Application for authorisation to place on the market MON 87708 × MON 89788 × A5547-127 soybean in the European Union, according to Regulation (EC) No 1829/2003 on genetically modified food and feed

EFSA-GMO-NL-2016-XXX / EFSA-GMO-Q-2016-XXXXX

Part VII

Summary of Application

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 any other names)

The Monsanto development code for this genetically modified soybean is MON 87708 × MON 89788 × A5547-127. 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 Tervuren 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) Genetically modified food

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

(b) Genetically modified feed

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

(c) Genetically modified plants for food or feed use

- ☑ Products other than food and feed containing of 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 genetically modified 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)

1.6. Has the genetically modified 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 subject to an application and/or authorised in a third country either previously or simultaneously to this application?

No ☐

Yes ☑ in that case, specify the third country, the date of application and, where available, a copy of the risk assessment conclusions, the date of the authorisation and the scope of the application

Regulatory submissions have been made in Mexico and Canada. Additional regulatory submissions are currently prepared to progress in selected countries around the world.

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 × A5547-127 is produced by crossing soybean plants containing MON 87708, MON 89788 and A5547-127 using traditional breeding methods. Therefore, this product inherited the traits as present in the parental lines, tolerance to dicamba (from MON 87708), glyphosate (from MON 89788) and glufosinate (from A5547-127).

(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 (such as seeds, cut-flowers, vegetative parts) as a proposed condition of the authorisation applied for

The scope of the current application is for authorisation of MON 87708 × MON 89788 × A5547-127 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 × A5547-127 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 recommendations for use, storage and handling, including mandatory restrictions proposed as a condition of the authorisation applied for

MON 87708 × MON 89788 × A5547-127 is not different from conventional soybean, except for its tolerance to dicamba, glyphosate and glufosinate, which are traits of agronomic interest. MON 87708 × MON 89788 × A5547-127 was shown to be as safe and nutritious as conventional soybean. Therefore, MON 87708 × MON 89788 × A5547-127 and derived products will be stored, packaged, transported, handeled and used in the same manner as curent commercial soybean. No specific instructions and/or recommendations are considered necessary for the placing on the market of MON 87708 × MON 89788 × A5547-127 for import, processing and all uses in the EU, as specified in Section 1.8(b) of this document.

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

MON 87708 × MON 89788 × A5547-127 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 × A5547-127, as any other soybean but excludes cultivation.

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

MON 87708 × MON 89788 × A5547-127 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 × A5547-127 as any other soybean but excludes cultivation.

(g) Any proposed packaging requirements

MON 87708 × MON 89788 × A5547-127 is not different from conventional soybean, except for its tolerance to dicamba, glyphosate and glufosinate. Therefore, MON 87708 × MON 89788 × A5547-127 and derived products will be used in the same manner as any other soybean and no specific packaging is required.

(h) Any proposed labelling requirements in addition to those required by other applicable EU legislation than Regulation (EC) No 1829/2003 and when necessary a proposal for specific labelling in accordance with Article 13(2) and (3), Article 25(2)(c) and (d) and Article 25(3) of Regulation (EC) No 1829/2003. In the case of products other than food and feed containing or consisting of genetically modified plants, a proposal for labelling has which complies with the requirements of point A(8) of Annex IV to Directive 2001/18/EC must be included.

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 × A5547-127 and derived products.

Operators shall be required to label products containing or consisting of MON 87708 × MON 89788 × A5547-127 with the words “genetically modified soybean” or “contains genetically modified soybean” and shall continue to declare the unique identifier MON-877Ø8-9 × MON-89788-1 × ACS-GMØØ6-4 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 × A5547-127 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 × A5547-127 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 EU Register of authorised GMOs, operators in the food/feed chain will be fully aware of the traceability and labelling requirements for MON 87708 × MON 89788 × A5547-127. Therefore, no further specific measures are to be taken by the applicant.

(i) Estimated potential demand

(i) In the EU

The EU is not a significant soybean producer. In 2015, the soybean area harvested in the EU accounted for approximately 859 thousand hectares distributed principally between Italy, France, Romania, Croatia, Hungary, Austria and Slovakia[1]. Because of its low production and high demand, especially for animal consumption, the EU imported 19 million metric tons of soybean meal in 2015 and 13 million metric tons of soybeans.

(ii) In EU export markets

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 Norway, Serbia, Bosnia, Herzegovina, Ukraine and Russia.

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

MON-877Ø8-9 × MON-89788-1 × ACS-GMØØ6-4

1.9. Measures suggested by the applicant to take in the case of unintended release or misuse of the product as well as measures for disposal and treatment

Because this application is for authorisation for import, process and all uses of MON 87708 × MON 89788 × A5547-127 as any other soybean, but excludes the cultivation of varieties of MON 87708 × MON 89788 × A5547-127 in the EU, the only potential means of environmental release would be more likely to occur during import, storage and processing of MON 87708 × MON 89788 × A5547-127. 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 87708 × MON 89788 × A5547-127 plants in the EU. Moreover, in the event of incidental spillage, the establishment of volunteer plants would be unlikely, since soybean cannot survive without human assistance and is not capable of surviving as a weed due to selection over centuries of cultivation. Soybean is not documented as a source of volunteer plants in rotational crops, which results from the combination of absence of seed dormancy, poor seed survivability in soils, frost sensitivity of soybean seedlings and soil preparations prior to the planting of a subsequent crop (which includes destruction of any existing vegetation and soil cultivation).

[1] Eurostat database, http://ec.europa.eu/eurostat/data/database, accessed on October 24 2016.

MON 87708 × MON 89788 × A5547-127 is shown not to be different from conventional soybean, except for its tolerance to dicamba, glyphosate and glufosinate. Therefore, MON 87708 × MON 89788 × A5547-127 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 (except dicamba, glyphosate and glufosinate) or by mechanical means. Therefore, no specific conditions are warranted or required for the placing on the market of MON 87708 × MON 89788 × A5547-127 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

MON 87708 × MON 89788 × A5547-127

(f) Common name

Soybean

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

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, Croatia and Hungary.

2.3. Information concerning reproduction (for environmental safety aspects)

(a) Mode(s) of reproduction

Soybean is a diploidised tetraploid (2n = 40 chromosomes) 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 a 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 × A5547-127 varieties in the EU. Therefore, any outcrossing between MON 87708 × MON 89788 × A5547-127 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 do not have pronounced seed 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 become established, volunteer plants would not compete well with the succeeding crop, and could be controlled readily by either mechanical or chemical means.

(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. In contrast to weed species that have various seed dispersal mechanisms, 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 and practices taken to reduce seed loss.

Soybean pollen may also be considered as a means 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 Union 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 genetically modified 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

Not applicable since MON 87708 × MON 89788 × A5547-127 is produced by crossing soybean plants containing MON 87708, MON 89788 and A5547-127 using traditional breeding methods. F_1 seed thereby inherits the traits from MON 87708, MON 89788 and A5547-127.

(b) Nature and source of the vector used

See Section 3.1.(a).

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

See Section 3.1.(a).

3.2. Information relating to the genetically modified plant

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

MON 87708 × MON 89788 × A5547-127 is produced by crossing MON 87708, MON 89788 and A5547-127 using traditional breeding methods and expresses:

- the DMO protein which imparts tolerance to dicamba;
- the CP4 EPSPS protein which imparts tolerance to glyphosate and
- the PAT protein which imparts tolerance to glufosinate.

3.2.2. *Information on the nucleic acid(s) sequences actually inserted or deleted*

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

The genome of MON 87708 × MON 89788 × A5547-127 contains three different inserts, one derived from each parental line. Molecular analyses on MON 87708, MON 89788 and A5547-127 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 three inserts in MON 87708 × MON 89788 × A5547-127 was confirmed through sequence analysis.

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

MON 87708 × MON 89788 × A5547-127 is produced by traditional breeding crossing MON 87708, MON 89788 and A5547-127. Since the inserts present in MON 87708 × MON 89788 × A5547-127 correspond to those of the parental lines, the characteristics of the insertions and the 5' and 3' flanking sequences should be conserved in this product.

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

The respective analyses of the segregation results for MON 87708, MON 89788 and A5547-127 are consistent with single active sites of integration of the inserts into the nuclear genomic DNA. MON 87708 × MON 89788 × A5547-127 contains the parental inserts and sequence analyses confirm that no detectable rearrangements of these inserts occurred in this product.

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

Since the inserts present in MON 87708 × MON 89788 × A5547-127 correspond to those of the parental lines, the characteristics of the insertions and the 5' and 3' flanking sequences should be conserved in this 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

The levels of the DMO, CP4 EPSPS and PAT proteins in various tissues of MON 87708 × MON 89788 × A5547-127 collected from a field trial conducted in the US during 2015 were assessed by validated enzyme-linked immunosorbent assay (ELISA). Tissues were collected from each replicated plot at five field sites. Results are presented in Table 1.

Table 1. Protein levels in MON 87708 × MON 89788 × A5547-127 (µg/g dwt)

	DMO	CP4 EPSPS	PAT
Forage	28	110	67
Seed	28	110	38

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

The expression of the DMO, CP4 EPSPS and PAT proteins occurs throughout the plant at appropriate times of plant development. In terms of food and feed safety assessment of MON 87708 × MON 89788 × A5547-127, seed and forage are the most relevant tissues.

3.2.4. *Genetic stability of the insert and phenotypic stability of the genetically modified plant*

MON 87708 × MON 89788 × A5547-127 is produced by crossing soybean plants containing MON 87708, MON 89788 and A5547-127 using traditional breeding methods. Thereby, each parental line passes on its inserted DNA sequence to the resulting MON 87708 × MON 89788 × A5547-127.

Sequence analyses demonstrate the presence of the inherited sequences in MON 87708 × MON 89788 × A5547-127.

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

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

Phenotypic and agronomic characterizations, as well as environmental interaction data were collected from eight sites at field trials in major soybean-growing areas of the US during the 2015 field season. A randomized complete block design with four replicates at each field site was used. In each of the assessments MON 87708 × MON 89788 × A5547-127, either treated or not with dicamba, glyphosate and glufosinate, was compared to an appropriate conventional counterpart which has a genetic background similar to MON 87708 × MON 89788 × A5547-127 but does not possess the *dmo,* the *cp4 epsps* or the *pat* expression cassettes. In addition, multiple conventional commercial reference varieties were included to provide a range of comparative values that are representative of existing conventional reference varieties for each measured phenotypic, agronomic and environmental 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 × A5547-127 compared to the conventional counterpart. These results concur with those obtained previously for MON 87708, MON 89788 and A5547-127.

On the basis of the study 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 × A5547-127 and that MON 87708 × MON 89788 × A5547-127 shows no difference to the conventional soybean counterpart in its phenotypic and agronomic behaviour, except for its tolerance to dicamba, glyphosate and glufosinate.

(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 genetically modified 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, MON 89788 and A5547-127 has a genetic transfer function. Therefore, no changes are expected in the ability of these soybeans or MON 87708 × MON 89788 × A5547-127 to transfer genetic material to bacteria.

(b) Plant to plant gene transfer

Not applicable, the scope of the current application does not include the cultivation of MON 87708 × MON 89788 × A5547-127 varieties in the EU.

4. COMPARATIVE ANALYSIS

4.1. Choice of the conventional counterpart and additional comparators

MON 87708 × MON 89788 × A5547-127 was compared to a conventional counterpart with background genetics similar to MON 87708 × MON 89788 × A5547-127, as well as with other commercially available soybean varieties.

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

MON 87708 × MON 89788 × A5547-127 soybean and the appropriate conventional soybean counterpart were grown at eight field sites in major soybean-growing areas of US during the 2015 field season. Additionally, conventional reference varieties were included at each field sites to provide reference substances representative for their respective growing regions. At each field site, the test, the conventional counterpart and reference seeds were planted in a randomized complete block design with four replicates per block. Field sites were representative of commercial soybean growing areas and were distributed to reflect a variety of agronomic practices, soils and climatic factors. Difference and equivalence tests were conducted using statistical models provided in EFSA guidance and according to the 2010 EFSA Scientific Opinion on Statistical considerations for the safety evaluation of GMOs (EFSA, 2010b).

4.3. Selection of material and compounds for analysis

The key identified endogenous allergens 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.

Certain characteristics together with environmental interactions were studied to assess for a potential indicator of phenotypic changes.

4.4. Comparative analysis of agronomic and phenotypic characteristics

The assessment of the phenotypic, agronomic and environmental interactions of MON 87708 × MON 89788 × A5547-127 compared to conventional soybean demonstrated that there are no unexpected changes in the phenotype or ecological interactions indicative of increased plant weed or pest potential of MON 87708 × MON 89788 × A5547-127 compared to the conventional counterpart (*see* also Section 0).

4.5. Effect of processing

MON 87708 × MON 89788 × A5547-127 has been shown not to be different from conventional soybean, except for its tolerance to dicamba, glyphosate and glufosinate. The processing of MON 87708 × MON 89788 × A5547-127 is therefore not expected to be any different from that of conventional soybean.

5. TOXICOLOGY

(a) Toxicological testing of newly expressed proteins

MON 87708 × MON 89788 × A5547-127 is not different from conventional soybean except for the expression of the DMO, CP4 EPSPS and PAT proteins. Therefore, the safety assessment of the newly expressed proteins is focused on the The DMO, CP4 EPSPS and PAT proteins which have been assessed for their potential toxicity according to the recommendations of Codex (Codex Alimentarius, 2009).

(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 × A5547-127 was shown to be compositionally similar to conventional soybean therefore no testing of any constituent other than the introduced proteins is required.

(c) Information on natural food or feed constituents

Anti-nutrients were evaluated in MON 87708 × MON 89788 × A5547-127 compositional analyses and their levels were demonstrated to be comparable in MON 87708 × MON 89788 × A5547-127 and in conventional soybean. Therefore, the levels of food and feed constituents in MON 87708 × MON 89788 × A5547-127 have not been altered.

(d) Testing of the whole genetically modified food and feed

The safety assessment demonstrates that MON 87708 × MON 89788 × A5547-127 is as safe as conventional soybean for food and feed use through the compositional assessment of MON 87708 × MON 89788 × A5547-127 harvested seed and forage to harvested seed and forage from conventional soybean already on the market. The safety for humans and animals of the DMO, CP4 EPSPS and PAT 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 × A5547-127 is as 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

As described in Section 1.2.2.2, the *dmo*, *cp4 epsps* and *pat* genes are the only genes expressing novel proteins in MON 87708 × MON 89788 × A5547-127. Therefore, the safety assessment is focused on the newly expressed DMO, CP4 EPSPS and PAT proteins which has been conducted according to the recommendations of Codex (Codex Alimentarius, 2009).

(b) Assessment of allergenicity of the whole genetically modified plant

MON 87708 × MON 89788 × A5547-127 is produced by crossing soybean plants containing MON 87708, MON 89788 and A5547-127 using traditional breeding methods. Therefore, this product inherited the traits as present in the parental lines.

As DMO, CP4 EPSPS and PAT proteins expressed in MON 87708 × MON 89788 × A5547-127 are not allergenic and as there are no new genetic modifications in MON 87708 × MON 89788 × A5547-127, there are no reasons to believe that the expression of these proteins in MON 87708 × MON 89788 × A5547-127 would alter its endogenous allergen content compared to commercial soybean.

7. NUTRITIONAL ASSESSMENT

(a) Nutritional assessment of the genetically modified food

Detailed compositional and nutritional comparisons of MON 87708 × MON 89788 × A5547-127, a conventional counterpart and commercially available reference soybean varieties confirmed that MON 87708 × MON 89788 × A5547-127 is compositionally not different from conventional soybean.

(b) Nutritional assessment of the genetically modified feed

See Section 7 (a).

8. EXPOSURE ASSESSMENT – ANTICIPATED INTAKE/EXTENT OF USE

The exposure assessment in humans and animals indicates that there is minimal dietary exposure to DMO, CP4 EPSPS and PAT proteins from consumption of foods and feed derived from MON 87708 × MON 89788 × A5547-127.

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 × A5547-127 to the soybean supply. MON 87708 × MON 89788 × A5547-127 is expected to replace a portion of current soybean such that its intake or use will represent some fraction of the total products derived from soybean.

9. RISK CHARACTERISATION

Based on the information provided in this application, it can be concluded that MON 87708 × MON 89788 × A5547-127 is as safe as conventional soybean. The molecular characterization of MON 87708 × MON 89788 × A5547-127 did not raise any safety concern and did not show any evidence of unintended changes in MON 87708 × MON 89788 × A5547-127. Detailed compositional comparisons of MON 87708 × MON 89788 × A5547-127, its conventional counterpart and conventional commercial reference varieties demonstrated that MON 87708 × MON 89788 × A5547-127 is compositionally similar to the conventional counterpart and that MON 87708 × MON 89788 × A5547-127 is not a contributor to compositional variability in soybean. The assessed phenotypic and agronomic characteristics of MON 87708 × MON 89788 × A5547-127 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 × A5547-127 compared to conventional soybean. An extensive characterisation of the DMO, CP4 EPSPS and PAT proteins expressed in MON 87708 × MON 89788 × A5547-127 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 × A5547-127. 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 THE GENETICALLY MODIFIED FOOD OR FEED

As demonstrated in this application, there are no intrinsic hazards related to MON 87708 × MON 89788 × A5547-127 as no signs of adverse or unanticipated effects have been obversed in a number of safety assessment studies. The pre-market risk characterisation for food and feed use of MON 87708 × MON 89788 × A5547-127 demonstrates that the risks of consumption of MON 87708 × MON 89788 × A5547-127 or its derived products are no different from the risks associated with the consumption of conventional soybean and soybean-derived products. As a consequence, specific risk management measures are not indicated and post-market monitoring of the use of this soybean for food and feed is not considered necessary.

11. ENVIRONMENTAL ASSESSMENT

11.1. Mechanism of interaction between the genetically modified plant and target organisms

According to the EFSA ERA Guidance (EFSA, 2010a), 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.

However, MON 87708 × MON 89788 × A5547-127 has been developed to confer tolerance to dicamba, glyphosate and glufosinate; 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 × A5547-127 in the EU is not relevant for this submission.

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

The scope of this application is the authorisation of MON 87708 × MON 89788 × A5547-127 for import, processing and all uses as any other soybean but excludes the cultivation of MON 87708 × MON 89788 × A5547-127 in the EU. Therefore, no deliberate release of viable plant material in the EU environment is expected, and interactions of MON 87708 × MON 89788 × A5547-127 with the biotic environment will be limited.

(a) Persistence and invasiveness

Results from the assessment support a conclusion that the abilities of MON 87708 × MON 89788 × A5547-127 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 × A5547-127 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.

(b) Selective advantage or disadvantage

Compared with conventional soybean, the tolerance to dicamba, glyphosate and glufosinate confer a selective advantage to MON 87708 × MON 89788 × A5547-127 only under specific conditions (*i.e.* following treatment(s) with dicamba, glyphosate and/or glufosiante), which are short in duration. The advantage is purely of agronomic interest and presents negligible risk to non-agricultural environments, because of the poor survival characteristics of soybean under most European conditions. Therefore, the likelihood is negligible for the inherited traits in MON 87708 × MON 89788 × A5547-127 to confer any meaningful competitive advantage or disadvantage of relevance to the environment.

(c) Potential for gene transfer

Given the low likelihood of occurrence of horizontal gene transfer and lack of adverse consequences if it were to occur, the import, processing, and all uses of MON 87708 × MON 89788 × A5547-127 as any other soybean in the EU is not likely to adversely impact human, animal, or environmental health, and poses negligible risk.

(d) Interactions between the genetically modified plant and target organisms

As cultivation of MON 87708 × MON 89788 × A5547-127 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.

(e) Interactions of the genetically modified plant with non-target organisms

Given the low levels of environmental exposure combined with low hazard from exposure to MON 87708 × MON 89788 × A5547-127 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 × A5547-127 is negligible.

(f) Effects on human health

Given the low levels of environmental exposure combined with the negligible hazard occurring from the contact of workers with MON 87708 × MON 89788 × A5547-127 seeds, the likelihood of adverse effects on workers handling MON 87708 × MON 89788 × A5547-127 for import, processing, and all uses as any other soybean in the EU is negligible.

(g) Effects on animal health

See Section 11.2.(f).

(h) Effects on biogeochemical processes

Given the low level of environmental exposure combined with a lack of hazard, the import, processing and all uses of MON 87708 × MON 89788 × A5547-127 as any other soybean 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.

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

Cultivation of MON 87708 × MON 89788 × A5547-127 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 × A5547-127 is therefore not relevant for this application.

11.3. Potential interactions with the abiotic environment

MON 87708 × MON 89788 × A5547-127 is tolerant to dicamba, glyphosate and glufosinate. As MON 87708 × MON 89788 × A5547-127 was shown to be not different from conventional soybean (with the exception of the inherited traits, imparted by the expression of the DMO, CP4 EPSPS and PAT proteins), with respect to its composition, or 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 DMO, CP4 EPSPS and PAT proteins 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 × A5547-127 with the environment will be limited. Moreover, no negative impact MON 87708 × MON 89788 × A5547-127 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 characterization

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 lied down in EFSA 2010 guidance, support the conclusion that the import, processing and all uses in the EU (excluding cultivation) of MON 87708 × MON 89788 × A5547-127, 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 the proposed monitoring plan for MON 87708 × MON 89788 × A5547-127 has been developed according to the principles and objectives outlined in Annex VII of Directive 2001/18/EC and Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC. The monitoring plan also takes into account the EFSA Scientific Opinion on guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants (EFSA, 2011)

(b) Interplay between environmental risk assessment and monitoring

The scope of this application is the authorisation of MON 87708 × MON 89788 × A5547-127 for import, processing and all uses as any other soybean in the EU under Regulation (EC) No 1829/2003. It does not include authorisation for the cultivation of MON 87708 × MON 89788 × A5547-127 varieties in the EU.

An environmental risk assessment (ERA) was carried out for MON 87708 × MON 89788 × A5547-127 according to the principles laid down in Annex II to Directive 2001/18/EC, Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC and the EFSA guidance on the environmental risk assessment of genetically modified plants. The scientific evaluation of the characteristics of MON 87708 × MON 89788 × A5547-127 in the ERA has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses of MON 87708 × MON 89788 × A5547-127 relative to:

- Persistence and invasiveness including plant-to-pant gene flow
- Plant to micro-organims gene transfer
- Interactions of the GM plant with target organisms
- Interactions of the GM plant with non-target organisms (NTOs)
- Impacts of the specific cultivation, management and harvesting techniques
- Effects on biogeochemical processes
- Effects on human and animal health

(c) Case-specific genetically modified plant monitoring (approach, strategy, method and analysis)

The scientific evaluation of the characteristics of MON 87708 × MON 89788 × A5547-127 in the ERA has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses of MON 87708 × MON 89788 × A5547-127. It is therefore considered that there is no need for case-specific monitoring.

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

Any potential adverse effects of MON 87708 × MON 89788 × A5547-127 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 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 × A5547-127 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 × A5547-127 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 × A5547-127 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

In accordance with Regulation (EC) No 1829/2003, the authorisation holder is responsible to inform the EC of the results of the general surveillance.

If information that confirms an adverse effect of MON 87708 × MON 89788 × A5547-127 and that alters the existing risk assessment becomes available, the authorisation holder will immediately investigate and inform the EC. The authorisation holder, in collaboration with the EC and based on a scientific evaluation of the potential consequences of the observed adverse effect, will define and implement management measures to protect human and animal health or the environment, as necessary. It is important that the remedial action is proportionate to the significance of the observed effect.

The authorisation holder will submit an annual monitoring report including results of the general surveillance in accordance with the conditions of the authorisation. The report will contain information on any unanticipated adverse effects that have arisen from handling and use of viable MON 87708 × MON 89788 × A5547-127.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of MON 87708 × MON 89788 × A5547-127 and, as appropriate, the measures that were taken to ensure the safety of human and animal health or the environment.

The report will also clearly state which parts of the provided information are considered to be confidential, together with a verifiable justification for confidentiality in accordance with Article 30.

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

As MON 87708 × MON 89788 × A5547-127 is produced by crossing MON 87708 MON 89788 and A5547-127 using traditional breeding methods, it contains their respective inserts in combination. Therefore, MON 87708 × MON 89788 × A5547-127 is detectable using any of the event-specific PCR method for detecting the introduced DNA present in MON 87708, MON 89788 or A5547-127. However, as for all plants in which one or more events are combined by traditional breeding, the unambiguous detection of MON 87708 × MON 89788 × A5547-127 in mixed consignments of seed will require single soybean seeds to be subjected to detection methods for MON 87708, MON 89788 and A5547-127, and to test positive for all.

The detection methods for MON 87708, MON 89788 and A5547-127 have already been validated by the EU-RL GM-FF[2].

[2] EU-RL GM-FF: http://gmo-crl.jrc.ec.europa.eu/ - Accessed on 17 October 2016.

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

14.1. History of previous releases of the genetically modified plant notified under Part B of Directive 2001/18/EC or 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 × A5547-127 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 genetically modified plant carried out outside the Union by the same notifier

(a) Release country

MON 87708 × MON 89788 × A5547-127 has been field tested in Puerto Rico, the US, and Chile since 2012, 2013 and 2015, respectively. It has also been tested in Argentina in 2015.

(b) Authority overseeing the release

US and Puerto Rico: 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)

(c) Release site

US: In major soybean growing states

Argentina: Entre Ríos, Córdoba, Santa Fe, Buenos Aires

Chile: Santa Julia and San Francisco de Mostazal.

Puerto Rico: Aguadilla, Isabela, Juana Diaz

(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/Puerto Rico: 12 months.

Chile: 6 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 with respect to any risk to human health and the environment

Field-testing provided no evidence that MON 87708 × MON 89788 × A5547-127 or derived products would be the cause of any adverse effects to human health or to the environment.

References

Codex Alimentarius, 2009. Foods derived from modern biotechnology. Codex Alimentarius, Second Edition, 1-76.

EFSA, 2010a. Guidance on the environmental risk assessment of genetically modified plants. The EFSA Journal, 8(11):1879, 1-111.

EFSA, 2010b. Scientific opinion on statistical considerations for the safety evaluation of GMOs. The EFSA Journal, 8(1):1250, 1-59.

EFSA, 2011. Guidance on the post-market environmental monitoring (PMEM) of genetically modified plants. The EFSA Journal, 9 (8), 1-40.