Application for authorisation to place on the market MON 87769 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 United Kingdom
b) Notification number Not available at the time of submission.
c) Name of the product (commercial and other names) The Monsanto development code for this genetically modified soybean is MON 87769. Currently, no commercial name has been attributed to this product.
d) Date of acknowledgement of notification Not available at the time of submission to EFSA.

2. Applicant

a) Name of applicant Monsanto Company, represented by Monsanto Europe S.A.	
b) Address of applicant	
Monsanto Europe S.A. Avenue de Tervuren 270-272 B-1150 Brussels BELGIUM	Monsanto Company 800 N. Lindbergh Boulevard St. Louis, Missouri 63167 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 87769 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 European Union.	

3. Scope of the application

- (×) **GM plants for food use**
- (×) **Food containing or consisting of GM plants**
- (×) **Food produced from GM plants or containing ingredients produced from GM plants**
- (×) **GM plants for feed use**
- (×) **Feed containing or consisting of GM plants**
- (×) **Feed produced from GM plants**
- (×) **Import and processing (Part C of Directive 2001/18/EC)**
- (   ) **Seeds and plant propagating material for cultivation in Europe (Part C of Directive 2001/18/EC)**

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

Yes ( )	**No (×)**
If *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 ( )	**No (×)**
If *n*o, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC The protein expression, composition, safety, agronomic and phenotypic characteristics of MON 87769 have been studied at multiple locations in North 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 87769 application. A summary of the conclusions of the risk analysis that demonstrate the safety of MON 87769 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 (×)**
If *ye*s, specify	

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

Yes (x)	No ( )

If *yes*, specify

MON 87769 has been notified to the United States Department of Agriculture Animal and Plant Health Inspection Service (USDA-APHIS) and the United States Food and Drug Administration (US FDA). Approvals from agencies in these countries have not yet been obtained.

In addition, a Generally Recognised As Safe (GRAS) notice was filed with the US FDA on soybean oil from MON 87769 (hereafter referred to as SDA soybean oil) containing 20 to 30% SDA (GRAS Notice No. GRN 000283[1]). A scientific panel has confirmed the safety of SDA soybean oil on 4 September 2009.

Regulatory submissions will also be made to countries that import significant soybean or food and feed products derived from US soybean and have functional regulatory review processes in place. These will include submissions to a number of governmental regulatory agencies including, but not limited to, the Canadian Food Inspection Agency (CFIA), Health Canada, Mexico's Intersectoral Commission for Biosafety of Genetically Modified Organisms (CIBIOGEM), the Japanese Ministry of Health, Labor and Welfare (MHLW), the Ministry of Agriculture, Forestry and Fisheries (MAFF) of Japan, the Korean Food and Drug Administration (KFDA), the Rural Development Agency of Korea (RDA), Food Standards Australia New Zealand (FSANZ), the Department of Agriculture Bureau of Plant Industries of the Philippines, the Singapore Agri-Food and Veterinary Authority (AVA), the Taiwan Department of Health (DOH). As appropriate, notifications will be made to countries that import significant quantities of US soybean and soybean products and do not have a formal regulatory review process for biotechnology-derived crops.

[1] GRAS notices filed in 2009: http://vm.cfsan.fda.gov/~rdb/opa-gras.html - Accessed Sep 09,09

8. General description of the product

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

Monsanto has developed biotechnology-derived soybean MON 87769 that contains stearidonic acid (SDA). The development of MON 87769 involved the introduction of two desaturase genes, *Primula juliae* Δ6 desaturase (*Pj.D6D*) and *Neurospora crassa* Δ15 desaturase (*Nc.Fad3*), through *Agrobacterium*-mediated transformation of conventional soybean. The introduction of these two genes results in the seed-specific production of the PjΔ6D and NcΔ15D proteins. These proteins desaturate certain endogenous fatty acids resulting in the production of SDA at approximately 20-30% of total fatty acids. SDA is an omega-3 fatty acid which is a normal metabolic precursor to the long chain, poly-unsaturated omega-3 fatty acids (PUFAs), eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) in humans and animals. The cardiovascular benefits of long-chain PUFAs are well established. The oil derived from MON 87769 can serve as an alternate sustainable source of omega-3 fatty acid and help meet the need for increased dietary intake of long chain omega-3 fatty acids.

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

The scope of this application is for authorisation of MON 87769 for import, processing, food and feed use in the EU, according to Articles 5 and 17 of Regulation (EC) No. 1829/2003 on genetically modified food and feed. The range of uses of this soybean for food and feed will be identical to the full range of equivalent uses of conventional soybean. The scope of this application does not include the cultivation of MON 87769 varieties in the EU.

c) Intended use of the product and types of users

MON 87769 is being developed as a sustainable means to produce oil enriched in an omega-3 fatty acid that will be utilised as a component of human foods. The refined oil produced from MON 87769 contains approximately 20 to 30% SDA (weight % of total fatty acids) and it can be used for the production of margarine, mayonnaise, shortenings, salad dressings and ready-to-eat foods. The use of SDA soybean oil in selected food categories could provide a wide range of dietary alternatives for increasing human omega-3 fatty acid intake. Given the targeted commercial applications of SDA soybean oil as an alternate source of omega-3 fatty acids, it is anticipated that MON 87769 will be a low acreage product planned initially for production in North America. In order to derive commercial value from this product, the MON 87769 soybean crop will be grown and processed in an identity preserved manner in the northern US soybean growing regions and MON 87769 soybeans will be processed in dedicated oil processing facilities that will also be operated in an identity preserved manner and oil will be sold to food processors for food formulation. The oil will be used in food applications where omega-3 products are currently being used. The co-product, soybean meal and other soybean derivatives will be used in a manner similar to conventional soybean meal and derivatives.

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

No specific conditions or instructions are considered necessary for placing on the market MON 87769 for food, feed, import and processing use in the EU. It has been demonstrated that, with the expected fatty acid changes, MON 87769 soybean is as safe as conventional soybean. Therefore, foods and feeds produced from MON 87769 will be stored, packaged, transported, used and handled in the same manner as for current commercial soybean varieties, with the exception of those practices needed to retain the commercial value of the MON 87769 oil and to ensure its functional suitability for incorporation into food and feed products.

e) Any proposed packaging requirements

MON 87769 is substantially equivalent to conventional soybean, except for the expected for the expected fatty acid changes. Therefore, MON 87769 and derived products will be used in the same manner as other soybean and soybean products and no specific packaging is required (for labelling, please see Section A.8.f.).

f) A proposal for labelling in accordance with Articles 13 and 25 of Regulation (EC) No 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) No 1830/2003 and Annex IV of Directive 2001/18/EC.

In accordance with Regulations (EC) No. 1829/2003 and 1830/2003, a labelling threshold of 0.9% is applied for the placing on the market of MON 87769 and derived products.

As MON 87769 differs from conventional soybean in terms of fatty acid composition and nutritional value, labelling in accordance with Article 13(2)(a) and Article 25(2) is proposed. Monsanto proposes that operators shall be required to label products containing or consisting of MON 87769 soybean with the words “genetically modified soybean containing SDA omega-3 oil” or “contains genetically modified soybean containing SDA omega-3 oil”, and operators shall be required to declare the unique identifier, MON-87769-7, in the list of GMOs that have been used to constitute the mixture that contains or consists of this GMO.

Operators shall be required to label foods and feeds derived from MON 87769 with the words “produced from genetically modified soybean containing SDA omega-3 oil”, and products containing or consisting of oil produced from MON 87769 with the words “oil produced from genetically modified soybean containing SDA omega-3”.

Monsanto proposes that products containing or consisting of derivatives (other than the oil) from MON 87769 are labelled with the words “produced from genetically modified soybean”.

Operators handling or using MON 87769 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 authorised 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 87769. 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).

The unique identifier for this genetically modified soybean is MON-87769-7.

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 87769 is suitable for food and feed 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 87769 as any other soybean, not including the cultivation of varieties of MON 87769 in the EU, the only potential means of environmental release would be during import, storage and processing of MON 87769. As described in Section A.8.c, to retain commercial value of the product, MON 87769 soybean will be processed in dedicated facilities and therefore it is not expected that significant quantities of MON 87769 soybean will commingle with general soybean supply in the EU. However, if some incidental spillage of soybean were to occur during import, handling, storage and processing of soybean in the EU, modern methods of soybean handling minimise losses of seed, so there is little chance of germination of spilt soybeans resulting in the development of mature MON 87769 plants in the EU. Moreover, in the case 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). With the expected fatty acid changes, MON 87769 is shown to be substantially equivalent to conventional soybean 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 specific conditions are warranted or required for placing on the market MON 87769 for import, processing and use for food and feed in the EU.

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

1. Complete name

a) Family name

Leguminosae

b) Genus

Glycine Willd.

c) Species

max

d) Subspecies

N/A

e) Cultivar / Breeding Line

A3525

f) Common name

Soybean

2. a) Information concerning reproduction

i) Mode(s) of reproduction

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

Pollination typically takes place on the day the flower opens. 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, and 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.

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 acidic soils and the addition of limestone may be required.

iii) Generation time

Soybean is an annual crop which is planted from April to May in the northern hemisphere, and from November to February in the southern hemisphere including second cropping. Soybean seed germinates when the soil temperature reaches 10°C and emerges in a 5-7 day period under favourable conditions.

Soybeans grow most rapidly when air temperatures are between 25°C and 35°C. The life cycle of soybean is approximately 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

Outcrossing with cultivated soybean species

Although soybean is a self-pollinated species, natural cross-pollination can occur, at very low rate. Cross-pollination frequencies may vary due to growing season and genotype, and most outcrossing occurs with immediately surrounding plants. Insect activity increases the outcrossing rate, but soybeans generally are not the preferred plant for pollinators.

It has to be noted, however, that the scope of the current application does not include the cultivation of MON 87769 varieties in the EU. Therefore, any outcrossing between MON 87769 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.

There are no known reports of successful natural hybridisation between cultivated soybean and wild perennial species of subgenus *Glycine*. Moreover, there are no wild relatives of subgenus *Glycine* in Europe.

The wild annual species *G. soja*, can hybridise naturally with the cultivated soybean, *G. max*, since they are both members of the subgenus *Soja*. Therefore, 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

Cultivated soybean plants are annuals and they reproduce solely by means of seeds. Mature soybean seeds have no innate dormancy, are sensitive to cold and are not likely to survive from one growing season to the next if left in the field over winter. Commercial soybean seeds are selected for lack of dormancy, enabling them to germinate quickly under adequate temperature and moisture which could potentially allow them to grow as volunteers in a field. However, volunteers likely would be killed by frost during autumn or winter of the year they were produced. If they did establish, volunteers would not compete well with the succeeding crop, and could be controlled readily either mechanically or chemically.

b) Ability to form structures for survival or dormancy

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. Soybean pods and seed do not have dispersal mechanisms that facilitate seed or pod movement over long distances. Furthermore, neither the soybean seedpod, nor the seed have morphological characteristics that would facilitate animal transportation. Primary movement of soybean seed is facilitated by human activities during planting, harvesting and transport of seed; however, few seeds are typically lost due to the relatively large seed size.

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 predominantly a self-pollinated species. The major barrier that prevents dissemination of soybean pollen and therefore cross-pollination, is the enclosure of both the stigma and anthers within the flower, even during maturation of the pollen. As a consequence, the potential for the pollen to become disseminated is reduced and the chance for self-pollination greatly increases. 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. From the first century A.D. to approximately the 15th to 16th centuries, soybean were introduced into several countries, with land races eventually developing in Japan, Indonesia, the Philippines, Vietnam, Thailand, Malaysia, Myanmar, Nepal and northern India. Soybean cultivation was probably introduced in Europe starting in the late 16th and throughout the 17th century and in the US in the 18th century. Today, soybean is the most prevalently grown oilseed in over 35 countries worldwide. The major producers of soybean are the US, Brazil, Argentina, and China. The largest soybean producers in the European Union are Italy and Romania, followed by France and Hungary.

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. It is sensitive to a number of economically important diseases and insect predators and is also susceptible to competition from surrounding weeds. In addition, soybean is involved in the fixation of atmospheric nitrogen into organic nitrogen through a symbiotic association with the bacterium *Bradyrhizobium japonicum.*

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, phytic acid, stachyose and raffinose. Some of these anti-nutrients relate to their impact on human nutrition, while others relate to animal nutrition in general, including livestock.

Soybean is one of the eight food groups that are known to elicit food allergic responses in humans. It contains several endogenous proteins that have been shown to elicit an allergenic response when ingested. Relatively few of the specific soybean proteins involved in allergenic reactions in soybean have been uniquely identified or characterised. Allergic responses to soybean are experiences by a very small percentage of the human population, but are considered clinically important. Allergy to soybean is more prevalent in children than adults and is considered a transient allergy of infancy/childhood.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification

MON 87769 was developed through *Agrobacterium*-mediated transformation of meristematic A3525 soybean tissue using the binary transformation plasmid PV-GMPQ1972.

2. Nature and source of the vector used

Vector PV-GMPQ1972 contains two T-DNAs. The first T-DNA (T-DNA I) region, contains two expression cassettes: the *Pj.D6D* gene expression cassette and the *Nc.Fad3* gene expression cassette. The second T-DNA region (T-DNA II), contains the *cp4 epsps* gene expression cassette that was used for early event selection, and was segregated away from T-DNA I by conventional breeding (self-pollination). The T-DNA I region containing the *Pj.D6D* and *Nc.Fad3* gene expression cassettes is the portion of plasmid PV-GMPQ1972 maintained in MON 87769.

Utilising a vector with two T-DNAs is the basis for an effective approach to generate marker-free plants. It allows for the T-DNA with the traits of interest (T-DNA I) and the T-DNA encoding the selectable marker (T-DNA II) to be inserted into two independent loci within the genome of the plant. Following selection of the transformants, the inserted T-DNA encoding the selectable marker can be segregated from progeny through subsequent traditional breeding and genetic selection processes, while the inserted T-DNA containing the trait of interest is maintained.

In MON 87769, the result is a marker-free, biotechnology-derived soybean that contains two desaturase genes, *Pj.D6D* and *Nc.Fad3,* resulting in expression of the PjΔ6D and NcΔ15D desaturases and subsequently, the production of SDA and GLA in soybean seed.

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

The T-DNA I region containing the *Pj.D6D* and *Nc.Fad3* gene expression cassettes is the portion of the plasmid PV-GMPQ1972 intended for insertion. The genetic elements of PV-GMPQ1972 comprised between the T-DNA I borders are, from the right border region, the P-*7Sα'* seed-specific promoter and leader sequence from the *Sphas1* gene encoding the alpha prime subunit of the beta-conglycinin storage protein of *Glycine max*, the *Pj.D6D* gene from *Primulae juliae,* and the 3' non-translated region of the *tml* gene from the octopine-type Ti plasmid of *Agrobacterium tumefaciens.* These elements together comprise the *Pj.D6D* gene expression cassette. The *Nc.Fad3* gene expression cassette is comprised of the seed-specific promoter and leader sequence from the *Sphas2* gene (P-*7Sα'*), the *Nc.Fad3* gene isolated from *Neurospora crassa*, and the 3' non-translated region of the pea (*Pisum sativum*) ribulose-1,5-bisphosphate carboxylase, small subunit (*rbcS2)* gene (T-*E9*).

More detail on all elements described above is presented in Table 1.

Table 1. Summary of genetic elements intended for insertion in MON 87769

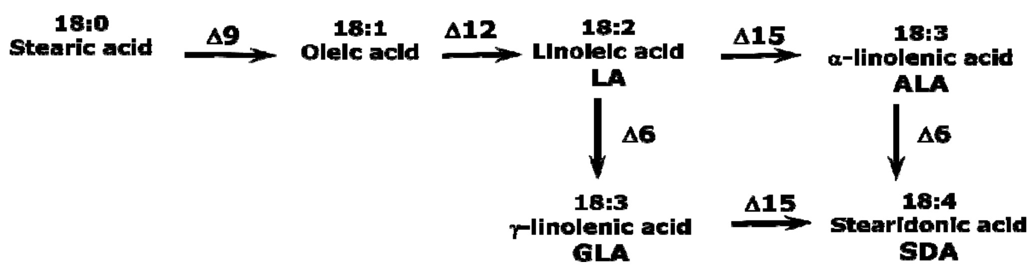
Genetic element[1]	Size (kb)	Source	Function
B-Right Border	0.34	*Agrobacterium tumefaciens*	DNA region from *Agrobacterium tumefaciens* containing the right border sequence used for transfer of the T-DNA
P-*7S α'*	0.84	*Glycine max*	Seed specific promoter and leader sequence from the *Sphas1* gene encoding beta-conglycinin storage protein (alpha'-bcsp)
CS-Pj.Δ6D	1.34	*Primula juliae*	Coding sequence for the fatty acid delta-6 desaturase
T-*tml*	0.94	*Agrobacterium tumefaciens*	Transcript termination sequence
P-*7S α*	1.68	*Glycine max*	Seed specific promoter and leader sequence from the *Sphas2* gene encoding beta-conglycinin storage protein (alpha'-bcsp)
CS-Nc.Fad3	1.29	*Neurospora crassa*	Coding sequence for the fatty acid delta-15 desaturase
T-*E9*	0.64	*Pisum sativum*	Transcript termination sequence
B-Left Border	0.44	*Agrobacterium tumefaciens*	DNA region from *Agrobacterium tumefaciens* containing the left border sequence used for transfer of the T-DNA

[1] B – Border; P – Promoter; CS – Coding Sequence, T – Transcript Termination Sequence and polyadenylation signal sequences.

D. INFORMATION RELATING TO THE GM PLANT

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

The development of MON 87769 involved the introduction of two desaturase genes, *Primulae juliae* Δ6 desaturase (*Pj.D6D*) and *Neurospora crassa* Δ15 desaturase (*Nc.Fad3*) that result in the seed-specific production of the PjΔ6D and NcΔ15D proteins. Soybean plants lack the Δ6 desaturase gene, which is a minimal requirement for the production of SDA. However, Δ6 desaturase also converts linoleic acid (LA) to gamma linoleic acid (GLA). The addition of a Δ15 desaturase with temporal expression similar to the Δ6 desaturase increases the flux of ALA to SDA and lowers the substrate pool for GLA production. To produce SDA in soybean, the conventional soybean variety A3525 was transformed with vector PV-GMPQ1972 that contained the *Pj.D6D* and *Nc.Fad3* genes driven by promoters that are known to be spatially and temporally active only in the developing soybean seed.



Recommendations to increase consumption of long chain omega-3 polyunsaturated fatty acids have been made by a number of world-wide government and public health agencies and scientific organisations. Although the benefits of omega-3 fatty acid consumption are widely recognised, typical Western diets contain very little fish, and the dietary intake of omega-3 fatty acids is generally quite low relative to recommended intake. An alternative approach to increase omega-3 fatty acid intake is to provide a wider range of foods that are enriched in omega-3 fatty acids so that people can choose foods that suit their usual dietary habits. The oil derived from MON 87769 (SDA soybean oil) contains increased levels of SDA (approximately 20-30%) and GLA (~7%) and can serve as an alternate sustainable source of omega-3 fatty acid and help meet the need for increased dietary intake of long chain omega-3 fatty acids. In mammals, SDA is a metabolic intermediate in the production of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) from alpha linolenic acid (ALA), a common dietary constituent. SDA is an eighteen carbon fatty acid with four double bonds (18:4). Since SDA has fewer double bonds than either EPA (20:5) or DHA (22:6), SDA soybean oil is more stable to oxidation (*i.e.* less prone to fishy or rancid odours and taste) than fish oils, thereby expanding the potential formulation options for food companies.

2. Information on the sequences actually inserted or deleted

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

MON 87769 contains one copy of the T-DNA I insert at a single locus and the insert contains one functional copy of the *Pj.D6D* and *Nc.Fad3* expression cassettes. No additional elements from the transformation vector PV-GMPQ1972, linked or unlinked to the *Pj.D6D* and *Nc.Fad3* expression cassettes, were detected in the genome of MON 87769. Additionally, backbone sequence from the plasmid PV-GMPQ1972 and T-DNA II were not detected.

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

No deletion was intended in the development of MON 87769. However, the analysis of the molecular structure at the insertion site of MON 87769 identified a 9 base pair deletion. Further analyses revealed that there is no known function associated with this deleted region.

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 87769 insert in the soybean nuclear genome is best shown by the Chi square (χ^2) analysis of the segregation data. The results show that inheritance of the SDA trait in MON 87769 follows Mendelian principles. This indicates that the single insert is stably integrated in the nuclear genome and is neither located in the mitochondria nor in the chloroplasts.

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

The insert in MON 87769 was characterised using Southern blot methods. Specifically, 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 insertion site), the integrity of the inserted *Pj.D6D* and *Nc.Fad3* expression cassettes and the presence or absence of plasmid backbone sequence and T-DNA II was assessed. DNA sequence analyses confirmed the sequence identity between the MON 87769 insert and the portion of the T-DNA from PV-GMPQ1972 that was integrated into the soybean genome. The results of PCR and sequence analyses further confirmed the organisation of the genetic elements within the *Pj.D6D* and *Nc.Fad3* expression cassettes of MON 87769, which were identical to that in plasmid PV-GMPQ1972.

3. Information on the expression of the insert

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

MON 87769 expresses the PjΔ6D and NcΔ15D proteins, which are driven by 7Sα' and 7Sα seed-specific promoters, respectively. These proteins desaturate certain endogenous fatty acids resulting in the production of SDA and GLA at approximately 20-30% of total fatty acids.

The levels of the PjΔ6D and NcΔ15D proteins in various tissues of MON 87769 collected from five US field sites in 2006 and five US field sites in 2007 were determined. At each site, three replicated plots of MON 87769, as well as the conventional control, were planted using a randomised complete block field design.

Protein levels were assessed in over-season leaf, root, forage and harvested seed tissues collected from each replicated plot at field sites. Due to their membrane localisation, PjΔ6D and NcΔ15D proteins require detergent-containing buffers in order to be effectively solubilised from the membranes and to decrease the potential for aggregation. Because detergent in the extraction buffer interferes with the protein's ability to interact with antibody, extracts containing solubilised PjΔ6D and NcΔ15D proteins are not well suited for analysis in liquid phase assays such as ELISA, but are compatible with a solid phase assay such as western blots.

In tissues harvested throughout the 2006 growing season, the mean PjΔ6D levels in MON 87769 across sites were highest in immature seeds (100 µg/g dwt), followed by forage (16 µg/g dwt) and mature seed (1.8 µg/g dwt). Protein levels in root and over-season leaf were below the limit of detection. The mean NcΔ15D levels in MON 87769 across sites were highest in immature seeds (200 µg/g dwt), followed by forage (14 µg/g dwt) and mature seed (10 µg/g dwt).

In tissues harvested throughout the 2007 growing season, the mean PjΔ6D levels in MON 87769 across sites were highest in immature seeds (47 µg/g dwt), followed by forage (10 µg/g dwt) and mature seed (3 µg/g dwt). Protein levels in root and over season leaf were below the limit of detection. The mean NcΔ15D levels in MON 87769 across sites were highest in immature seeds (110 µg/g dwt), followed by forage (17 µg/g dwt) and mature seed (8.7 µg/g dwt).

The expression of the PjΔ6D and NcΔ15D proteins are driven by seed specific promoters, and as expected, protein levels in root and over-season leaf tissues in both the 2006 and 2007 seasons, were below the limit of detection of the immunoblot assay. However, proteins were detected at low levels in forage tissues because forage usually contains small quantities of immature seed.

Overall, comparison between the 2006 and 2007 US field trials indicates that the ranges of the PjΔ6D and NcΔ15D protein levels were comparable.

b) Parts of the plant where the insert is expressed

The expression of the PjΔ6D and NcΔ15D proteins is driven by 7Sα' and 7Sα seed specific promoters, respectively. As expected in MON 87769, both PjΔ6D and NcΔ15D proteins were undetectable across all field sites in OSL1, OSL2, OSL3, OSL4, and root tissues as determined by the lack of measurable specific protein in the immunoblot assay for each protein at or above the tissue specific limit of detection. Both proteins were detected in immature seed, mature seed, and at low levels in forage tissues because it usually contains small quantities of immature seed. The PjΔ6D and NcΔ15D proteins were not detected in the control soybean A3525.

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

a) Reproduction

Phenotypic and agronomic data were collected from 21 field locations over two consecutive years (17 US locations in 2006, and 4 US locations in 2007) to assess whether the presence of the introduced genes (*Pj.D6D* and *Nc.Fad3*), the production of the proteins from the introduced genes (PjΔ6D and NcΔ15D) or the expected fatty acid changes, altered the plant pest potential of MON 87769. These locations provided a diverse range of environmental and agronomic conditions representative of US soybean production regions. In each of these assessments, MON 87769 was compared to an appropriate conventional soybean (control) which has a genetic background similar to MON 87769 but does not possess the *Pj.D6D* and *Nc.Fad3* expression cassettes. In addition, multiple commercial soybean varieties (reference) were employed to provide a range of baseline values that are common to the existing commercial soybean varieties for each measured phenotypic, agronomic, and ecological interaction characteristic.

Results from the phenotypic and agronomic assessments showed that there are no unexpected changes in the phenotype or ecological interactions indicative of increased pest or weed potential of MON 8776 compared to the conventional soybean control.

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 87769, and that MON 87769 is equivalent to conventional soybean in its phenotypic and agronomic behaviour.

b) Dissemination

See Section D.4.a; the introduced trait has no influence on soybean reproductive morphology and, hence, no changes in seed dissemination are to be expected in MON 87769 compared to conventional soybean.

c) Survivability

See Section D.4.a; soybean is known to be a weak competitor in the wild, which cannot survive outside cultivation without human intervention. Field observations have demonstrated that MON 87769 has not been altered in its survivability when compared to conventional soybean.

d) Other differences

See Section D.4.a; comparative assessments in the field did not reveal any biologically significant differences between MON 87769 and conventional soybean.

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

MON 87769 contains one insert with a single copy of the transformed DNA, which is stably integrated into the nuclear soybean genome. The insert is inherited in a Mendelian fashion. This has been 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

None of the genetic elements in MON 87769 has a genetic transfer function. Therefore, no changes are expected in the ability of this soybean to transfer genetic material to bacteria.

b) Plant to plant gene transfer

Based on the observation that reproductive morphology in MON 87769 is unchanged compared to conventional 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 87769, when compared to other conventional soybean varieties.

However, the scope of the current application does not include the cultivation of MON 87769 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 87769 was compared to A3525, a conventional soybean variety with background genetics similar to MON 87769, but does not possess the introduced genes (*Pj.D6D* and *Nc.Fad3*), the proteins produced by the introduced genes (PjΔ6D and NcΔ15D), and the expected fatty acid change, as well as with other commercially available soybean varieties.

7.2 Production of material for comparative assessment

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

Compositional analyses were conducted on MON 87769 and conventional control soybean seed and forage grown at 10 sites in major soybean-growing areas of the US in the 2006 and 2007 field seasons (5 sites per year). Three commercially available soybean varieties were grown also at each of the same field sites to provide reference substances representative for their respective growing regions. At each field site, the MON 87769 test, control and reference seed were planted in a randomised complete block design with three replicates per block. All the plants were grown under normal agronomic field conditions for their respective geographic regions.

In addition, harvested seed samples were collected for preparing soybean processed fractions from a field trial conducted with MON 87769, the conventional soybean control A3525, and eight conventional varieties at two field sites in the US during the 2006 growing season. The harvested seed samples were processed according to industry standards into defatted toasted soybean meal (DT soybean meal); refined, bleached, and deodorised soybean oil (RBD oil); protein isolate; and crude lecithin fractions.

Compositional analysis confirmed that MON 87769 harvested seed had the expected change in fatty acid composition, while the other components analysed in MON 87769 seed were compositionally equivalent to conventional soybean seed. Across the two seasons, MON 87769 seed had expected levels of SDA and GLA and small changes in two minor fatty acids, trans-SDA and trans-ALA. As anticipated, LA values were also significantly different. Forage analysis showed no significant differences between MON 87769 and conventional control.

Compositional analysis of refined, bleached and deodorised soybean oil, defatted toasted soybean meal, protein isolates and crude lecithin derived from MON 87769 also demonstrated no significant differences between MON 87769 and conventional control in components analysed, except for the expected changes in fatty acid composition in oil and residual oil in the processed fractions.

b) the baseline used for consideration of natural variations

Levels of the components in seed and forage of MON 87769 were compared to the corresponding levels in the control conventional comparator, which has a similar genetic background to MON 87769, but does not possess the introduced genes (*Pj.D6D* and *Nc.Fad3*), the proteins produced by the introduced genes (PjΔ6D and NcΔ15D), and the expected fatty acid change. Reference varieties were grown in the same field locations and under the same conditions as the MON 87769 test and conventional soybean control to provide data for the development of a 99% tolerance interval for each analyte evaluated. Where statistical differences occurred, the measured analyte was compared to a tolerance interval developed from these references. Differences were also compared to ranges reported in the ILSI Crop Composition Database and those ranges reported in literature.

7.3 Selection of material and compounds for analysis

Analytes measured in MON 87769 compositional analyses of harvested seed and forage and processed fractions were selected based on guidance outlined in the OECD consensus document for soybean composition. Additional fatty acid analyses were included based upon the compositional changes expected for MON 87769 soybean, including the known propensity of unsaturated acids to form trans-isomers.

7.4 Agronomic traits

Field trials with MON 87769 were conducted and the set of agronomic observations supports the conclusion that from an agronomic and phenotypic (morphological) point of view, MON 87769 is equivalent to traditional soybean, except for the introduction of genes (*Pj.D6D* and *Nc.*Fad3), the production of the proteins from the introduced genes (PjΔ6D and NcΔ15D) and the expected fatty acid changes (*see* Section D.4.).

7.5 Product specification

MON 87769 was created by introducing a Δ6 desaturase gene from *Primula juliae* and a Δ15 desaturase gene from *Neurospora crassa,* into conventional soybean, A3525. The introduction of these two genes results in the seed-specific production of PjΔ6D and NcΔ15D proteins. These proteins desaturate certain endogenous fatty acids resulting in the production of SDA at approximately 20-30% of total fatty acids.

The presence of the *Pj.D6D* and *Nc.Fad3* genes and/or the PjΔ6D and NcΔ15D proteins in soybean or in soybean derived products can be identified by employing different techniques. Southern blot or PCR techniques can identify the inserted nucleotide sequence, while the PjΔ6D and NcΔ15D proteins can be detected in immature and mature seed from MON 87769, by optimised tissue extraction, standardised electrophoretic, blotting and immunodetection methodologies.

7.6 Effect of processing

Although MON 87769 soybeans will be processed in dedicated oil processing facilities, operated in an identity preserved manner to retain the commercial value of the product, processing is not expected to be any different from that of conventional soybeans. Processing of MON 87769 results in an oil with roughly the same fatty acid composition as the seed.

7.7 Anticipated intake/extent of use

The main commercial product from MON 87769 is the oil which may be used as a replacement for fish oil or other omega-3 fatty acid rich products. It is expected that initially, MON 87769 will be grown and processed in an identity preserved manner in the northern US soybean growing region. Because of the identity preserved status of this product, it would not be expected that MON 87769 soybean will enter the current soybean or soybean oil supply to the EU in significant quantities, however may potentially enter the EU in a variety of food products. Products that might be derived from MON 87769 soybean meal and entering the human food supply would likely be blended with other commercial soybean meal or meal-derived products. The effect of the introduction of SDA soybean oil is discussed further in Section 7.10.

7.8 Toxicology

7.8.1 Safety assessment of newly expressed proteins

MON 87769 contains the *Pj.D6D* and *Nc.Fad3* expression cassettes that produce the PjΔ6D and NcΔ15D proteins, respectively. The conclusion of safety to humans of the PjΔ6D and NcΔ15D proteins was based upon the following considerations:

- The PjΔ6D and NcΔ15D proteins have a demonstrated history of safe use;
- The PjΔ6D and NcΔ15D proteins have no structural similarity to known toxins or other biologically active proteins that could cause adverse effects in humans or animals;
- The PjΔ6D and NcΔ15D proteins do not exert any acute toxic effects on mammals;
- The PjΔ6D and NcΔ15D proteins have large margins of exposure (MOE).

In addition, the low concentrations of PjΔ6D and NcΔ15D proteins in tissues that are consumed and their rapid digestibility in simulated digestive fluids provide additional assurance of their safety.

It is therefore possible to conclude that the PjΔ6D and NcΔ15D proteins are safe and pose 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. As described in Section D.7.1., compositional analysis confirmed that MON 87769 has the expected change in fatty acid composition, while the other components analysed in MON 87769 were compositionally equivalent to conventional soybean. As expected, MON 87769 seed had expected levels of SDA and GLA and small changes in two minor fatty acids, trans-SDA and trans-ALA. The safety of these fatty acids are discussed in Section D.7.8.3. There are no other new constituents present in MON 87769 and therefore, no further testing is required.

7.8.3 Information on natural food and feed constituents

MON 87769 contains SDA, GLA, trans-ALA and trans-SDA, slightly increased levels of ALA and reduced concentrations of LA. Since SDA, GLA, and ALA are produced at the expense of LA, the level of LA is lower in MON 87769 compared to conventional soybean. The saturated and unsaturated fatty acids in SDA soybean oil are typical of those consumed from other food sources, and indeed occur at low levels in fish oils and other foods. Therefore, SDA soybean oil and the fatty acids present in the oil are expected to be absorbed, distributed, and metabolised in the same general manner as fatty acids from other sources.

Soybean is known to contain a number of natural anti-nutritional components, such as trypsin inhibitors, lectins, isoflavones (daidzein, genistein and glycitein), stachyose, raffinose and phytic acid, which are inactivated when the beans are toasted or heated during processing. Nonetheless, these anti-nutrients were evaluated in MON 87769 compositional analyses and their levels were demonstrated to be comparable in MON 87769 and in conventional soybean.

Therefore, except for the fatty acid changes and the presence of the introduced proteins, PjΔ6D and NcΔ15D, there have been no biologically-relevant changes to the composition (including nutrients and anti-nutrients) of food or feed derived from MON 87769 compared to other conventional soybean varieties.

7.8.4 Testing of the whole GM food/feed

The safety assessment demonstrates that MON 87769, with the expected production of SDA and GLA, is as safe as conventional soybean for food and feed use through:

- The compositional equivalence of MON 87769 harvested seed (except for the fatty acid changes) and forage to harvested seed and forage from conventional soybean;
- The safety of the SDA soybean oil and expected fatty acids;
- The history of safe use of the introduced proteins;
- The familiarity of the host organism from which the genes are derived.

The dietary safety of MON 87769 was further confirmed by a repeat-dose animal feeding studies in broiler chickens and rats fed diets containing soybean meal produced from MON 87769.

There were no biologically relevant differences in broiler performance, carcass yield or meat composition between broilers fed diets containing meal from MON 87769 and those fed diets containing genetically similar conventional control or reference soybean meal. Therefore, this study confirms the absence of any toxic effects associated to the proteins in MON 87769 and the absence of any unanticipated or pleiotropic effects linked to the genetic modification, and supports the conclusion that defatted meal from MON 87769 is as nutritious as conventional soybean meal.

No effects on the growth or health of Sprague-Dawley rats were observed when MON 87769 processed soybean meal was fed to rats for at least 90 consecutive days at inclusions of up to 15% (w/w) in the diet.

Taken altogether, there was no evidence of any adverse effects on human or animal health.

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

It is unlikely that the PjΔ6D and NcΔ15D proteins will cause allergenic concerns due to the following considerations:

- The PjΔ6D and NcΔ15D proteins were obtained from non-allergenic sources (*Primula juliae* for PjΔ6D and *Neurospora crassa* for NcΔ15D);
- The PjΔ6D and NcΔ15D proteins lack structural similarity to known allergens, as demonstrated by bioinformatics analyses;
- The PjΔ6D and NcΔ15D proteins are rapidly digested in simulated gastric fluid;
- The PjΔ6D and NcΔ15D proteins constitute a very small portion of the total protein present in the seed of MON 87769.

Based on a weight of evidence, it can be concluded that the allergenic potential of the PjΔ6D and NcΔ15D proteins is negligible and therefore, these proteins do not pose a significant allergenic risk.

7.9.2 Assessment of allergenicity of the whole GM plant or crop

To assess whether MON 87769 has altered endogenous allergenic potential compared to traditional soybean, the potential allergenicity of each of the parental lines against a conventional soybean was performed. Results of these assessments support the conclusion that MON 87769 is comparable to conventional soybean in terms of allergenicity potential. Thus, it is concluded that MON 87769 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

Detailed compositional and nutritional comparisons of MON 87769, a conventional soybean control and commercially available reference soybean varieties confirmed that MON 87769 had the expected change in fatty acid composition, while the other components analysed were compositionally equivalent to conventional soybean.

In addition, the dietary safety of MON 87769 was further confirmed by repeat-dose animal feeding studies in the rat and broiler chickens. These studies found no adverse effects related to the consumption of diets containing MON 87769.

Finally, an assessment of the anticipated intake of SDA from the proposed uses of SDA soybean oil in selected food categories and the impact on the intakes of individual fatty acids was conducted. This analysis demonstrated that fatty acid consumption would not appreciably change compared to dietary recommendations with the introduction of MON 87769, except for an increase in the intake of omega-3 fatty acids, SDA and ALA, and would have minimal effects on the intake of other fatty acids present in the diet.

In conclusion, MON 87769 is nutritionally equivalent to conventional control soybean, as well as to soybean varieties in commerce.

7.10.2 Nutritional assessment of GM feed

MON 87769 was demonstrated to be compositionally equivalent to traditional soybean. The safety assessment of MON 87769 demonstrated that MON 87769 does not pose any adverse effects for humans and animals. As described above (Section 7.8.4), the nutritional value of MON 87769 was assessed by a feed performance study conducted in rapidly growing broiler chickens. Broilers were fed diets containing soybean meal produced from MON 87769. There were no biologically relevant differences in broiler performance, carcass yield or meat composition between broilers fed diets containing meal from MON 87769 and those fed diets containing genetically similar conventional control or reference soybean meal. Therefore, diets containing meal from MON 87769 were as wholesome as the diets formulated with conventional control or reference soybean meal regarding their ability to support the rapid growth of broiler chickens. These data support the conclusion that soybean meal from MON 87769 is as nutritious as conventional soybean meal.

In conclusion, MON 87769 is nutritionally equivalent to conventional control soybean, as well as to soybean varieties in commerce.

7.11 Post-market monitoring of GM food/feed

There are no signs of adverse or unanticipated effects observed in a number of safety studies and the pre-market risk characterisation for food and feed use of MON 87769 demonstrates that the risks of consumption of MON 87769 or its derived products are no different from the risks associated with the consumption of conventional soybean. Furthermore, the scientific evidence presented does not indicate any potential for adverse effects in humans following the consumption of SDA soybean oil under the conditions of intended use in foods. As a consequence, specific risk management measures for MON 87769 or SDA soybean oil are not considered necessary.

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

MON 87769 is a biotechnology-derived soybean that contains SDA, an omega-3 fatty acid, and therefore is not pesticidal to any target organism.

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 87769 is substantially equivalent to conventional soybean, except for the introduced trait, *i.e.* presence of SDA and GLA in seed. Field trial data demonstrated that this soybean has not been altered in its phenotypic, agronomic, reproductive, survival and dissemination characteristics when compared to conventional soybean.

This application is limited to import of MON 87769 seed into the EU and use thereof as any other soybean commodity seed. As such, exposure to the environment will be rare. In the event MON 87769 seed is spilt in the environment, its introduced trait would have negligible consequences for the environment. Hence the risk to the environment from MON 87769 through increased persistence and invasiveness of this soybean is negligible.

9.2 Selective advantage or disadvantage

It was demonstrated previously that the introduced genetic sequences in MON 87769 did not lead to any biologically meaningful alterations of other phenotypic characteristics, such as plant growth and development, morphology, or agronomic performance, when compared to conventional soybean. Therefore, it was concluded that MON 87769 is not substantially different from conventional soybean, with the exception of the introduced trait. Compared with conventional soybean, the presence of the introduced trait does not confer a selective advantage to MON 87769. Additionally, soybean has poor survival characteristics under most European conditions.

Therefore, the likelihood is negligible that the inherited traits in MON 87769 will 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 87769 to wild plant species in the EU since soybean is not sexually compatible with any indigenous or introduced wild plant species present in European countries. Furthermore, there is negligible likelihood for gene transfer from MON 87769 to other soybean crops since this application is not for consent to cultivate MON 87769 varieties in the EU but limited to import of MON 87769 seed into the EU and use of it thereof as any other soybean commodity seed.

As the likelihood of accidentally spilt MON 87769 seed to germinate, establish, mature and flower is very low (soybeans are predominantly self-pollinated), and the majority of soybean pollen is largely confined to short distances from the source plant, the transfer of the introduced traits to neighbouring soybean plants through cross-pollination is negligible.

In the highly unlikely event that the introduced genes would outcross to another soybean plant, its transfer would, in any event, have negligible consequences for the environment. The environmental risk posed by this transfer, and hence by the intended import and use of MON 87769 for food, feed and processing is negligible.

9.4 *Interactions between the GM plant and target organisms*

MON 87769 is not pesticidal and thus does not have any target organisms.

9.5 *Interactions of the GM plant with non-target organisms*

The only meaningful differences between MON 87769 and conventional soybean are the expected seed fatty acid compositional changes, particularly the presence of SDA and GLA, conferred by the introduced PjΔ6D and NcΔ15D proteins. Thus, the baseline interaction of MON 87769 with other organisms in the environment is considered no different from traditional soybean, except for the additional direct exposure to the PjΔ6D and NcΔ15D proteins, SDA, and GLA that are produced in MON 87769 of soybean pests and animals that feed on soybean seeds. Through trophic interactions and decomposition processes, additional organisms such as predators and prey of the soybean pests could be exposed to some very low levels of the PjΔ6D and NcΔ15D proteins, SDA, and GLA. Potential exposure of non-target organisms in the receiving environment to the PjΔ6D and NcΔ15D proteins, SDA, and GLA, produced in MON 87769 is a characteristic of the GMHP that may, theoretically, cause an adverse environmental effect. The PjΔ6D and NcΔ15D proteins or their close structural and functional homologues have been present in foods and feeds for significant periods of time with no documented history of any adverse effects. The fatty acids present in MON 87769 exist in many sources in the environment without known adverse effects.

There are many plants producing SDA in the environment, such as plants of the *Echium* family, black currant *etc*. GLA is present in oats, barley, and human breast milk while small concentrations are found in meats, fish and a variety of foods. Additionally, as the scope of the current application does not include planting of MON 87769 varieties in the EU, any meaningful exposure of non-target organisms to this soybean is highly unlikely.

9.6 Effects on human health

MON 87769 was shown to be compositionally equivalent to conventional soybean, with the exception of the expected seed fatty acid changes (particularly the presence of SDA and GLA) imparted by the expression of the PjΔ6D and NcΔ15D proteins. There are no substantial differences from conventional soybean with respect to safety characteristics and agronomic and phenotypic characteristics.

The likelihood for any adverse effects occurring in humans as a result of their occupational contact with this soybean and derived products is no different from conventional soybean and soybean products. MON 87769 contains the PjΔ6D and NcΔ15D proteins, SDA and GLA, which have negligible potential to cause any toxic or allergenic effects in humans. Therefore, the risk of changes in the occupational health aspects of this soybean are negligible.

9.7 Effects on animal health

Based on centuries of experience with conventional, domesticated soybean in Europe, there is a very low potential for soybean to cause any adverse health effects in animals.

MON 87769 has no meaningful differences compared to conventional soybean except for the production of the PjΔ6D and NcΔ15D proteins and the expected seed fatty acid changes, particularly the presence of SDA.

The likelihood of potential adverse effects in animals fed on MON 87769 and in humans consuming those animals, is negligible. Therefore, the risk of MON 87769 on the food/feed chain is also negligible.

9.8 Effects on biogeochemical processes

This application is limited to import of MON 87769 seed into the EU and use thereof as any other soybean commodity seed. As such, exposure to the environment will be rare, occurring only through incidental release during shipment and handling. As for conventional soybean, spillage of MON 87769 during transport or storage of seed could cause some seed to fall to the ground. Although such seed could eventually germinate if the local soil and environmental conditions are favourable, soybean is a poor competitor and cannot persist as a weed. Environmental conditions at the sites of handling are, however, unlikely to be conducive to germination, growth and reproduction of soybean seed that is incidentally released.

Therefore, it is highly unlikely that there would be any significant immediate or delayed adverse effects from MON 87769 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 87769 in the EU and for the use of this soybean as any other soybean, excluding the cultivation of MON 87769 varieties in the EU.

10. Potential interactions with the abiotic environment

This application is limited to import of MON 87769 seed into the EU and use thereof as any other soybean commodity seed. As such, exposure to the environment will be rare.

Therefore, no negative impact of MON 87769 on the abiotic environment is expected to result from the import of MON 87769 seed into the EU and use thereof as any other soybean commodity seed.

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 (ERA) of MON 87769 was undertaken in the context of the scope of the application, that is, for import, processing, food and feed use of MON 87769, but not including the cultivation of MON 87769 varieties in the EU. Analysis of the characteristics of MON 87769 has shown that the risk for potential adverse effects on human health and the receiving environment, resulting from the proposed use of MON 87769 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 87769 on human health and the environment, which were not anticipated in the ERA, 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 87769 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 authorised. 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 87769 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 87769 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

The presence of the *Pj.D6D* and *Nc.Fad3* genes and/or the PjΔ6D and NcΔ15D proteins in soybean or in soybean derived products can be identified by employing different techniques. Southern blot or PCR techniques can identify the inserted nucleotide sequence, while the PjΔ6D and NcΔ15D proteins can be detected in immature and mature seed from MON 87769, by optimised tissue extraction, standardised electrophoretic, blotting and immunodetection methodologies.

A MON 87769-specific PCR assay allowing the identification and the quantification of MON 87769 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 87769 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 87769 has been field tested in the US since 2003, Puerto Rico and Argentina from 2004 - 2008, Chile in 2005-06 and Japan 2008.

b) Authority overseeing the release

US: United States Department of Agriculture (USDA)

Argentina: Secretary of Agriculture, livestock, fishery and feed (SAGPyA) – National Advisory Commission on Agricultural Biotechnology (CONABIA)

Chile: Agriculture and Livestock Service (SAG).

Japan: Ministry of Agriculture, Fisheries and Forestry.

c) Release site

US: In major soybean growing states (Arkansas, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Missouri, Nebraska, North and South Dakota, Ohio, Pennsylvania, and Wisconsin).

Argentina: Balcarce, Buding, Carabellas, Carmen de Areco, Chivilcoy, Colón, Coronel Suárez, Fontezuela, Haissman, Los Pinos, Manuel Ocampo, Miramar, Napaleofu, Nueve De Julio, Otamendi, Pergamino, Peyrano, Rojas, Salto, San Augustin, and Tandil.

Chile: Rancagua

Puerto Rico: Isabela

Japan: Ibaraki Prefecture

d) Aim of the release

US/Argentina/Chile/Puerto Rico: regulatory trials, efficacy, yield, breeding, product development.

Japan: Stage III environmental assessment.

e) Duration of the release

US/Argentina/Chile/Puerto Rico/Japan: One growing season.

f) Aim of post-releases monitoring

US/Argentina/Chile/Puerto Rico: Assessment of volunteers.

g) Duration of post-releases monitoring

US/Argentina/Chile/Puerto Rico: 12 months.

h) Conclusions of post-release monitoring

US/Argentina/Chile/Puerto Rico: In general, no volunteers have been observed since soybean is an annual crop. If volunteers occur, practice is to eliminate them manually or chemically 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 87769 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.ec.europa.eu/gmp_browse.aspx) and (http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm) and the EFSA website (http://www.efsa.europa.eu/) 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 87769.
b) Assessment Report of the Competent Authority (Directive 2001/18/EC) A notification for MON 87769 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) The Commission Register can be seen at: http://ec.europa.eu/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.ec.europa.eu/default.htm
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.cbd.int/
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.europa.eu/