

**Application for authorization to place on the market
MON 87708 × MON 89788 soybean
in the European Union, according to
Regulation (EC) No 1829/2003
on genetically modified food and feed**

Part VII

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.

1. GENERAL INFORMATION

1.1. Details of application

- (a) Member State of application

The Netherlands

- (b) Application 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 87708 × MON 89788. Currently, no commercial name has been attributed to this product.

- (d) Date of acknowledgement of valid application

Not available at the time of submission.

1.2. Applicant

- (a) Name of applicant

Monsanto Company, represented by Monsanto Europe S.A.

- (b) Address of applicant

Monsanto Europe S.A.

Avenue de Tervueren 270-272

B-1150 Brussels

BELGIUM

Monsanto Company

800 N. Lindbergh Boulevard

St. Louis, Missouri 63167

US

- (c) Name and address of the representative of the applicant established in the Union (if the applicant is not established in the Union)

See above.

1.3. Scope of the application

- (a) GM food

- ☒ Food containing or consisting of GM plants
- ☒ Food produced from GM plants or containing ingredients produced from GM plants

- (b) GM feed

- ☒ Feed containing or consisting of GM plants
- ☒ Feed produced from GM plants

- (c) GM plants for food or feed use

- ☒ Products other than food and feed containing or consisting of GM plants with the exception of cultivation
- ☐ Seeds and plant propagating material for cultivation in the EU

1.4. Is the product or the uses of the associated plant protection product(s) already authorised or subject to another authorisation procedure within the Union?

No ☒

Yes ☐ (in that case, specify)

1.5. Has the GM plant been notified under Part B of Directive 2001/18/EC?

Yes ☐

No ☒ (in that case, provide risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC)

The protein expression, the composition, the safety and the agronomic and phenotypic characteristics of MON 87708 × MON 89788 have been studied at multiple locations in the US that cover a range of environmental conditions. The risk assessment presented in the MON 87708 × MON 89788 application includes data collected from these field trials. A summary of the conclusions of the risk analysis that demonstrate the safety of MON 87708 × MON 89788 to humans, animals and to the environment, has been presented in the respective sections throughout this summary.

1.6. Has the GM plant or derived products been previously notified for marketing in the Union under Part C of Directive 2001/18/EC?

No ☒

Yes ☐ (in that case, specify)

1.7. Has the product been notified/authorised in a third country either previously or simultaneously?

No ☒

Yes ☐ (in that case, specify the third country and provide a copy of the risk assessment conclusions, the date of the authorisation and the scope)

Applications for the full range of uses will be made in Argentina, Brazil, Canada and Japan. Regulatory submissions will also be made to countries that import significant quantities of soybean or food and feed products derived from soybean and that have regulatory approval processes in place. These will include submissions to countries such as Colombia, The Philippines, Mexico, Taiwan, and Korea.

1.8. General description of the product

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

MON 87708 × MON 89788 was obtained by traditional breeding of two parental lines, one derived from MON 87708 and the other one derived from MON 89788.

MON 87708, developed through *Agrobacterium*-mediated transformation of soybean tissues, contains a gene derived from *Stenotrophomonas maltophilia* (*S. maltophilia*) that expresses DMO, a mono-oxygenase enzyme that rapidly demethylates dicamba rendering it inactive, thereby conferring tolerance to dicamba.

MON 89788 also developed through *Agrobacterium*-mediated transformation of soybean tissues, contains a gene derived from *Agrobacterium* sp. strain CP4 (*cp4 epsps*) that expresses CP4 EPSPS protein conferring tolerance to glyphosate.

- (b) Types of products planned to be placed on the market according to the authorisation applied for and any specific form in which the product must not be placed on the market (seeds, cut-flowers, vegetative parts, etc.) as a proposed condition of the authorisation applied for

The scope of the current application is for authorisation of MON 87708 × MON 89788 in the EU for all uses according to Art 3(1) and 15(1) of Regulation (EC) No 1829/2003, with the exception of cultivation. The range of uses of this soybean will be identical to the full range of equivalent uses of conventional soybean.

- (c) Intended use of the product and types of users

MON 87708 × MON 89788 soybean 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) Any specific instructions and/or recommendations for use, storage and handling, including mandatory restrictions proposed as a condition of the authorisation applied for

MON 87708 × MON 89788 is not different from conventional soybean, except for its tolerance to dicamba and glyphosate, which are traits of agronomic interest and was shown to be as safe and nutritious as conventional soybean. Therefore, MON 87708 × MON 89788 and its derived products will be stored, packaged, transported, used and handled in the same manner as current commercial soybean. No specific conditions or instructions are warranted or required for the placing on the market of MON 87708 × MON 89788 for import, processing and all uses as specified in Section 1.8(b) above.

- (e) If applicable, geographical areas within the EU to which the product is intended to be confined under the terms of the authorisation applied for.

MON 87708 × MON 89788 is suitable for use throughout the EU as any other soybean. The scope of this application covers the import, processing and all uses of MON 87708 × MON 89788, excluding cultivation.

- (f) Any type of environment to which the product is unsuited

MON 87708 × MON 89788 is suitable for use throughout the EU as any other soybean. The scope of this application covers the import, processing and all uses of MON 87708 × MON 89788, excluding cultivation.

- (g) Any proposed packaging requirements

MON 87708 × MON 89788 is not different from conventional soybean, except for its tolerance to dicamba and glyphosate. Therefore, MON 87708 × MON 89788 and derived products will be used in the same manner as other soybean and no specific packaging is required.

- (h) Any proposed labelling requirements in addition to those required by law and when necessary a proposal for specific labelling in accordance with Articles 13(2), (3) and 25(2)(c), (d) and 25(3) of Regulation (EC) No 1829/2003. In the case of GMO plants, food and/or feed containing or consisting of GMO plants, a proposal for labelling has to be included complying with the requirements of Annex IV, A(8) of Directive 2001/18/EC.

In accordance with Regulations (EC) No. 1829/2003 and 1830/2003, the current labelling threshold of 0.9% will continue to be applied for the marketing of MON 87708 × MON 89788 and derived products.

Operators shall be required to label products containing or consisting of MON 87708 × MON 89788 with the words “genetically modified soybean” or “contains genetically modified soybean” and shall continue to declare the unique identifier MON-87708-9 × MON-89788-1 in the list of GMOs that have been used to constitute a mixture that contains or consists of this GMO.

Operators shall be required to label foods and feeds derived from MON 87708 × MON 89788 with the words “produced from genetically modified soybean”. In the case of products for which no list of ingredients exists, operators shall continue to ensure that an indication that the food or feed product is produced from GMOs is transmitted in writing to the operator receiving the product.

Operators handling or using MON 87708 × MON 89788 and derived foods and feeds in the EU shall be required to be aware of the legal obligations regarding traceability and labelling of these products. Given that explicit requirements for the traceability and labelling of GMOs and derived foods and feeds are laid down in Regulations (EC) No. 1829/2003 and 1830/2003, and that authorized foods and feeds shall be entered in the Community Register, operators in the food/feed chain will be fully aware of the traceability and labelling requirements for MON 87708 × MON 89788. Therefore, no further specific measures are to be taken by the applicant.

(i) Estimated potential demand

(i) In the Union

The EU is not a significant soybean producer. In 2010, the soybean area harvested in the EU-27 accounted for approximately 374 thousand hectares¹ distributed principally between Italy, Romania and France, Hungary and Austria (42.6%, 16.9%, 13.6%, 10.1% and 9.2% of the harvested area, respectively). Because of its low production and its high demand, especially for animal consumption, the EU is the world's largest importer of soybean meal (22 million metric tons of soybean meal were imported in the EU-27 during the period 2010-2011) and the second largest importer of whole soybeans, after China. 13 million metric tons of soybeans were imported in the EU-27 during the period 2010-2011².

(ii) In export markets for EU supplies

Soybean imports into the EU mainly come from Brazil, the US, Paraguay and Canada while soybean meal is largely imported from Argentina, Brazil and the US. Imports of soybean oil are principally from Argentina, Russia and Brazil.

(j) Unique identifier in accordance with Regulation (EC) No 65/2004

The unique identifier for this genetically modified soybean is MON-87708-9 × MON-89788-1.

1.9. 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 87708 × MON 89788 as any other soybean, not including the cultivation of varieties of MON 87708 × MON 89788 in the EU, the only potential means of environmental release would be during import, storage and processing of MON 87708 × MON 89788. However, modern methods of soybean handling minimize losses of seed, so there is little

¹ <http://faostat.fao.org/site/567/DesktopDefault.aspx?PageID=567#ancor> – Accessed on March 22, 2012.

² <http://www.fas.usda.gov/psdonline/psdHome.aspx> – Accessed on March 22, 2012.

chance of germination of spilt soybeans resulting in the development of mature MON 87708 × MON 89788 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 87708 × MON 89788 is shown to be not different from conventional soybean, except for the dicamba and glyphosate-tolerance traits, 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 herbicides (other than dicamba and glyphosate) or by mechanical means. Therefore, no specific conditions are warranted or required for the placing on the market of MON 87708 × MON 89788 for import, processing and all uses as specified in Section 1.8 (b).

2. INFORMATION RELATING TO THE RECIPIENT OR (WHERE APPROPRIATE) PARENTAL PLANTS

2.1. Complete name

(a) Family name

Leguminosae

(b) Genus

Glycine Willd.

(c) Species

max

(d) Subspecies

Not applicable

(e) Cultivar/breeding line or strain

A3525

(f) Common name

Soybean

2.2. Geographical distribution and cultivation of the plant, including the distribution within the Union

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 EU are Italy followed by France, Romania, Hungary and Austria.

2.3. Information concerning reproduction (for environmental safety aspects)

(a) 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.

(b) 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.

(c) 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.

2.4. Sexual compatibility with other cultivated or wild plant species (for environmental safety aspects)

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 87708 × MON 89788 varieties in the EU. Therefore, any outcrossing between MON 87708 × MON 89788 and cultivated *Glycine* varieties is highly unlikely.

Outcrossing with wild soybean species

From a taxonomic standpoint, both the wild annual species of subgenus *Soja* and the wild perennial species of subgenus *Glycine* are candidates for gene exchange with the cultivated soybean. No other genus is 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.

2.5. Survivability (for environmental safety aspects)

(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) Specific factors affecting survivability

See Section 2.5 (a).

2.6. Dissemination (for environmental safety aspects)

(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 Section 2.4.

(b) Specific factors affecting dissemination

See Section 2.6 (a).

2.7. Geographical distribution within the Union of the sexually compatible species (for environmental safety aspects)

There are no sexually compatible species of cultivated soybean present in Europe.

2.8. 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 (for environmental safety aspects)

Not applicable, as soybean is grown in Europe.

2.9. 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 (for environmental safety aspects)

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 experienced 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.

3. MOLECULAR CHARACTERISATION

3.1. Information relating to the genetic modification

(a) Description of the methods used for the genetic modification

MON 87708 × MON 89788 is produced by crossing soybean plants of MON 87708 and MON 89788 using traditional breeding methods. Both parental lines, MON 87708 and MON 89788, were developed through *Agrobacterium*-mediated transformation of soybean tissues.

(b) Nature and source of the vector used

MON 87708 × MON 89788 results from traditional breeding of MON 87708 and MON 89788 and no vector has been used to produce this combined trait soybean.

However, genetic modification has been used in the development of the parental soybean lines by *Agrobacterium*-mediated transformation using vectors PV-GMHT4355 (in the case of MON 87708) and PV-GMGOX20 (in the case of MON 89788).

Plasmid vector PV-GMHT4355 contains two T-DNAs. The first T-DNA designated T-DNA I, contains the *dmo* expression cassette. The second T-DNA, designated T-DNA II, contains the *cp4 epsps* 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 containing the *dmo* expression cassette is the portion of plasmid PV-GMHT4355 maintained in MON 87708.

Plasmid vector PV-GMGOX20 is a binary vector containing a T-DNA which hosts the *cp4 epsps* expression cassette.

- (c) Source of donor DNA used for transformation, size and intended function of each constituent fragment of the region intended for insertion

MON 87708 × MON 89788 results from traditional breeding of MON 87708 and MON 89788 and therefore, MON 87708 × MON 89788 inherits the inserted DNA fragments from both parental soybean lines.

The genetic elements of PV-GMHT4355 intended for insertion into MON 87708 comprised between the T-DNA I borders are from the right border region, the *PCISV* promoter (P-*PCISV*), the *TEV* leader (L-*TEV*), the *RbcS* targeting sequence (TS-*RbcS*), the *dmo* coding sequence (CS-*dmo*) and the *E9* 3' non-translated region (T-*E9*). These elements together constitute the *dmo* expression cassette.

The genetic elements of PV-GMGOX20 intended for insertion into MON 89788 comprised between the T-DNA borders are: the *cp4 epsps* coding sequence (*cp4 epsps*) from *Bacillus thuringiensis*, the *FMV/Tsfl* promoter (*FMV/Tsfl*) from the Figwort Mosaic Virus and *Arabidopsis thaliana*, the non-translated *Tsfl* leader sequence (*Tsfl*) from *Arabidopsis thaliana*, and the *Tsfl* intron (*Tsfl*) from *Arabidopsis thaliana*, the *CTP2* chloroplast transit peptide (*CTP2*) from *Arabidopsis thaliana* and the *E9* transit termination sequence (*E9*) from *Glycine max*.

The individual components and the function of the DNA sequences intended for insertion into MON 87708 and MON 89788 are given in Tables 1 and 2.

Table 1. Summary of genetic elements intended for insertion in MON 87708

Genetic Element	Size (kb)	Source	Function
B - Right Border Region	0.36	<i>Agrobacterium tumefaciens</i>	Portion of the right border region used for transfer of the T-DNA remaining after integration
P - <i>PCISV</i>	0.43	Peanut chlorotic streak caulimovirus	Promoter
L - <i>TEV</i>	0.13	Tobacco Etch virus	Leader
TS - <i>RbcS</i>	0.24	<i>Pisum sativum</i> (pea)	Targeting sequence
CS - <i>dmo</i>	1.02	<i>Stenotrophomonas maltophilia</i>	Coding sequence for the MON 87707 DMO protein
T - <i>E9</i>	0.64	<i>Pisum sativum</i> (pea)	Transcript termination sequence
B - Left Border Region	0.44	<i>Agrobacterium tumefaciens</i>	Portion of the left border region used for transfer of the T-DNA remaining after integration

B – Border; P – Promoter; L – Leader; TS – Targeting sequence; CS – Coding sequence; T – 3' nontranslated transcriptional termination and polyadenylation signal sequences.

Table 2. Summary of genetic elements intended for insertion in MON 89788

Genetic element	Size (kb)	Source	Function
B – Right Border Region	0.04	<i>Agrobacterium tumefaciens</i>	Portion of the right border region used for transfer of the T-DNA remaining after integration
P – FMV/TsfI	1.04	Figwort Mosaic Virus and <i>Arabidopsis thaliana</i>	Promoter
L – TsfI	0.05	<i>Arabidopsis thaliana</i>	Leader
I – TsfI	0.62	<i>Arabidopsis thaliana</i>	Intron
TS – CTP2	0.23	<i>Arabidopsis thaliana</i>	Targeting sequence
CS – cp4 epsps	1.37	<i>Bacillus thuringiensis</i>	Coding sequence for the CP4 EPSPS protein
T – E9'	0.64	<i>Glycine max</i>	Transcript termination sequence
B – Left Border Region	0.15	<i>Agrobacterium tumefaciens</i>	Portion of the left border region used for transfer of the T-DNA remaining after integration

B – Border; P – Promoter; L – Leader; I – Intron; TS – Targeting sequence; CS – Coding sequence; T – 3' nontranslated transcriptional termination and polyadenylation signal sequences.

3.2. Information relating to the GM plant

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

MON 87708 × MON 89788 is produced by crossing MON 87708 and MON 89788 using traditional breeding methods and expresses:

- A mono-oxygenase enzyme (DMO) that rapidly demethylates dicamba (3,6-dichloro-2-methoxybenzoic acid) rendering it inactive, thereby conferring tolerance to dicamba herbicide.
- The CP4 EPSPS protein which imparts tolerance to glyphosate herbicide.

The use of MON 87708 × MON 89788 will enable growers to utilize both dicamba and glyphosate for effective control of weeds.

3.2.2. Information on the sequences actually inserted or deleted

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

The genome of MON 87708 × MON 89788 contains two different inserts, one derived from MON 87708 and one derived from MON 89788. The results of Southern blot analyses on MON 87708 and MON 89788 indicate that each of these parental lines contain a single copy of the T-DNA of interest at a single insertion site. The presence of these two inserts in MON 87708 × MON 89788 was confirmed through Southern blot analysis.

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

MON 87708 × MON 89788 is produced by traditional breeding crossing MON 87708 and MON 89788. Since the inserts present in MON 87708 × MON 89788 correspond to those of the parental lines, the characteristics of the insertions and the 5' and 3' flanking sequences should be conserved in this combined-trait product. No deletion was intended in the development of the single parental lines. However, the analysis of the molecular

structure of MON 87708 identified a 899 bp deletion (and a 128 bp insertion just 5' of T-DNA I, and a 35 bp insertion just 3' of T-DNA I) of soybean genomic DNA sequence at the site of cassette insertion. The analysis of the genomic organization of the MON 89788 insertion site identified a 40 bp deletion. Deletions and/or insertions of DNA due to double-strand break repair mechanisms in the plant during *Agrobacterium*-mediated transformation process are not uncommon. Furthermore, the bioinformatic analyses of the DNA sequences flanking the insertion sites of MON 87708 and MON 89788 revealed that there is no known function associated with these deleted regions and therefore it is not expected that they could affect the safety of these two products, or of the combined product MON 87708 × MON 89788.

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

The respective analyses of the segregation results for MON 87708 and MON 89788 are consistent with single active sites of integration of the inserts into the nuclear genomic DNA. Southern blot analyses further demonstrate the stability of the inserted sequences of MON 87708 and MON 89788, respectively, and their progeny. The traditionally bred MON 87708 × MON 89788 contains both of the parental inserts and Southern analyses confirm that no detectable rearrangements of these inserts occurred.

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

Since the inserts present in MON 87708 × MON 89788 correspond to those of the parental lines, the characteristics of the insertions and the 5' and 3' flanking sequences should be conserved in this combined trait product.

- (e) In case of modifications other than insertion or deletion, describe function of the modified genetic material before and after the modification as well as direct changes in expression of genes as a result of the modification

Not applicable.

3.2.3. *Information on the expression of the insert*

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

MON 87708 × MON 89788 produces MON 87708 DMO and CP4 EPSPS proteins, providing tolerance to dicamba and glyphosate.

The levels of the MON 87708 DMO and CP4 EPSPS proteins in various tissues of MON 87708 × MON 89788 collected from a field trial conducted in the US during 2009 were assessed by validated enzyme-linked immunosorbent assay (ELISA). Tissues were collected from each replicated plot at eight field sites.

The mean DMO protein levels in MON 87708 × MON 89788 across all sites were, 33 µg/g dwt in forage, and 41 µg/g dwt in seed. The mean CP4 EPSPS protein levels in MON 87708 × MON 89788 across all sites were, 87 µg/g dwt in forage and 93 µg/g dwt in seed.

- (b) Parts of the plant where the insert is expressed

The expression of the MON 87708 DMO and CP4 EPSPS proteins occurs throughout the plant at appropriate times of plant development. In terms of food and feed safety assessment of MON 87708 × MON 89788, seed and forage are the most relevant tissues.

3.2.4. *Genetic stability of the insert and phenotypic stability of the GM plant*

MON 87708 × MON 89788 is produced by crossing MON 87708 and MON 89788 parental lines by traditional breeding. Thereby, each parental line passes on its inserted DNA sequence to the resulting MON 87708 × MON 89788 combined trait seed.

The respective analyses of the segregation results for MON 87708 and MON 89788 are consistent with single active sites of integration of the inserts into the nuclear genomic DNA. Southern blot analyses further demonstrate the stability of the inserted sequences of MON 87708 and MON 89788, respectively, and in their progeny.

3.2.5. *Information (for environmental safety aspects) on how the GM plant differs from the recipient plant in:*

(a) Mode(s) and/or rate of reproduction

Phenotypic and agronomic as well as environmental interaction data were collected from eight sites at field trials conducted in 2009 in major US soybean growing regions. Randomized complete block design with four replicates at each field site was used. In each of the assessments MON 87708 × MON 89788, either treated or not with dicamba and glyphosate, was compared to an appropriate soybean conventional counterpart (control) which has a genetic background similar to MON 87708 × MON 89788 but does not possess the *dmo* or the *cp4 epsps* expression cassettes. In addition, multiple commercial soybean varieties (references; three per site; a total of 14 different varieties) 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 of this field study showed that there are no unexpected changes in the phenotype or ecological interactions indicative of increased pest or weed potential of MON 87708 × MON 89788 compared to the conventional soybean counterpart. These results concur with those obtained previously for the single traits MON 87708 and MON 89788.

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 87708 × MON 89788 and that MON 87708 × MON 89788 is equivalent to conventional soybean in its phenotypic and agronomic behaviour, except for the dicamba and glyphosate-tolerance traits.

(b) Dissemination

See Section 3.2.5 (a).

(c) Survivability

See Section 3.2.5 (a).

(d) Other differences

See Section 3.2.5 (a).

3.2.6. *Any change to the ability of the GM plant to transfer genetic material to other organisms (for environmental safety aspects)*

(a) Plant to bacteria gene transfer

None of the genetic elements in MON 87708 and MON 89788 has a genetic transfer function. Therefore, no changes are expected in the ability of these soybeans or MON 87708 × MON 89788 to transfer genetic material to bacteria.

(b) Plant to plant gene transfer

Based on the observation that reproductive morphology in MON 87708, MON 89788 and MON 87708 × MON 89788 is unchanged compared to conventional soybean, the outcrossing frequency to other soybean varieties or to wild relatives (which are not present in the EU) would be unlikely to be different for MON 87708 × MON 89788 when compared to MON 87708 and MON 89788, or when compared to other conventional soybean varieties.

Moreover, the scope of the current application does not include the cultivation of MON 87708 × MON 89788 varieties in the EU.

4. COMPARATIVE ANALYSIS

4.1. Choice of the conventional counterpart and additional comparators

MON 87708 × MON 89788 was compared to a conventional soybean counterpart with background genetics similar to MON 87708 × MON 89788, as well as with other commercially available soybean varieties.

4.2. Experimental design and statistical analysis of data from field trials for comparative analysis

Description of the experimental design (Number of locations, growing seasons, geographical spread, replicates and number of commercial varieties in each location).

MON 87708 × MON 89788 and soybean conventional counterpart were grown at eight field sites in major soybean-growing areas of US during the 2009 field season. Three commercially available conventional 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 test, control and reference seed were planted in a randomized complete block design with four replicates per block. All the plants were grown under normal agronomic field conditions for their respective geographic regions. The test MON 87708 × MON 89788 was either treated with dicamba and glyphosate herbicides or untreated.

An analysis of variance (ANOVA) was conducted in a combined-site analysis in which the data was pooled across all sites. ANOVA models were chosen to perform difference and equivalence tests according to the 2010 EFSA Scientific opinion on statistical considerations for the safety evaluation of GMOs.

4.3. Selection of material and compounds for analysis

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

4.4. Comparative analysis of agronomic and phenotypic characteristics

An assessment of the phenotypic, agronomic and environmental interactions of MON 87708 × MON 89788 compared to conventional soybean has been performed in the field. It was guided by the OECD concept of familiarity by scientists who are familiar with the production and evaluation of soybean.

Results of this field study showed that there are no unexpected changes in the phenotype or ecological interactions indicative of increased pest or weed potential of MON 87708 × MON 89788 compared to the soybean conventional counterpart. These results concur with those obtained previously for the single traits products MON 87708 and MON 89788.

4.5. Effect of processing

MON 87708 × MON 89788 has been shown not to be different from conventional soybean, except for the dicamba and glyphosate-tolerance traits. The processing of MON 87708 × MON 89788 is therefore not expected to be any different from that of conventional soybeans.

5. TOXICOLOGY

(a) Toxicological testing of newly expressed proteins

MON 87708 × MON 89788 is produced by traditional breeding of MON 87708 and MON 89788. Both of the introduced traits from the parental lines are inherited by the MON 87708 × MON 89788 progeny. This results in the combined expression of the MON 87708 DMO and CP4 EPSPS proteins in the same plant. Therefore, the safety assessment of newly expressed proteins is based on the characterization and safety of those two proteins. The conclusion of safety to humans of the MON 87708 DMO and CP4 EPSPS proteins was based upon the following considerations:

- The DMO and CP4 EPSPS proteins have a demonstrated history of safe use;
- The MON 87708 DMO and CP4 EPSPS proteins have no structural similarity to known toxins or other biologically active proteins that could cause adverse effects in humans or animals;
- The MON 87708 DMO and CP4 EPSPS proteins do not exert any acute toxic effects on mammals;
- The MON 87708 DMO and CP4 EPSPS proteins have a large margin of exposure (MOE)

In addition, the rapid digestibility of MON 87708 DMO and CP4 EPSPS in simulated gastric fluid provides additional assurance of their safety.

It is therefore possible to conclude that the MON 87708 DMO and CP4 EPSPS proteins are safe and pose no concerns for humans, animals and the environment.

(b) Testing of new constituents other than proteins

Soybean has a long history of safe use and consumption around the world. MON 87708 × MON 89788 was demonstrated to be compositionally similar to conventional soybean. There are no new constituents present in MON 87708 × MON 89788 and therefore, no further testing is required.

(c) Information on natural food and feed constituents

Soybean is known to contain a number of natural anti-nutritional components, such as trypsin inhibitors, lectins, isoflavones (daidzein, genistein and glycitein), 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 87708 × MON 89788 compositional analyses and their levels were demonstrated to be comparable in MON 87708 × MON 89788 and in conventional soybean.

(d) Testing of the whole GM food/feed

The safety assessment demonstrates that MON 87708 × MON 89788 is as safe as conventional soybean for food and feed use through the compositional assessment of MON 87708 × MON 89788 harvested seed and forage to harvested seed and forage from conventional soybean already on the market. The safety for humans and animals of the MON 87708 DMO and CP4 EPSPS proteins has been demonstrated on the basis of extensive characterization, history of safe use, lack of structural similarities with known protein toxins and allergens, absence of acute toxicity in oral gavage studies in rodents and rapid digestion in simulated digestive fluids. Moreover, the history of safe use of the introduced proteins and the familiarity of the host organisms from which the genes are derived have been demonstrated.

Based on this weight of evidence, no more data is required to demonstrate that MON 87708 × MON 89788 is as safe as conventional soybean from a food and feed perspective and therefore it can be concluded that there was no evidence of any adverse effects on human or animal health.

6. ALLERGENICITY

(a) Assessment of allergenicity of the newly expressed protein

It is unlikely that the MON 87708 DMO and CP4 EPSPS proteins will cause allergenic concerns due to the following considerations:

- The MON 87708 DMO and CP4 EPSPS proteins were obtained from a non-allergenic source (*Stenotrophomonas maltophilia* and *Agrobacterium* sp. strain CP4, respectively);
- The MON 87708 DMO and CP4 EPSPS proteins constitute a very small portion of the total protein present in MON 87708 × MON 89788;
- The MON 87708 DMO and CP4 EPSPS proteins lack structural similarity to known allergens, as demonstrated by bioinformatics analyses;
- The MON 87708 DMO and CP4 EPSPS proteins are rapidly digested in simulated gastric fluid;

Based on a weight of evidence, it can be concluded that the allergenic potential of the MON 87708 DMO and CP4 EPSPS proteins is negligible and therefore, the proteins do not pose a significant allergenic risk.

(b) Assessment of allergenicity of the whole GM plant

MON 87708 × MON 89788 is produced by traditional breeding of MON 87708 and MON 89788. Both of the introduced traits from the parental lines are inherited by the MON 87708 × MON 89788 progeny. The assessment of a potential allergenicity of each of the parental lines against a conventional soybean has been previously performed. Results of these assessments support the conclusion that both MON 87708 and MON 89788 are comparable to conventional soybean in terms of allergenicity potential.

As MON 87708 DMO and CP4 EPSPS proteins expressed in MON 87708 × MON 89788 are not allergenic and as there are no new genetic modifications in MON 87708 × MON 89788, there are no reasons to believe that the expression of these proteins in MON 87708 × MON 89788 would alter its endogenous allergen content compared to commercial soybean.

7. NUTRITIONAL ASSESSMENT

(a) Nutritional assessment of GM food

The inherited traits in MON 87708 × MON 89788 are of agronomic interest, and are not intended to change any nutritional aspects of this soybean. The presence of these traits is not expected to alter patterns or volumes of soybean consumption.

Results of the extensive compositional analyses indicate that observed differences fell within the range of natural variability for soybean with a history of safe usage, and the seed and forage composition of MON 87708 × MON 89788 is not different to the seed and forage composition of the conventional counterpart. It is equivalent to seed and forage composition of the set of conventional commercial reference varieties, except for the expression of the MON 87708 DMO and CP4 EPSPS proteins

Overall, MON 87708 × MON 89788 reveals comparable nutritional characteristics to conventional counterpart soybean, as well as to soybean varieties in commerce. Hence this soybean is not expected to be more or less attractive for use as food (or feed), for processing or as a food (or feed) ingredient. Therefore, anticipated dietary intake of soybean-derived foods (and feeds) is not expected to be altered, and no nutritional imbalances are expected as a result of the presence of MON 87708 × MON 89788 in the soybean supply.

(b) Nutritional assessment of GM feed

See Section 7 (a).

8. EXPOSURE ASSESSMENT – ANTICIPATED INTAKE/EXTENT OF USE

There are no anticipated changes in the intake and/or extent of use of soybean or derived products for use as or in food or feed as a result of the addition of MON 87708 × MON 89788 to the soybean supply.

MON 87708 × MON 89788 is not expected to affect current usage patterns of soybean, but to replace a portion of the commodity seed from current soybean varieties such that their intake or use will represent some fraction of the total products derived from soybean.

9. RISK CHARACTERISATION FOR THE SAFETY ASSESSMENT OF GM FOOD AND FEED

Based on the information provided in this application, it can be concluded that MON 87708 × MON 89788 is as safe as conventional soybean. The molecular characterization of MON 87708 × MON 89788 did not raise any safety concern and did not show any evidence of unintended changes in MON 87708 × MON 89788. Detailed compositional comparisons of MON 87708 × MON 89788, its conventional counterpart and conventional commercial reference varieties demonstrated that MON 87708 × MON 89788 is compositionally similar to the conventional soybean counterpart and that MON 87708 × MON 89788 is not a contributor to compositional variability in soybean. The assessed phenotypic and agronomic characteristics of MON 87708 × MON 89788 were within the range expected for soybean and did not show any phenotypic changes indicative of increased plant weed/pest potential of MON 87708 × MON 89788 compared to conventional soybean. An extensive characterisation of the MON 87708 DMO and CP4 EPSPS proteins expressed in MON 87708 × MON 89788 confirmed that these proteins are safe for human and animal consumption. Additionally, the exposure assessment in humans and animals did not indicate any safety concerns.

In summary, 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 87708 × MON 89788. The consumption of food and feed derived from GM plants is as safe as the consumption of its respective comparators. It can be concluded that the food derived from a GM plant is not nutritionally disadvantageous for the consumer compared to the food which is intended to replace. Finally, it can be also concluded that the feed derived from a GM plant does not harm or mislead the consumer by impairing distinctive features of the animal products compared to conventionally produced feed.

10. POST-MARKET MONITORING ON GM FOOD/FEED

There are no intrinsic hazards related to MON 87708 × MON 89788 as no signs of adverse or unanticipated effects have been observed in a number of safety assessment studies.

The pre-market risk characterization for food and feed use of MON 87708 × MON 89788 demonstrates that the risks of consumption of MON 87708 × MON 89788 or its derived products are consistently negligible and no different from the risks associated with the consumption of conventional soybean. As a consequence, specific risk management measures are not indicated, and post-market monitoring of the use of soybean for food and feed is not considered warranted.

11. ENVIRONMENTAL ASSESSMENT

11.1. Mechanism of interaction between the GM plant and target organisms

According to the EFSA ERA Guidance, the primary focus for the assessment on target organisms is the development of resistance to the insect or pathogen tolerance traits expressed by the GM plant.

MON 87708 × MON 89788 has been developed to confer tolerance to dicamba and glyphosate, no target organisms are associated with this product, and therefore an assessment of the potential resistance development in target organisms resulting from import, processing and all uses as any other soybean, but excluding the cultivation of MON 87708 × MON 89788 in the EU is not relevant for this submission.

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

(a) Persistence and invasiveness including plant to plant gene flow

Results from the assessment support a conclusion that the abilities of MON 87708 × MON 89788, that receive the trait to persist in agricultural fields or invade non-agricultural habitats, are comparable to those of conventional soybean in the EU. Thus, MON 87708 × MON 89788 is not more likely to represent an agronomic problem in agricultural fields or become more invasive in natural habitats and no adverse effects on ecological functions within agricultural production fields or on biodiversity are expected as a result of the import, processing and all uses as any other soybean. Given the negligible hazard and the low levels of environmental exposure that could arise from the import, processing and all uses as any other soybean of this products and the fact that any exposure would be limited spatially and temporally, the uncertainties associated with this risk characterization and the probability of long-term adverse environmental effects are negligible.

(b) Potential for gene transfer

The scope of this application covers the import, processing, and food and feed use of MON 87708 × MON 89788 in the EU. Therefore, no deliberate release of viable plant material in the EU environment is expected, and interactions of MON 87708 × MON 89788 with the biotic environment will be limited. Given the low likelihood of occurrence of horizontal gene transfer and lack of adverse consequences if it were to occur, the import, processing, and food and feed use of MON 87708 × MON 89788 in the EU is not likely to adversely impact human, animal, or environmental health, and poses negligible risk. Considering the low exposure and lack of hazard from horizontal gene transfer of the *dmo* or *cp4 epsps* genes from MON 87708 × MON 89788 to micro-organisms, the uncertainties associated with this risk characterization and the probability of long-term adverse environmental effects are negligible.

(c) Interactions between the GM plant and target organisms

The scope of this application covers the import, processing and all uses as any other soybean, but excluding the cultivation of MON 87708 × MON 89788 in the EU, no deliberate release of viable plant material in the EU environment is expected and no target organisms are associated with this event. Therefore as cultivation of MON 87708 × MON 89788 in the EU is not in the scope of this application, an assessment of the potential resistance development in target organisms resulting from the import, processing and all uses as any other soybean is not relevant for this submission.

(d) Interactions of the GM plant with non-target organisms (NTO's)

The scope of this application covers the import, processing and all uses as any other soybean, but excluding the cultivation of MON 87708 × MON 89788 in the EU. Therefore, no deliberate release of viable plant material in the EU environment is expected and interactions of MON 87708 × MON 89788 with the biotic environment will be very limited. Importantly, MON 87708 DMO and CP4 EPSPS are heat inactivated during processing for feed and MON 87708 DMO and CP4 EPSPS can also be inactivated in the digestive tract of animals. Given the low levels of environmental exposure combined with low hazard from exposure to MON 87708 × MON 89788 to NTOs, the likelihood of adverse effects to NTO communities that perform in-field ecological functions and NTO communities outside of the field from import of MON 87708 × MON 89788 is negligible. Considering low exposure and hazard from MON 87708 × MON 89788 to NTOs, there is a low level of uncertainties associated with the conclusion of this NTO risk assessment and therefore the probability of long-term adverse environmental effects on NTOs is negligible.

(e) Effects on human and animal health

The scope of this application covers the import, processing and all uses as any other soybean, but excluding the cultivation of MON 87708 × MON 89788 in the EU. Therefore, no deliberate release of viable plant material in the EU environment is expected and interactions of MON 87708 × MON 89788 with humans and animal health will be limited to the occupational hazards associated with the storage, handling and processing of MON 87708 × MON 89788. Given the low levels of environmental exposure combined with the negligible hazard occurring from the contact of workers with MON 87708 × MON 89788 seeds, the likelihood of adverse effects on workers handling MON 87708 × MON 89788 import and processing in the EU is negligible.

(f) Effects on biogeochemical processes

The scope of this application covers the import, processing, and all uses of MON 87708 × MON 89788 in the EU as any other soybean (excluding the cultivation of MON 87708 ×

MON 89788). Therefore, no deliberate release of viable plant material in the EU environment is expected, and interactions of MON 87708 × MON 89788 with the biotic environment will be very limited. Importantly, MON 87708 DMO and CP4 EPSPS proteins are heat inactivated during processing for feed, and MON 87708 DMO and CP4 EPSPS can also be inactivated in the digestive tract of animals thereby limiting any exposure via faeces of animals fed processed or unprocessed seed of MON 87708 × MON 89788. Given the low level of environmental exposure combined with a lack of hazard, the import, processing, and food and feed use of MON 87708 × MON 89788 in the EU is not likely to adversely impact soil micro-organisms that perform ecological functions in-field or in non-agricultural habitats, and therefore poses negligible environmental risk. Considering the low exposure and hazard from MON 87708 × MON 89788 to soil micro-organisms, the uncertainties associated with this risk characterization and the probability of long-term adverse environmental effects are negligible.

(g) Impacts of the specific cultivation, management and harvesting techniques

Cultivation of MON 87708 × MON 89788 in the EU is not included in the scope of this application. An assessment of the impacts of specific cultivation, management and harvesting techniques of MON 87708 × MON 89788 is therefore not relevant for this application.

11.3. Potential interactions with the abiotic environment

MON 87708 × MON 89788 carries two traits of agronomic interest: tolerance to dicamba and glyphosate herbicides. As MON 87708 × MON 89788 was shown to be not different from conventional soybean (with the exception of the inherited traits, imparted by the expression of the MON 87707 DMO and CP4 EPSPS proteins), with respect to its composition, phenotypic and agronomic characteristics, 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 MON 87708 DMO and CP4 EPSPS are introduced proteins in soybean, they already have a safe history of use and have no known negative interactions with the abiotic environment.

In addition, because this application is for import, processing and all uses as any other soybean in the EU, interactions of MON 87708 × MON 89788 with the environment will be limited. Moreover no negative impact of MON 87708 × MON 89788 on the abiotic environment is expected to result from the import, processing and all uses as any other soybean in the EU.

11.4. Risk characterisation for the environmental risk assessment

Results from the environmental risk assessment which takes into consideration the risk characterization and includes results described above addressing risk hypotheses for the specific areas of assessment laid down in EFSA 2010 guidance, support a conclusion that the import, processing and all uses in the EU (excluding cultivation) of MON 87708 × MON 89788, as any other soybean, represents negligible risk to human and animal health and the environment, and poses no greater risk than the import and processing of conventional soybean. Because no immediate adverse effects are expected, the probability of long-term adverse effects is also negligible.

12. ENVIRONMENTAL MONITORING PLAN

(a) General (risk assessment, background information)

As required by Article 5(5)(b) and 17(5)(b) of Regulation (EC) No. 1829/2003, an environmental monitoring plan in accordance to Annex VII of Directive 2001/18/EC is included.

(b) Interplay between environmental risk assessment and monitoring

An environmental risk assessment (ERA) of MON 87708 × MON 89788 was undertaken in the context of the scope of the application, that is, for import, processing and all uses of MON 87708 × MON 89788 as any other soybean, but not including the cultivation of MON 87708 × MON 89788 varieties in the EU. Analysis of the characteristics of MON 87708 × MON 89788 has shown that the risk for potential adverse effects on human health and the receiving environment, resulting from the proposed use of MON 87708 × MON 89788 in the EU is consistently negligible. Therefore, the overall environmental risk posed by this genetically modified higher plant is negligible, and no specific strategies for risk management and no case-specific post-market monitoring actions are considered required.

(c) 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.

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

Any potential adverse effects of MON 87708 × MON 89788 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 87708 × MON 89788 and relevant legislation will be available for the relevant networks, in addition to further relevant information from a number of sources, including industry and government websites, official registers and government publications.

Following the approval of this soybean in the EU, the consent holder will approach key stakeholders and key networks of stakeholders of the product (including international grain traders, soybean processors and users of soybean seed for animal feed) and inform them that the product has been 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 87708 × MON 89788 will be provided to them.

Where there is scientifically valid evidence of a potential adverse effect (whether direct or indirect), linked to the genetic modification, then further evaluation of the consequence of that effect should be science-based and compared with available baseline information. Relevant baseline information will reflect prevalent use practices and the associated impact of these practices on the environment. Where scientific evaluation of the observation confirms the possibility of an unanticipated adverse effect, this would be investigated further to establish a correlation, if present, between the use of MON 87708 × MON 89788 and the observed effect. The evaluation should consider the consequence of the observed effect and remedial action, if necessary, should be proportionate to the significance of the observed effect.

(e) 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.

13. DETECTION AND EVENT-SPECIFIC IDENTIFICATION TECHNIQUES FOR THE GM PLANT

As MON 87708 × MON 89788 is the result of a traditional cross of MON 87708 and MON 89788, it contains both inserts in combination. Therefore, MON 87708 × MON 89788 is detectable using either the event-specific PCR method for detecting the introduced DNA present in MON 87708 or the equivalent method for MON 89788. However, as for all plants in which one or more events are combined by traditional breeding, the unambiguous detection of MON 87708 × MON 89788 in mixed consignments of seed will require single soybean seeds to be subjected to detection methods for both MON 87708 and MON 89788, and to test positive for both.

A MON 87708-specific PCR-based assay allowing the identification and quantification of MON 87708 has been provided to the Joint Research Centre (JRC), acting as the European Union Reference Laboratory (EURL). The detection method for MON 89788 has already been validated by the EURL.

14. INFORMATION RELATING TO PREVIOUS RELEASES OF THE GM PLANT (FOR ENVIRONMENTAL SAFETY ASPECTS)

14.1. 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 87708 × MON 89788 in the EU.

(b) Conclusions of post-release monitoring

Not applicable

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

Not applicable

14.2. History of previous releases of the GM plant carried out outside the Union by the same notifier

- (a) Release country

MON 87708 × MON 89788 has been field tested in the US since 2007, Argentina in 2009 and 2010, Chile in 2009 and Puerto Rico since 2006.

- (b) Authority overseeing the release

US and Puerto Rico: United States Department of Agriculture (USDA)

Argentina: Secretary of Agriculture, livestock, fishery and feed (SAGPyA)

Chile: Agriculture and Livestock Service (SAG)

- (c) Release site

US: In major soybean growing states (Alabama, Arkansas, Illinois, Indiana, Iowa, Kansas, Kentucky, Maryland, Minnesota, Mississippi, Missouri, Nebraska, North Carolina, Ohio, Pennsylvania, South Dakota, Tennessee and Wisconsin).

Argentina: Buenos Aires, Chaco and Santioga del Estero

Chile: Paine and Rancagua

Puerto Rico: Aguadilla, Juana Diaz and Isabela

- (d) Aim of the release

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

- (e) Duration of the release

US/Argentina/Chile/Puerto Rico: 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 87708 × MON 89788 or derived products would be the cause of any adverse effects to human health or to the environment.