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, phenotypic or ecological characteristics are expected in MON 89788 and that MON 89788 is equivalent to traditional soybean in its phenotypic and agronomic behaviour, except for the glyphosate-tolerance trait.

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 insert is integrated in the plant nuclear genome of MON 89788 and is stably inherited, following a Mendelian one-locus model.

Additionally, on a phenotypic level, since the initial development and breeding of MON 89788, the glyphosate-tolerance trait has been consistently inherited in a Mendelian fashion for several generations without reported instability.

The genetic stability of MON 89788 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

Based on the observation that reproductive morphology in MON 89788 is unchanged compared to traditional soybean and that pollen production and pollen viability were unaffected by the genetic modification, the out-crossing frequency to other soybean varieties or to wild relatives (which are not present in the EU) would be unlikely to be different for MON 89788, when compared to traditional soybean varieties.

However, the scope of the current application does not include the cultivation of MON 89788 varieties 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

MON 89788 was compared to A3244, a traditional soybean variety with background genetics similar to MON 89788.

7.2 Production of material for comparative assessment

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

Compositional analyses were conducted on MON 89788 soybean seed and forage grown under replicated field conditions at five U.S.A. and five Argentinean locations during the 2005 and 2004-2005 growing seasons, respectively. Field trials were located in regions that are representative of commercial soybean production. MON 89788 was compared to A3244, a traditional soybean variety with background genetics similar to MON 89788 and to traditional soybean varieties. MON 89788 was found to be compositionally equivalent to traditional soybeans and thus as safe as traditional soybeans for uses in food and feed applications.

b) the baseline used for consideration of natural variations

In both locations, 12 traditional soybean reference varieties grown in the same plots were included as references to provide data for the development of a 99% tolerance interval for each analyte analyzed. This interval is expected to contain, with 95% confidence, 99% of the values obtained from the population of traditional soybean varieties.

7.3 Selection of material and compounds for analysis

The key nutrients and other nutritionally important components that were selected for analysis in the compositional studies were chosen on the basis of internationally accepted guidance provided by the OECD on compositional considerations for new varieties of soybean.

7.4 Agronomic traits

Field trials with MON 89788 were conducted and the set of agronomic observations supports the conclusion that from an agronomic and phenotypic (morphological) point of view, MON 89788 is equivalent to traditional soybean, except for the introduced glyphosate tolerance trait (*see* Section D.4.).

7.5 Product specification

MON 89788 contains a functionally intact gene cassette encoding the CP4 EPSPS protein, which confers tolerance to glyphosate. MON 89788 will be imported into the EU in mixed shipments of soybean products, produced in other world areas, for use by operators that have traditionally been involved in the commerce, processing and use of soybean and soybean derived products in the EU.

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 ELISAs have been developed to detect the presence of the CP4 EPSPS protein in individual MON 89788 plants or in specific tissues. A MON 89788-specific PCR assay allowing the identification and the quantification of MON 89788 has been developed and provided to the Joint Research Centre (JRC), acting as the Community Reference Laboratory (CRL).

7.6 Effect of processing

As MON 89788 is compositionally equivalent to traditional soybean, the use of MON 89788 for the production of foods and feeds is not expected to be different from that of traditional soybean. The production and processing of MON 89788 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

There are no anticipated changes in the intake and/or extent of use of soybean or derived products for use as or in food or feed as a result of the addition of MON 89788 to the soybean supply. MON 89788 is expected to replace a portion of current soybean such that its intake or use will represent some fraction of the total products derived from soybean.

7.8 Toxicology

7.8.1 Safety assessment of newly expressed proteins

MON 89788 contains the *cp4 epsps* expression cassette that produces the CP4 EPSPS protein. The assessment of human and animal safety of the CP4 EPSPS protein includes (i) the safety of the donor organism, *Agrobacterium* sp. strain CP4; (ii) the similarity of CP4 EPSPS to other EPSPSs naturally present in foods with a long history of safe consumption; (iii) the presence of CP4 EPSPS in commercial food and feed crops; (iv) the bioinformatic comparisons of the CP4 EPSPS protein to known toxic or pharmacologically active proteins and (v) an acute oral toxicity study with CP4 EPSPS in mice.

Agrobacterium sp. strain CP4 was chosen as the donor organism because this bacterium exhibited tolerance to glyphosate by producing a naturally glyphosate-tolerant EPSPS protein (CP4 EPSPS). *Agrobacterium* species are not known for human or animal pathogenicity and are not commonly allergenic.

The CP4 EPSPS protein is a member of the EPSPS family, a well-known class of proteins that are ubiquitous in nature, as they are present in algae, plants, fungi and bacteria, but not in animals. The similarity of the CP4 EPSPS protein to EPSPSs in a variety of foods supports extensive human consumption of the family of EPSPS proteins and the lack of health concerns.

CP4 EPSPS-containing crops have been commercialized and consumed as foods and feeds since their initial introduction in 1996. Roundup Ready soybean 40-3-2, which produces the same CP4 EPSPS protein contained in MON 89788, represents a significant portion of commodity crops containing CP4 EPSPS protein. Globally, Roundup Ready soybean 40-3-2 was produced on approximately 54.4 million hectares in 2005, which represented 60% of global soybean area. Consequently, 60% of the soybean and soybean products consumed globally are likely to contain the CP4 EPSPS protein. In the EU, Roundup Ready soybean 40-3-2 has been approved for import and use as from 1996. Since its authorization Roundup Ready soybean 40-3-2 and derived products represent a significant portion of the soybean products used in Europe. In addition to soybean, the CP4 EPSPS protein is also expressed in other Roundup Ready crops that are used primarily as food and feed sources, such as Roundup Ready maize NK603, Roundup Ready oilseed rape and Roundup Ready cotton. The cumulative experience with release of crops expressing the CP4 EPSPS protein showed no evidence of any harmful or undesirable effects associated with Roundup Ready crops or with the CP4 EPSPS protein. This demonstrates the history of safe use of Roundup Ready crops and of the CP4 EPSPS protein they produce, including the safe use of MON 89788.

Finally, the CP4 EPSPS protein has been shown not to be homologous to known toxins or pharmacologically-active proteins and no indications of toxicity were reported in mice administered the CP4 EPSPS protein by oral gavage.

On the basis of the information presented, it is therefore possible to conclude that the CP4 EPSPS protein is safe and poses no concerns for humans, animals and the environment.

7.8.2 Testing of new constituents other than proteins

Soybean has a long history of safe use and consumption around the world. MON 89788 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 (daidzein, genistein and glycitein), stacchyose, raffinose and phytic acid, which are inactivated when the beans are toasted or heated during processing. Nonetheless, these antinutrients were evaluated

in MON 89788 compositional analyses and their levels were demonstrated to be comparable in MON 89788 and in traditional soybean.

7.8.4 Testing of the whole GM food/feed

Compositional analyses and comparative phenotypic assessments have demonstrated that MON 89788 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 MON 89788 is shown to be safe for consumption by humans and animals. The safety of MON 89788 has been further confirmed by a 90-day feeding study in rats and by a 42-day feeding study in broiler chickens.

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 obtained from *Agrobacterium* species and therefore, it does not originate from a source known to be allergenic; (2) the CP4 EPSPS protein represents approximately 0.04% of the total protein in MON 89788 seed. Since this constitutes only a small portion of the total protein in MON 89788 seed, CP4 EPSPS is not likely to be an allergenic protein; (3) the updated bioinformatic analysis confirmed that the CP4 EPSPS protein shows no structurally significant amino acid sequence similarity to any known protein allergens, gliadins or glutenins. Therefore, it is unlikely that CP4 EPSPS contains allergenic epitopes; (4) the CP4 EPSPS protein is extremely labile to digestion in an *in vitro* pepsin digestion assay, a characteristic shared among proteins with a history of safe consumption. Thus, using the best methodology available today, it can be concluded that the allergenic potential of the CP4 EPSPS protein is negligible and therefore, this protein does not pose a significant allergenic risk.

7.9.2 Assessment of allergenicity of the whole GM plant or crop

Soybean is known to cause food allergies on certain individuals. Therefore, to assess whether MON 89788 has altered endogenous allergenic potential compared to traditional soybean, a study was conducted to determine binding levels of human IgE antibody to protein extracts prepared from MON 89788 and A3244, a traditional soybean with background genetics similar to MON 89788. In addition, 24 commercially available soybean varieties were included in the study for the establishment of the tolerance interval for each serum and they represent the normal variations of responses expected from soybeans.

The results of this study indicate that MON 89788 has similar IgE-binding values to A3244 and in all cases, MON 89788 IgE-binding

values are within the ranges established by commercially available soybean varieties. Thus, it is concluded that MON 89788 soybean has no greater allergenic potential than soybean varieties that are currently on the market.

7.10 Nutritional assessment of GM food/feed

7.10.1 Nutritional assessment of GM food

MON 89788 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. Therefore, anticipated dietary intake of soybean-derived foods is not expected to be altered in the EU and no nutritional imbalances are expected as a result.

7.10.2 Nutritional assessment of GM feed

MON 89788 was demonstrated to be compositionally equivalent to traditional soybean. The safety assessment of MON 89788 showed that this glyphosate-tolerant soybean does not pose any adverse effects for humans and animals. The nutritional value of MON 89788 was assessed by a 42-day feeding broiler chicken feeding study, which established the nutritional equivalence of this soybean to traditional soybean for use as feed. This study 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 MON 89788 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 MON 89788 demonstrates that the risks of consumption of MON 89788 or its derived products are consistently negligible and no different from the risks associated with the consumption of traditional soybean. 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. MON 89788 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 environment without the aid of human intervention.

MON 89788 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. In the unlikely event of establishment of a MON 89788 plant, *e.g.* from a seed spilt in the environment, its introduced trait would have negligible consequences for the environment.

Therefore, the likelihood of unintended spreading of MON 89788 into the environment is negligible.

9.2 Selective advantage or disadvantage

It was previously demonstrated that the introduced genetic sequences in MON 89788 did not lead to any biologically meaningful alterations of other phenotypic characteristics, such as plant growth and development, morphology, agronomic performance, composition, nutritional value or safety characteristics, when compared to traditional soybean. It was concluded that MON 89788 is substantially equivalent to traditional soybean, with the exception of the intentionally introduced glyphosate-tolerance trait. Therefore, the assessment of any conferred competitive advantages is limited to the glyphosate-tolerance trait, as no other new traits were introduced in this soybean.

The only selective advantage of MON 89788 that results from the genetic modification is the plant's tolerance to glyphosate. This 'selective advantage' over other plants, however, is the basis of the Roundup Ready agronomic system and only applies where the crop is treated with a herbicide containing the active ingredient glyphosate, which are predictable conditions, that are spatially limited, short in duration, and with negligible consequences to natural environments. In environments where the selective pressure from glyphosate applications is absent, the glyphosate-tolerance trait does not confer a selective advantage or disadvantage and would not be of direct competitive importance to wild plants, nor indirectly for wildlife interacting with those wild plants. Even when spillage of MON 89788 seed would result in the short survival of some soybean volunteers, it would not represent a meaningful advantage over wild plants since MON 89788, like any other soybean, is a poor competitor in European conditions and the likelihood for spilt soybeans to survive and establish is negligible.

Therefore, the likelihood is negligible for the introduced trait in MON 89788 to confer any meaningful competitive advantage or disadvantage of relevance to the environment.

9.3 Potential for gene transfer

There is no potential for gene transfer from MON 89788 to wild plant species in the EU and negligible likelihood for gene transfer to other soybean crops, as this application is not for consent to cultivate MON 89788 varieties in the EU.

Moreover, as the likelihood of accidentally spilt MON 89788 seed to germinate, establish, mature and flower is very low, as soybeans are predominantly self-pollinated and the majority of the remaining soybean pollen are largely confined to short distances from the source plant, the transfer of the introduced trait to neighbouring soybean plants through cross-pollination is negligible. Furthermore, in the highly unlikely case where a trait would be transferred, the risk of the trait to be the cause of any meaningful competitive advantage or disadvantage that could impact the receiving environment is negligible.

In light of the above, the likelihood of out-crossing of the introduced trait is negligible in the EU.

9.4 Interactions between the GM plant and target organisms

No characteristics could be identified which may cause an adverse environmental effect. MON 89788 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

Given the scope of the current application, which does not include the cultivation of MON 89788 varieties in the EU, the likelihood for direct or indirect interactions of this soybean with non-target organisms is considered to be negligible. In addition, even if incidental spillage of MON 89788 seed during import, storage, transport or use would lead to the short survival of MON 89788 plants, the newly produced protein in MON 89788, CP4 EPSPS, is not novel in the environment. The *cp4 epsps* coding sequence introduced into MON 89788 was derived from *Agrobacterium* sp. strain CP4, a common bacterium in the soil. Endogenous plant EPSPSs and the introduced CP4 EPSPS protein belong to a larger family of EPSPS proteins, which form a class of enzymes that are ubiquitous in all compartments of nature as they are found in bacteria, fungi, algae and all higher plants. Any non-target organisms in the environment that could be exposed to CP4 EPSPS from incidentally spilt MON 89788 seed or from any resulting volunteers interacting with the crop have co-evolved in close interaction with a wide spectrum of green plants and microorganisms and therefore have historically been exposed to members of this safe class of proteins. Based on the ubiquitous occurrence of natural EPSPSs and the history of safe use of CP4 EPSPS-producing crops such as Roundup Ready soybean 40-3-2, Roundup Ready oilseed rape and Roundup Ready cotton, which produce the same CP4 EPSPS protein present in MON 89788, it is highly unlikely that the CP4 EPSPS or any other EPSPS protein would possess biological activity towards non-target organisms such as plants, microorganisms, invertebrates or vertebrates.

To conclude, there is negligible risk for harmful effects of MON 89788 on

non-target organisms, either through direct or indirect interactions of this soybean or through contact with the newly expressed protein.

9.6 Effects on human health

The likelihood for any adverse effects occurring in humans as a result of their contact with MON 89788 is no different from traditional soybean. MON 89788 is substantially equivalent to traditional soybean, except for the introduced glyposate-tolerance trait, which is imparted by the production of the CP4 EPSPS protein. The safety of the CP4 EPSPS protein has been extensively investigated. The CP4 EPSPS protein present in MON 89788 is similar to EPSPS proteins, a class of enzymes that is ubiquitous in all compartments of nature and benefit from a long history of safe use, and is identical to the CP4 EPSPS protein produced in Roundup Ready soybean 40-3-2 and Roundup Ready oilseed rape, which have been commercialized and safely used for human and animal consumption since 1996 in several world areas, including Europe. The safety of the CP4 EPSPS protein to humans is further confirmed by (1) lack of acute toxicity as determined in a mouse acute gavage study, (2) rapid digestion in simulated gastric fluids, (3) lack of homology with known protein toxins and (4) lack of homology with known allergens. The safety of MON 89788 is corroborated by animal feeding studies in the rat and in broiler chickens using MON 89788 containing diets, demonstrating the absence of any toxic or pleiotropic effects linked to the genetic modification.

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.

MON 89788 is substantially equivalent to traditional soybean, except for the introduced glyphosate-tolerance trait imparted by the CP4 EPSPS protein. As previously discussed, the CP4 EPSPS protein belongs to the ubiquitous class of EPSPS enzymes. Based on the presence of EPSPS enzymes in algae, plants, fungi and bacteria, it is unlikely that these proteins will possess any harmful properties or biological activity towards livestock animals.

In addition, the CP4 EPSPS protein has been shown to have no significant homology to known allergens or protein toxins and its non-hazardous nature has been assessed by extensive safety studies, including an acute gavage study in mice. Furthermore, the CP4 EPSPS protein produced in MON 89788 is identical to the full length, mature CP4 EPSPS protein found in Roundup Ready soybean 40-3-2 and other glyphosate-tolerant crops with established history of safe human and animal consumption. In Europe, experience with domestic livestock fed on Roundup Ready soybean 40-3-2 meal from the millions of hectares grown in the U.S.A. and other producing countries and imported into the EU since 1996, has not provided any indication of potential adverse

effects in livestock.

Finally, the safety and wholesomeness of MON 89788 was established by feeding studies in rats and broiler chickens using MON 89788-containing diets.

Therefore, it is possible to conclude that MON 89788 is as safe and as wholesome as traditional soybean and the risk posed by this soybean to the feed/food chain is negligible.

9.8 Effects on biogeochemical processes

As for traditional soybean, during transport or storage MON 89788 seed could spill and fall to the ground. Although such seed could eventually germinate if the local soil and environmental conditions are favourable, this soybean is a poor competitor and does not persist as a weed. Environmental conditions at the sites of handling are, however, unlikely to be conducive to germination, growth and reproduction of soybeans that is incidentally released.

There is no evidence that MON 89788 plants would be any different from traditional soybean regarding their direct influence on biogeochemical processes or nutrient levels in the soil, as MON 89788 has equivalent growth and development, morphology, plant health and survival characteristics to traditional soybean. Furthermore, any indirect interactions of the GMO with other organisms in the vicinity of an incidental release of the grain are not likely to cause hazardous effects on the biogeochemical processes in the soil. As previously discussed, CP4 EPSPS is widely present in the environment.

In conclusion, as for traditional soybean, it is highly unlikely that there would be any significant immediate or delayed adverse effects from MON 89788 on the biogeochemical processes in the soil.

9.9 Impacts of the specific cultivation, management and harvesting techniques

Not applicable. This application is for consent to import MON 89788 grain in the EU and for the use of this soybean as any other soybean, excluding the cultivation of MON 89788 varieties in the EU.

10. Potential interactions with the abiotic environment

MON 89788 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 a newly 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 MON 89788 is innocuous and belongs to a large class of EPSPS proteins that are ubiquitous in nature and benefit from a long history of safe use. The safety of the CP4 EPSPS protein is further confirmed by the history of safe use of CP4 EPSPS crops.

No deleterious impact of MON 89788 on the abiotic environment is expected to result from the import, processing or use of this product for food and feed 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, a environmental monitoring plan in accordance to Annex VII of Directive 2001/18/EC is included.

11.2 Interplay between environmental risk assessment and monitoring

An environmental risk assessment (e.r.a.) of MON 89788 was undertaken as required by Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003. Analysis of the characteristics of MON 89788 has shown that the risk for potential adverse effects on human health and the receiving environment, resulting from the proposed use of MON 89788 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 MON 89788 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 consent holder will ensure that appropriate technical information on MON 89788 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 in the EU, the consent holder will approach key stakeholders and key networks of stakeholders of the product (including international grain traders, soybean processors and users of soybean seed for animal feed) and inform them that the product has been authorized. The consent holder 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 and the consent. Key stakeholders and networks will be requested to be aware of their use of this soybean and to inform the consent holder in case of potential occurrence of any unanticipated adverse effects to health or the environment, which they might attribute to the import or use of this product. Appropriate technical information on MON 89788 will be provided to them.

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 MON 89788 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 an 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. ELISAs have been developed and can be used to detect the CP4 EPSPS protein in individual plants. A MON 89788-specific PCR-based assay allowing the identification and quantification of MON 89788 has been provided to the Joint Research Centre (JRC), acting as the Community Reference Laboratory (CRL).

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

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

a) Notification number

There is no history of release of MON 89788 in the EU.

b) Conclusions of post-release monitoring

Not applicable.

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

Not applicable.

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

a) Release country

MON 89788 has been field tested in the U.S.A. since 2001, in Argentina in the 2004-2005 growing season, in Chile in the 2005-2006 growing season and in Japan in 2006.

b) Authority overseeing the release

U.S.A.: United States Department of Agriculture (USDA).

Argentina: Secretary of Agriculture (SAGPyA) – CONABIA.

Japan: Ministry of Agriculture Fisheries and Forestry.

Chile: Agricultural and Livestock Service (SAG).

c) Release site

U.S.A.: in the major soybean growing states and Puerto Rico.

Argentina: Buenos Aires, Cordoba, Santa Fe.

Japan: Ibaraki Prefecture.

Chile: Graneros.

d) Aim of the release

U.S.A./Argentina/Chile: efficacy, yield, breeding.

Japan: stage III environmental assessment.

e) Duration of the release

U.S.A./Argentina/Chile/Japan: 12 months.

f) Aim of post-releases monitoring

U.S.A./Argentina: assess for volunteers.

g) Duration of post-releases monitoring

U.S.A./Argentina: 12 months.

h) Conclusions of post-release monitoring

U.S.A./Argentina: in general, no volunteers have been observed since soybean is an annual crop. In southern geographies such as Puerto Rico, volunteers were eliminated to prevent occurrence in subsequent crops.

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

Field-testing provided no evidence that MON 89788 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 MON 89788.

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

A notification for MON 89788 according to Directive 2001/18/EC has not been submitted by Monsanto Company.

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.