Application for authorization to place on the market MON 87705 soybean in the European Union, according to Regulation (EC) No 1829/2003 on genetically modified food and feed

Part II

Summary

Data protection.
This application contains scientific data and other information which are protected in accordance with Art. 31 of Regulation (EC) No 1829/2003.

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 Monsanto development code for this genetically modified soybean is MON 87705. 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 USA

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 87705 will be produced in other world areas and will be imported and used in the European Union (EU) 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 *yes*, specify	

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

Yes ( )	**No (×)**
If *no*, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC The protein expression, composition, safety, agronomic and phenotypic characteristics of MON 87705 have been studied at multiple locations in North America and Chile that cover a range of environmental conditions. The data collected from these field trials have been used in the risk assessment presented in the MON 87705 application. A summary of the conclusions of the risk analysis that demonstrate the safety of MON 87705 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 *yes*, specify	

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

Yes (x)	No ( )

If *yes*, specify

MON 87705 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. Regulatory submissions will also be made to countries that import significant soybean or food and feed products derived from soybean grown in the northern US regions and have functional regulatory review processes in place. These will include submissions to a number of countries and regulatory authorities, including China, Australia, New Zealand, The Philippines, Mexico, Malaysia, Taiwan, Korea and Indonesia. 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.

8. General description of the product

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

Monsanto Company has developed biotechnology-derived soybean MON 87705 with an improved fatty acid profile to enhance the suitability of soybean oil for food and industrial uses.

MON 87705 was developed to selectively down-regulate two key enzymes, FATB and FAD2, involved in the soybean seed fatty acid biosynthetic pathway. As a result, the fatty acid (FA) levels in MON 87705 soybean oil are lower for saturated fats (6% vs. 15% of total FA) and higher for oleic acid (76% vs. 23% of total FA). The increase in monounsaturated fatty acid (oleic) in MON 87705 is accompanied by an overall decrease in polyunsaturated fatty acids (17% vs 60% of total FA).

The improved fatty acid profile of MON 87705 soybean oil is expected to increase oxidative stability and enable formulation of foods with lower saturated fat content. The improved nutritional benefit of decreased saturated fatty acids coupled with the expected increased stability makes it well suited for use in bottled vegetable oil, salad dressings, margarine and other similar food products for which commodity soybean oil is used.

The fatty acid profile of MON 87705 soybean oil is also well suited for industrial applications. Soybean oils have very good lubricating properties, and are highly biodegradable compared to mineral oils, but typically lack the stability needed to meet industrial requirements. The fatty acid profile of MON 87705 provides industrial oil with improved

stability that could serve as a lubricant without needing hydrogenation.

MON 87705 also contains the 5-enolpyruvylshikimate-3-phosphate synthase gene derived from *Agrobacterium* sp. strain CP4 (*cp4 epsps*), which encodes the CP4 EPSPS protein.

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 87705 for import, processing and all uses as any other soybean 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 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 87705 varieties in the EU.

c) Intended use of the product and types of users

The improved fatty acid profile of MON 87705 soybean oil is expected to increase oxidative stability and enable formulation of foods with lower saturated fat content. The improved nutritional benefit of decreased saturated fatty acids coupled with the expected increased stability makes it well suited for use in bottled vegetable oil, salad dressings, margarine and other similar food products for which commodity soybean oil is used.

The fatty acid profile of MON 87705 soybean oil is also well suited for industrial applications. Soybean oils have very good lubricating properties, and are highly biodegradable compared to mineral oils, but typically lack the stability needed to meet industrial requirements. The fatty acid profile of MON 87705 provides industrial oil with improved stability that could serve as a lubricant without needing hydrogenation.

In the cultivating markets, MON 87705 is intended primarily for use as a broad acre field soybean. In that respect, MON 87705 will be used and traded 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

No specific conditions or instructions are considered necessary for placing on the market MON 87705 for import, processing and all uses as specified in Section 8(b) in the EU. It has been demonstrated that, with the improved fatty acid profile, MON 87705 soybean is as safe as conventional soybean. Therefore, foods and feeds produced from MON 87705 will be stored, packaged, transported, used and handled in the same manner as for current commercial soybean varieties. No specific conditions or instructions are required for the placing on the market of MON 87705 for import, processing and all uses as specified in Section 8(b).

e) Any proposed packaging requirements

MON 87705 is substantially equivalent to conventional soybean, except for the improved fatty acid profile and glyphosate-tolerance trait. Therefore, MON 87705 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 87705 and derived products.

As MON 87705 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 87705 soybean with the words "genetically modified soybean containing high oleic, low saturated fatty acid oil" or "contains genetically modified soybean containing high oleic, low saturated fatty acid oil", and operators shall be required to declare the unique identifier, MON-87705-6, 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 87705 with the words "produced from genetically modified soybean containing high oleic, low saturated fatty acid oil", and products containing or consisting of oil produced from MON 87705 with the words "high oleic, low saturated fatty acid oil produced from genetically modified soybean".

Monsanto proposes that products containing or consisting of derivatives (other than the oil) from MON 87705 are labelled with the words "produced from genetically modified soybean".

Operators handling or using MON 87705 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 87705. 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-877Ø5-6.

h) If applicable, geographical areas within the EU to which the product is intended to be confined under the terms of the authorisation applied for. Any type of environment to which the product is unsuited

MON 87705 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, process and all uses of MON 87705 as any other soybean, not including the cultivation of varieties of MON 87705 in the EU, the only potential means of environmental release would be during import, storage and processing of MON 87705. 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 87705 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). MON 87705 is shown to be substantially equivalent to conventional soybean, except for the improved fatty acid profile and glyphosate-tolerance trait, 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 the placing on the market of MON 87705 for import, processing and all uses as specified in Section 8(b).

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

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. Soybean does 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.

Soybean grows 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 soybean generally is 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 87705 varieties in the EU. Therefore, any outcrossing between MON 87705 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 related closely enough 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 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, 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 87705 was developed through *Agrobacterium*-mediated transformation of soybean A3525 meristem tissue using the double-border, binary vector PV-GMPQ/HT4404.

2. Nature and source of the vector used

Vector PV-GMPQ/HT4404 contains two T-DNAs. The first T-DNA, designated T-DNA I, contains the *cp4 epsps* expression cassette from *Agrobacterium* sp. strain CP4 and the soybean (*Glycine max*) derived partial suppression cassette that contains the sense segments of the *FAD2-1A* intron and *FATB1-A* 5' UTR. The second T-DNA, designated T-DNA II, contains a *Glycine max* derived partial suppression cassette that consists of the *FAD2-1A* and *FATB1-A* antisense segments. During the *Agrobacterium*-mediated plant transformation the two T-DNAs co-integrate at one locus in the soybean genome, creating a DNA insert that contains the *cp4 epsps* cassette and a single *FAD2-1A/FATB1-A* suppression cassette.

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

The T-DNA I region contains the *cp4 epsps* expression cassette from *Agrobacterium* sp. strain CP4 and is under the regulation of *FMV/Tsf1* chimeric promoter and *E9* 3' UTR derived from figwort mosaic virus/*Arabidopsis thaliana* and the garden pea *Pisum sativum*, respectively. The soybean (*Glycine max*) derived partial suppression cassette in T-DNA I contains the sense segments of the *FAD2-1A* intron and *FATB1-A* 5' UTR that are under the regulation of the seed *7Sα*' promoter also derived from *Glycine max*. The second T-DNA, designated T-DNA II, contains a *Glycine max* derived partial suppression cassette that consists of the *FAD2-1A* and *FATB1-A* antisense segments terminated by the *H6* 3'UTR sequence which is derived from pima cotton (*Gossypium barbadense*). During plant transformation, the two T-DNAs co-integrate at one locus in the soybean genome, creating a DNA insert that contains a *cp4 epsps* cassette and a single *FAD2-1A/FATB1-A* suppression cassette.

The individual components and the function of the DNA sequences in MON 87705 are given in Table 1.

Table 1. Summary of genetic elements intended for insertion in MON 87705

Genetic element[1]	Size (kb)	Function and source
		T-DNA I
B-Left border region	0.44	DNA region from *Agrobacterium tumefaciens* containing the left border sequence used for transfer of the T-DNA
P-*FMV/Tsf1*	1.04	Chimeric promoter consisting of enhancer sequences from the promoter of the figwort mosaic virus *35S* RNA combined with the promoter from the *Tsf1* gene of *Arabidopsis thaliana* that encodes elongation factor EF-1 alpha
L-*Tsf1*	0.04	5' untranslated leader sequence from the *Tsf1* gene of *Arabidopsis thaliana* that encodes elongation factor EF-1 alpha
I-*Tsf1*	0.62	Intron with flanking exon sequence from the *Tsf1* gene of *Arabidopsis thaliana* that encodes elongation factor EF-1 alpha
TS-*CTP2*	0.23	Targeting sequence from the *ShkG* gene encoding the transit peptide region of *Arabidopsis thaliana* EPSPS that directs transport of the CP4 EPSPS protein to the chloroplast
CS-*cp4 epsps*	1.37	Codon modified coding sequence of the *aroA* gene from the *Agrobacterium* sp. strain CP4 encoding the CP4 EPSPS protein
T-*E9*	0.64	3' untranslated region of the pea *RbcS2* gene which functions to direct polyadenylation of the mRNA
P-*7Sa'*	0.84	Non-coding promoter and leader sequence from the *Sphas1* gene of *Glycine max* encoding beta-conglycinin storage protein (alpha'-bcsp) that directs transcription in seed
***FAD2-1A*^{p}**	0.26	Partial sequence from intron #1 of the *Glycine max FAD2-1A* gene that encodes the delta-12 desaturase which suppresses endogenous *FAD2-1A* RNA levels
***FATB1-A*^{p}**	0.30	Partial sequence from the 5' untranslated region and the plastid targeting sequence from *Glycine max FATB1-A* gene that encodes the palmitoyl acyl carrier protein thioesterase which suppresses endogenous *FATB1-A* RNA levels
B-Right border region	0.36	DNA region from *Agrobacterium tumefaciens* containing the right border sequence used for transfer of the T-DNA

T-DNA II		
B-Right border region	0.33	DNA region from *Agrobacterium tumefaciens* containing the right border sequence used for transfer of the T-DNA
***FATB1-A*^{p1}**	0.30	Partial sequence from the 5' untranslated region and the plastid targeting sequence from *Glycine max FATB1-A* gene that encodes the palmitoyl acyl carrier protein thioesterase which suppresses endogenous *FATB1-A* RNA levels
***FAD2-1A*^{p}**	0.27	Partial sequence from intron #1 of the *Glycine max FAD2-1A* gene that encodes the delta-12 desaturase which suppresses endogenous *FAD2-1A* RNA levels
T-*H6*	0.43	3' UTR sequence of the *H6* gene from *Gossypium barbadense* encoding a fiber protein involved in secondary cell wall assembly
B-Left border region	0.44	DNA region from *Agrobacterium tumefaciens* containing the left border sequence used for transfer of the T-DNA

[1] B – Border; P – Promoter; L – Leader; I – Intron; TS – Targeting Sequence; CS – Coding Sequence; T – 3' untranslated transcriptional termination sequence and polyadenylation signal sequences; *P* - Partial sequence; *P1* – Truncated partial sequence of *FATB1-A*.

D. INFORMATION RELATING TO THE GM PLANT

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

The improved fatty acid profile in MON 87705 soybean oil is achieved through the use of endogenous soybean gene segments configured to suppress *FATB* and *FAD2* gene expression. The MON 87705 insert contains the *FATB1-A* and *FAD2-1A* sense and antisense gene segments under the control of a seed promoter, limiting oil composition modification to the seed tissue. The assembled gene transcript has an inverted repeat that produces double stranded RNA (dsRNA) that, via RNA-based suppression, suppresses endogenous *FATB* and *FAD2* genes, thereby producing the desired fatty acid phenotype of decreased saturated (16:0 palmitic acid and 18:0 stearic acid), increased oleic and decreased linoleic fatty acid composition in the oil.

Acyl-acyl carrier protein (acyl-ACP) thioesterases (FATB enzymes) are localized in plastids and hydrolyze saturated fatty acids from the ACP-fatty acid moiety. The suppression of *FATB* RNAs ultimately results in a decrease in the transport of the saturated fats out of the plastid, thus retaining their availability for desaturation to 18:1 oleic acid (Figure 1, Panel A). Therefore, suppression of *FATB* RNAs decreases saturated fat content in the oil as well as increases 18:1 oleic acid. Subsequently, this increased amount of 18:1 oleic acid is either delivered to the oil body or to the endoplasmic reticulum for further desaturation. Delta-12 desaturases (hereafter referred to as FAD2 enzymes) desaturate 18:1 oleic acid to 18:2 linoleic acid. The suppression of *FAD2* RNAs in soybean seed ultimately causes reduced desaturation of 18:1 oleic to 18:2 linoleic acid, thus contributing further to the increase in 18:1 oleic acid while reducing 18:2 linoleic acid content in the oil (Figure 1, Panel A). Therefore, the overall result of the MON 87705 RNA-based suppression cassette is a reduction in saturated; 16:0 palmitic and 18:0 stearic acids, an increase in monounsaturated; 18:1 oleic acid, and lower levels of polyunsaturated; 18:2 linoleic acid, relative to commodity soybean (Figure 1, Panel B).

The improved fatty acid profile of MON 87705 soybean oil is anticipated to have positive health benefits for consumers through a reduction in saturated fat intake when MON 87705 soybean oil substitutes for commodity soybean oil in a variety of foods.

It is also anticipated that substitution of commodity soybean oil with MON 87705 soybean oil will increase the intake of oleic acid. When substituted for saturated fatty acids in metabolic studies, both MUFAs, primarily oleic acid, and n-6 polyunsaturated fatty acids (n-6 PUFAs), primarily linoleic acid, lower plasma total cholesterol and LDL-C concentrations.

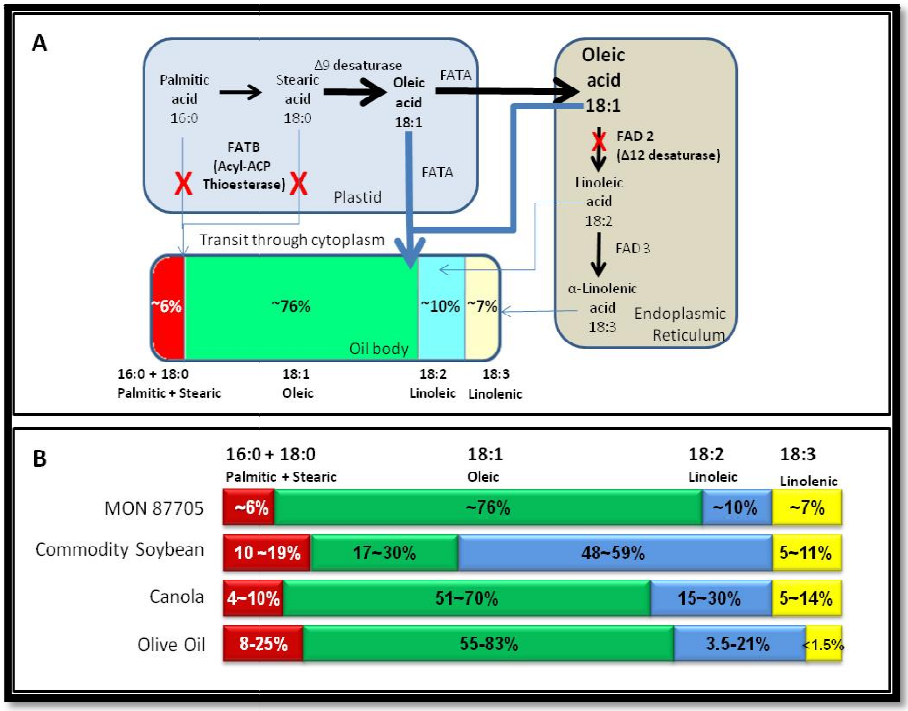

Figure 1. Schematic of soybean fatty acid biosynthetic pathway and comparison of the fatty acid content of MON 87705 soybean oil with other vegetable oils

2. Information on the sequences actually inserted or deleted

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

MON 87705 contains a single copy of T-DNA I and T-DNA II sequences that are integrated into a single locus of the soybean genome. The insert contains the *FATB1-A/FAD2-1A* suppression and *cp4 epsps* expression cassettes as an intact entity at a single site in MON 87705. No additional elements from the transformation vector PV-GMPQ/HT4404, linked or unlinked to the expression cassettes were detected in the genome of MON 87705. Additionally, backbone sequences from the plasmid PV-GMPQ/HT4404 were not detected.

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

No deletions were intended, however there was a 36 bp deletion of soybean genomic DNA sequence at the site of cassette insertion in MON 87705. Deletions and/or insertions of DNA due to double-strand break repair mechanisms in the plant during *Agrobacterium*-mediated transformation process are not uncommon. 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 87705 insert in the nuclear genome is best shown by the Chi square analysis of the segregation results. The Chi square analysis of the segregation pattern, according to Mendelian genetics, was consistent with a single site of insertion into the soybean nuclear DNA.

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

The insert in MON 87705 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 *FATB1-A/FAD2-1A* suppression and *cp4 epsps* expression cassettes and the presence or absence of plasmid backbone sequences were assessed. DNA sequence analyses confirmed the sequence identity between the MON 87705 insert and the corresponding insert from the plasmid PV-GMPQ/HT4404. The results of PCR and sequence analyses further confirmed the organisation of the genetic elements within the *FATB1-A/FAD2-1A* suppression and *cp4 epsps* expression cassettes of MON 87705, which were identical to that in plasmid PV-GMPQ/HT4404.

3. Information on the expression of the insert

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

The MON 87705 insert contains a *cp4 epsps* expression cassette and a *FAD2-1A/FATB1-A* suppression cassette. The *FAD2-1A/FATB1-A* suppression cassette encodes for dsRNA, and it is extremely unlikely to code for a protein. Therefore, CP4 EPSPS is the only newly expressed protein in MON 87705.

The levels of CP4 EPSPS protein in various tissues of MON 87705 collected from five Chilean field sites during the 2007/2008 growing season and four US field sites in 2008 were determined. At each site, three replicated plots of MON 87705, as well as the conventional control,A3525, were planted using a randomised complete block field design.

Protein levels were assessed in over-season leaf, forage, root and mature seed tissues collected from each replicated plot at each site. The levels of CP4 EPSPS protein were assessed by a validated enzyme-linked immunosorbent assay (ELISA).

In tissues collected throughout the 2007/2008 growing season in Chile, the CP4 EPSPS protein was detected in all tissue types across all five sites with a range from 40 – 1000 µg/g dwt. The mean CP4 EPSPS protein level in MON 87705 across all sites was 120 µg/g dwt in forage, 110 µg/g dwt in

mature seed, and 77 µg/g dwt in root. In leaf tissue samples harvested throughout the growing season, mean CP4 EPSPS protein levels in MON 87705 across all sites ranged from 200 - 530 µg/g dwt.

In tissues collected throughout the 2008 growing season in the US, the CP4 EPSPS protein was detected in all tissue types across all four sites with a range from 91-420 µg/g dwt. The mean CP4 EPSPS protein level in MON 87705 across all sites was 160 µg/g dwt in forage, 160 µg/g dwt in mature seed, and 130 µg/g dwt in root. In leaf tissue samples harvested throughout the growing season, mean CP4 EPSPS protein levels in MON 87705 across all sites ranged from 160 - 220 µg/g dwt.

Overall, comparison between the 2007/2008 Chile and 2008 US field trials indicates that the range of the CP4 EPSPS protein levels were comparable.

b) Parts of the plant where the insert is expressed

The *cp4 epsps* gene in MON 87705 is driven by the *FMV/Tsf1* promoter and results in detectable CP4 EPSPS protein levels in all tissue types, with the highest expression level in leaf, followed by forage, mature seed, and root. The levels of the CP4 EPSPS protein from the conventional control, A3525, were less than the assay limits of detection (LOD) or limit of quantitation LOQ in all tissue types.

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 in the US over two consecutive years; 17 locations in 2007 and 4 locations in 2008 to assess whether the presence of the *FAD2-1A/FATB1-A* suppression cassette, the production of the CP4 EPSPS protein or the improved fatty acid profile, altered the plant pest potential of MON 87705. These locations provided a diverse range of environmental and agronomic conditions representative of US soybean production regions. In each of these assessments, MON 87705 was compared to an appropriate conventional soybean control, A3525, with genetic background similar to MON 87705, but lacking the introduced traits. The control material neither possesses the *FAD2-1A/FATB1-A* suppression and *cp4 epsps* expression cassettes nor it expresses CP4 EPSPS protein and has improved fatty acid profile. In addition, multiple commercial soybean varieties (references) were included to provide a range of comparative values that are representative of existing commercial soybean varieties for each measured phenotypic, agronomic, and environmental 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 87705 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 87705, and that MON 87705 is equivalent to conventional soybean in its phenotypic and agronomic behaviour.

b) Dissemination

See Section D.4.a; the introduced traits have no influence on soybean reproductive morphology and, hence, no changes in seed dissemination are to be expected in MON 87705 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 87705 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 87705 and conventional soybean.

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

MON 87705 contains a single copy of the T-DNA I and T-DNA II sequences that were integrated into a single locus of the 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 inserted in MON 87705 has a genetic transfer function. Therefore, no changes are expected in the ability of these soybean line to transfer genetic material to bacteria.

b) Plant to plant gene transfer

Based on the observation that reproductive morphology in MON 87705 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 87705, when compared to other conventional soybean varieties.

Furthermore, the scope of the current application does not include the cultivation of MON 87705 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 87705 was compared to A3525, a conventional soybean variety with genetic background similar to MON 87705, but lacking the introduced traits. The control material neither possesses the *FAD2-1A/FATB1-A* suppression and *cp4 epsps* expression cassettes nor it expresses CP4 EPSPS protein and has improved fatty acid profile.

7.2 Production of material for comparative assessment

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

Compositional analyses were conducted on MON 87705 and conventional control soybean,A3525, seed and forage, grown at 10 sites in major soybean-growing areas of the Chile in the 2007/2008 and US in the 2008 growing seasons (5 sites per year). Commercially available conventional soybean varieties were also grown at each of the field sites to provide a total of 20 different reference substances both in the 2007/2008 Chile and 2008 US growing seasons. At each field site, the MON 87705 test, control and reference seeds 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 87705, the conventional soybean control, A3525 and twelve conventional varieties at two field sites in the US during the 2007 growing season. The seed samples were processed according to typical industry standards into toasted defatted soybean meal (TD soybean meal); refined, bleached and deodorized soybean oil (RBD oil); protein isolate; and crude lecithin fractions.

Compositional analyses demonstrated that MON 87705 had the intended fatty acid profile in both Chile 2007/2008 and US 2008 growing seasons. Also the processed fractions produced from MON 87705 were compositionally equivalent to those of conventional soybean except for the intended changes in fatty acids.

b) the baseline used for consideration of natural variations

Levels of the components in seed and forage of MON 87705 were compared to the corresponding levels in the control. Reference varieties were grown in the same field locations and under the same conditions as the MON 87705 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

The key nutrients and other nutritionally important components that were selected for analysis of MON 87705 in the compositional studies were chosen on the basis of internationally accepted guidance provided by the OECD consensus document for soybean composition.

7.4 Agronomic traits

Field trials with MON 87705 were conducted and the set of agronomic observations supports the conclusion that from an agronomic and phenotypic (morphological) point of view, MON 87705 is equivalent to traditional soybean, except for the presence of *FATB1-A*/*FAD2-1A* suppression and *cp4 epsps* expression cassettes, the production of the CP4 EPSPS protein from the introduced genes (*cp4 epsps*) and the improved fatty acid profile (*see* Section D.4.).

7.5 Product specification

The improved fatty acid profile in MON 87705 soybean oil is achieved through the use of endogenous soybean gene segments configured to suppress *FATB* and *FAD2* gene expression. MON 87705 contains *FATB1-A* and *FAD2-1A* gene segments under the control of a seed promoter, limiting oil composition modification to the seed tissue. The assembled gene transcript has an inverted repeat that produces dsRNA that, via RNA-based suppression, suppresses endogenous *FATB* and *FAD2* gene expression, thereby producing the desired fatty acid phenotype of decreased saturate, increased oleic and decreased linoleic fatty acid composition in the oil.

MON 87705 also contains the 5-enolpyruvylshikimate-3-phosphate synthase gene derived from *Agrobacterium* sp. strain CP4 (*cp4 epsps*) encoding the CP4 EPSPS protein.

The presence of the *FATB1-A*/*FAD2-1A* suppression cassette and the *cp4 epsps* gene and the CP4 EPSPS protein 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 CP4 EPSPS protein can be detected in all tissues of MON 87705, by optimised tissue extraction, standardised electrophoretic blotting and immunodetection methodologies.

7.6 Effect of processing

MON 87705 has been shown to be substantially equivalent to conventional soybean, except for improved fatty acid profile and glyphosate-tolerance trait. The processing of MON 87705 is therefore not expected to be any different from that of conventional soybeans.

7.7 Anticipated intake/extent of use

Soybean products derived from MON 87705 will represent only a portion of the total soybean products consumed by the EU population. Soybean is mostly a blended commodity that in general is highly processed before being consumed by humans. After the extraction of the nutritionally-improved soybean oil from MON 87705, the remaining processed fractions derived from MON 87705 will likely be blended with those derived from other commercial soybean varieties before entering the human food supply. Thus, most food products derived from MON 87705 and entering the human food supply will likely be blended with other commercial soybean products before being processed and consumed. The effect of the introduction of high oleic, low saturated fatty acid soybean oil is discussed further in Section 7.10.

7.8 Toxicology

7.8.1 Safety assessment of newly expressed proteins

MON 87705 insert contains a *cp4 epsps* expression cassette and a *FAD2-1A/FATB1-A* suppression cassette. The *FAD2-1A/FATB1-A* suppression cassette encodes for dsRNA, and it is extremely unlikely to code for a protein. Therefore, the safety assessment of newly expressed proteins is based on the characterization and safety of the CP4 EPSPS protein produced by MON 87705. The conclusion of safety to humans of the CP4 EPSPS protein was based upon the following considerations:

- The CP4 EPSPS protein has a demonstrated history of safe use;
- The CP4 EPSPS protein has no structural similarity to known toxins or other biologically active proteins that could cause adverse effects in humans or animals;
- The CP4 protein does not exert any acute toxic effects on mammals;
- The CP4 EPSPS protein has a large margin of exposure (MOE)

In addition, the rapid digestibility of CP4 EPSPS in simulated gastric fluid provides additional assurance of its safety.

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. As described in Section D.7.1, compositional analysis confirmed that MON 87705 has the intended change in fatty acid composition, while the other components analysed in MON 87705 were compositionally equivalent to conventional soybean. As expected, MON 87705 has decreased levels of saturated fatty acids and increased level of monounsaturated fatty acid (18:1 oleic acid) with an associated decrease in the level of the polyunsaturated 18:2 linoleic acid. There are no new constituents present in MON 87705 and therefore, no further testing is required.

7.8.3 Information on natural food and feed constituents

Except for the intended fatty acid changes, there were no biologically relevant changes to the composition (including nutrients and anti-nutrients) of food or feed derived from MON 87705 compared to other conventional soybean varieties. Soybean is known to contain a number of natural anti-nutritional analytes, 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 87705 compositional analyses and their levels were demonstrated to be comparable in MON 87705 and in conventional soybean.

7.8.4 Testing of the whole GM food/feed

The safety assessment demonstrates that MON 87705 (with the improved fatty acid profile and glyphosate-tolerance trait), is as safe as conventional soybean for food and feed use through:

- The compositional equivalence of MON 87705 harvested seed and forage (except for the changes at fatty acid profile) to harvested seed and forage from conventional soybean;
- The safety of the intended changes in fatty acid profile;
- The history of safe use of the introduced CP4 EPSPS protein;
- The familiarity of the host organisms from which the genes are derived.

The dietary safety of MON 87705 was further confirmed by repeat-dose animal feeding studies in broiler chickens and rats fed diets containing soybean meal produced from MON 87705.

No effects on the growth or health of Sprague-Dawley rats were observed when MON 87705 processed soybean meal was fed to rats for at least 90 consecutive days at a concentration of 30% (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 CP4 EPSPS protein will cause allergenic concerns due to the following considerations:

- The CP4 EPSPS protein was obtained from a non-allergenic source (*Agrobacterium* sp. strain CP4);
- The CP4 EPSPS protein constitutes a very small portion of the total protein present in MON 87705;
- The CP4 EPSPS protein lacks structural similarity to known

allergens, as demonstrated by bioinformatics analyses;

- The CP4 EPSPS protein is rapidly digested in simulated gastric fluid;

Based on a weight of evidence, it can be concluded that the allergenic potential of the CP4 EPSPS protein is negligible and therefore, the protein does not pose a significant allergenic risk.

7.9.2 Assessment of allergenicity of the whole GM plant or crop

To assess whether MON 87705 has altered endogenous allergenic potential compared to traditional soybean, the potential allergenicity of MON 87705 was compared to conventional soybean varieties. Results of these assessments support the conclusion that MON 87705 is comparable to conventional soybean in terms of allergenicity potential. Thus, it is concluded that MON 87705 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 87705, a conventional soybean control, A3525, and commercially available reference soybean varieties confirmed that MON 87705 had the intended improved fatty acid profile, while the other components analysed were compositionally equivalent to conventional soybean. In addition, the dietary safety of MON 87705 was further confirmed by repeat-dose animal feeding studies in broiler chickens. These studies found no adverse effects related to the consumption of diets containing MON 87705.

A nutritional assessment of foods derived from MON 87705 was performed to assess whether the consumption of the modified food could lead to adverse nutritional effects compared to the food it is intended to replace. Based on the highly conservative approach taken in the nutritional assessment, the substitution of MON 87705 soybean oil for liquid soybean oil results in nutritionally positive shifts in saturated fat (particularly palmitic acid) intake, and modest changes in other fatty acids that do not present nutritional concerns.

7.10.2 Nutritional assessment of GM feed

MON 87705 was demonstrated to be compositionally equivalent to traditional soybean, except for the improved fatty acid profile. The safety assessment of MON 87705 demonstrated that MON 87705 does not pose any adverse effects for humans and animals. As described above (Section 7.8.4), the nutritional value of MON 87705 was assessed by a feed performance study conducted in rapidly growing broiler chickens. Broilers were fed diets containing soybean meal produced from MON 87705. There were no biologically relevant differences in broiler performance, carcass yield or meat composition between broilers fed diets containing meal from MON 87705 and those fed diets containing genetically similar conventional

control or reference soybean meal. Therefore, diets containing meal from MON 87705 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 87705 is as nutritious as conventional soybean meal.

In conclusion, MON 87705 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 87705. The studies demonstrate that the risks of consumption of MON 87705 or its derived products are no different from the risks associated with the consumption of conventional soybean. Several studies have investigated the consequence of increasing dietary oleic acid intake by replacing dietary oils with specific diets featuring modified fatty acid profiles. Collectively, the scientific literature supports the conclusion that dietary oils rich in oleic acid are a suitable option to provide energy when replacing the use of oils high in saturated fats or *trans* fatty acids. None of the publications report any incidence of adverse events as a consequence of dietary modifications evaluated in the studies. As a consequence, specific risk management measures for MON 87705 are not considered necessary.

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

MON 87705 is a biotechnology-derived soybean that expresses the CP4 EPSPS protein and contains the same five major fatty acids that are found in conventional soybean: 16:0 palmitic and 18:0 stearic (saturated); 18:1 oleic (monounsaturated); and 18:2 linoleic, and 18:3 linolenic acids (polyunsaturated), but in different proportions. Therefore, MON 87705 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

This application under Regulation (EC) No 1829/2003 is for the authorisation of MON 87705 for import, processing and all uses as any other soybean, excluding the cultivation of MON 87705 in the EU.

As the scope of this application under Regulation (EC) No 1829/2003 includes the import and use of the viable GMO, an environmental risk assessment in accordance with the principles of Annex II to Directive 2001/18/EC is included in this section.

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 87705 is substantially equivalent to conventional soybean, except for the improved fatty acid profile and 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 conventional soybean.

This application is limited to import of MON 87705 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 87705 seed is spilt in the environment, its introduced trait would have negligible consequences for the environment. Hence the risk to the environment from MON 87705 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 87705 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 87705 is not substantially different from conventional soybean, with the exception of the improved fatty acid profile and the glyphosate-tolerance trait.

Compared with conventional soybean, changes in fatty acid composition and expression of the CP4 EPSPS protein would not confer a selective advantage or disadvantage to MON 87705 and would not be of direct competitive importance to wild plants, nor indirectly for wildlife interacting with those wild plants. Conventional soybean is a well known source of fatty acids used in food and feed, and MON 87705 seed does not contain any new fatty acids that are not present in conventional soybean seed.

Compared with conventional soybean, the presence of the glyphosate tolerance trait would only confer a selective advantage to MON 87705, where its control was attempted using glyphosate alone and if no other, more important factors limiting the survival of soybean in the receiving environment were present. In practice, however, this advantage would be of short duration and of limited consequence because of the poor survival characteristics of soybean under most European conditions.

Therefore, the likelihood is negligible that the inherited traits in MON 87705 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 87705 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 87705 to other soybean crops since this application is not for consent to cultivate MON 87705 varieties in the EU but limited to import of MON 87705 seed into the EU and use thereof as any other soybean commodity seed.

As the likelihood of accidentally spilt MON 87705 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 case that an introduced gene outcrossed to other soybean, its transfer would only confer a selective advantage under specific conditions (*i.e.* upon applications of glyphosate-containing herbicide), as discussed in Section 9.2.

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, processing and all uses of MON 87705 is negligible.

9.4 Interactions between the GM plant and target organisms

MON 87705 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 87705 and conventional soybean are the improved seed fatty acid profile conferred by the *FAD2-1A*/*FATB1-A* suppression cassette, and the glyphosate-tolerance trait conferred by the CP4 EPSPS protein. Thus, the baseline interaction of MON 87705 with other organisms in the environment is considered no different from conventional soybean, except for the additional direct exposure of pests and animals that feed on soybean seeds to the dsRNA molecules mediating the change in seed fatty acid profile and the improved fatty acid profile. There will also be direct exposure to the CP4 EPSPS protein for soybean pests and animals that feed on MON 87705. Additionally, through trophic interactions and decomposition processes predators and prey of soybean pests could be exposed to very low levels of dsRNA and the CP4 EPSPS protein. Potential exposure of non-target organisms in the receiving environment to the dsRNA mediating the change in seed fatty acid profile, the improved fatty acid profile itself, and CP4 EPSPS protein produced in MON 87705 are characteristics of the GMHP that may, theoretically, cause an adverse environmental effect. However, as the scope of the current application does not include planting of

MON 87705 varieties in the EU, any meaningful exposure of non-target organisms to this soybean is highly unlikely.

Furthermore, no adverse effects were observed in field trials conducted since 2007 across a broad geographic range of environments involving MON 87705.

9.6 Effects on human health

The likelihood for any adverse effects occurring in humans as a result of their contact with MON 87705 is no different from that of conventional soybean, as MON 87705 contains the CP4 EPSPS protein, which has negligible potential to cause any toxic or allergenic effects in humans.

MON 87705 was shown to be compositionally equivalent to conventional soybean with the exception of the improved fatty acid profile. No substantial differences from conventional soybean were found with respect to safety characteristics and agronomic and phenotypic characteristics.

The likelihood for any adverse effects occurring in humans as a result of their contact with this soybean is no different from conventional soybean, as MON 87705 has an improved fatty acid profile and contains dsRNAs and the CP4 EPSPS protein, 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 is negligible.

9.7 Effects on animal health

Based on centuries of experience with conventional, domesticated soybean in Europe, there is negligible potential for soybean to cause any adverse health effects in animals. MON 87705 contains the CP4 EPSPS protein, which has negligible potential to cause any toxic or allergenic effects in humans.

MON 87705 has no meaningful compositional differences compared to conventional soybean with the exception of the improved fatty acid profile. As previously discussed, the CP4 EPSPS protein has a history of safe use and its safety has been extensively investigated.

No substantial differences with conventional soybean were found with respect to safety characteristics and agronomic and phenotypic characteristics.

The likelihood of potential adverse effects in animals fed on MON 87705 and in humans consuming those animals, is no different from conventional soybean, as MON 87705 has an improved fatty acid profile and contains dsRNAs and the CP4 EPSPS protein, which have negligible potential to cause any toxic or allergenic effects in humans. is negligible. Therefore, the risk of MON 87705 on the food/feed chain is also negligible.

9.8 Effects on biogeochemical processes

This application is limited to import of MON 87705 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 87705 during transport or storage of grain could cause some seed to 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 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.

Soybean production in general is known to have indirect impacts on biogeochemical processes through tillage, fertilizer application, and establishment of a monoculture in a defined area. As MON 87705 was shown to be compositionally equivalent to conventional soybean with no biologically meaningful differences in agronomic and phenotypic characteristics, except for the inherited traits, there is no evidence that this soybean would be any different from conventional soybean regarding its influence on biogeochemical processes and nutrient levels in the soil. 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.

Therefore, in the event of an incidental release of MON 87705 in the environment, the risk for direct or indirect, immediate or delayed adverse effects on biogeochemical processes is negligible.

9.9 Impacts of the specific cultivation, management and harvesting techniques

Not applicable. This application is for consent to import MON 87705 in the EU and for the use of this soybean as any other soybean, excluding the cultivation of MON 87705 varieties in the EU.

10. Potential interactions with the abiotic environment

MON 87705 was shown to be compositionally equivalent to conventional soybean, with the exception of the improved seed fatty acid profile and glyphote-tolerance trait. There are no substantial differences from conventional soybean with respect to safety characteristics and agronomic and phenotypic characteristics, and thus, there is no evidence that this soybean would be any different from conventional soybean with regard to its baseline interactions with the abiotic environment.

Although the improved seed fatty acid profile and glyphosate-tolerance are the introduced traits in soybean, they have no known negative interactions with the abiotic environment. The fatty acids present in MON 87705 seed are widely prevalent in the environment. As natural components of the

plant and animal world, these fatty acids are not expected to accumulate, persist or be detrimental to the environment. CP4 EPSPS is an introduced protein in soybean, however it has a history of safe use and has no known negative interactions with the abiotic environment. The CP4 EPSPS protein is innocuous and belongs to a large class of EPSPS enzymes that are ubiquitous in nature. The family of EPSPS proteins has no known negative interactions with the abiotic environment.

Because this application is for import into the EU, interactions of MON 87705 with the environment will be limited. Moreover no negative impact of MON 87705 on the abiotic environment is expected to result from the import, processing or all uses of this product 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 (ERA) of MON 87705 was undertaken in the context of the scope of the application, that is, for import, processing and all uses of MON 87705 as any other soybean, but not including the cultivation of MON 87705 varieties in the EU. Analysis of the characteristics of MON 87705 has shown that the risk for potential adverse effects on human health and the receiving environment, resulting from the proposed use of MON 87705 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 87705 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 87705 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 87705 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 87705 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 *FATB1-A/FAD2-1A* suppression cassette, the *cp4 epsps* gene and the CP4 EPSPS protein 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 CP4 EPSPS protein can be detected in all tissues of MON 87705, by optimised tissue extraction, standardised electrophoretic blotting and immunodetection methodologies.

A MON 87705-specific PCR assay allowing the identification and the quantification of MON 87705 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 87705 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 87705 has been field tested in the US since 2005, Argentina from 2006-2007, Chile in 2006-2007 and Japan 2009.

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, Maryland, Michigan, Missouri, Mississippi, Nebraska, Ohio, Pennsylvania, Puerto Rico (Isabela, Juana Diaz and Montana) and Wisconsin).

Argentina: Buenos Aires, Santa Fe

Chile: Santiago Metro, O'Higgins

Japan: Ibaraki Prefecture

d) Aim of the release

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

Japan: Stage III environmental assessment.

e) Duration of the release

US : Five growing seasons

Argentina: Three growing seasons

Chile: One growing season

Japan: One growing season.

f) Aim of post-releases monitoring

US/Argentina/Chile: Assessment of volunteers.

g) Duration of post-releases monitoring

US/Argentina/Chile: 12 months.
Note: The volunteers in Puerto Rico field trials were monitored 6 months after destruct date of the trial.

h) Conclusions of post-release monitoring

US/Argentina/Chile: 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 87705 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 87705.
b) Assessment Report of the Competent Authority (Directive 2001/18/EC) A notification for MON 87705 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/