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

Part II

Summary

A. GENERAL INFORMATION

1. Details of application

a) Member State of application

The Netherlands.

b) Notification number

Not available at the time of submission.

c) Name of the product (commercial and other names)

The Monsanto development code for this genetically modified soybean is MON 87708. Currently, no commercial name has been attributed to this product.

d) Date of acknowledgement of notification

Not available at the time of submission.

2. Applicant

a) Name of applicant

Monsanto Company, represented by Monsanto Europe S.A.

b) Address of applicant

Monsanto Europe S.A.
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 person established in the Community who is responsible for the placing on the market, whether it be the manufacturer, the importer or the distributor, if different from the applicant (Commission Decision 2004/204/EC Art 3(a)(ii))

MON 87708 will be produced in other world areas and will be imported and used in the European Union (EU) by operators that have traditionally been involved in the commerce, transport, processing and use of soybean and soybean-derived products in the EU.

3. Scope of the application

(x) GM plants for food use

(x) Food containing or consisting of GM plants

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

(x) GM plants for feed use

(x) Feed containing or consisting of GM plants

(x) Feed produced from GM plants

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

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

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

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

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

Yes ( )	**No (x)**
If *no*, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC The protein expression, composition, safety, agronomic and phenotypic characteristics of MON 87708 have been studied at multiple locations in North America that cover a range of environmental conditions. The data collected from these field releases have been used in the risk assessment presented in the MON 87708 application. A summary of the conclusions of the risk analysis that demonstrate the safety of MON 87708 to humans, animals and to the environment, have been presented in the respective sections throughout this summary.	

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

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

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

Yes (x)	No ( )

If *yes*, specify

MON 87708 has been notified to the United States Department of Agriculture Animal and Plant Health Inspection Service (USDA-APHIS) and the United States Food and Drug Administration (US FDA). Approvals from these agencies have not yet been obtained. Regulatory submissions will also be made to countries that import significant soybean or food and feed products derived from US soybean and have functional regulatory review processes in place. Also, as appropriate, notifications will be made to countries that import significant quantities of US soybean and soybean products and do not have a formal regulatory review process for biotechnology-derived crops.

8. General description of the product

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

Monsanto Company has developed biotechnology-derived soybean MON 87708 that is tolerant to dicamba (3,6-dichloro-2-methoxybenzoic acid) herbicide.

MON 87708 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.

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

This application is for authorization of MON 87708 for import, processing and all uses as any other soybean in the EU, according to Articles 5 and 17 of Regulation (EC) No. 1829/2003 on genetically modified food and feed. The range of uses of this soybean will be identical to the full range of equivalent uses of conventional soybean. The scope of this application does not include the cultivation of MON 87708 varieties in the EU.

c) Intended use of the product and types of users

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

MON 87708 is substantially equivalent to conventional soybean, except for its tolerance to dicamba, which is a trait of agronomic interest and was shown to be as safe and nutritious as conventional soybean. Therefore, MON 87708 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 for import, processing and all uses as specified in Section A.8(b).

e) Any proposed packaging requirements

MON 87708 is substantially equivalent to conventional soybean, except for its tolerance to dicamba. Therefore, MON 87708 and derived products will be used in the same manner as other soybean and no specific packaging is required. (For labelling, *see* question A.8.f).

f) A proposal for labelling in accordance with Articles 13 and 25 of Regulation (EC) 1829/2003. In the case of GMOs, food and/or feed containing, consisting of GMOs, a proposal for labelling has to be included complying with the requirements of Article 4, B(6) of Regulation (EC) 1830/2003 and Annex IV of Directive 2001/18/EC.

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

Operators shall be required to label products containing or consisting of MON 87708 with the words "genetically modified soybean" or "contains genetically modified soybean" and shall continue to declare the unique identifier MON-877Ø8-9 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 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 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. Therefore, no further specific measures are to be taken by the applicant.

g) Unique identifier for the GM plant (Regulation (EC) 65/2004; does not apply to applications concerning only food and feed produced from GM plants, or containing ingredients produced from GM plants)

The unique identifier for this genetically modified soybean is MON-877Ø8-9

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

MON 87708 is suitable for use throughout the EU as any other soybean.

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 as any other soybean, not including the cultivation of varieties of MON 87708 in the EU, the only potential means of environmental release would be more likely to occur during import, storage and processing of MON 87708. 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 plants in the EU. Moreover, in the event of incidental spillage, the establishment of volunteer plants would be unlikely, since soybean cannot survive without human assistance and is not capable of surviving as a weed due to selection over centuries of cultivation. Soybean is not documented as a source of volunteer plants in rotational crops, which results from the combination of absence of seed dormancy, poor seed survivability in soils, frost sensitivity of soybean seedlings and soil preparations prior to the planting of a subsequent crop (which includes destruction of any existing vegetation and soil cultivation). MON 87708 is shown to be substantially equivalent to conventional soybean, except for the introduced tolerance to dicamba and, therefore, is unlikely to pose any threat to the EU environment or to require special measures for its containment. Furthermore, soybean volunteers can be easily controlled using currently available selective herbicides (other than dicamba) or by mechanical means. Therefore, no special measures are considered to be required in case of misuse or unintended release.

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

1. Complete name

a) Family name Leguminosae
b) Genus *Glycine* Willd.
c) Species *max*
d) Subspecies Not applicable
e) Cultivar/breeding line A3525
f) Common name Soybean

2. a) Information concerning reproduction

(i) Mode(s) of reproduction Soybean is a diploidized tetraploid (2n = 40) and is a self-pollinated species, propagated by seed. Pollination typically takes place on the day the flower opens. The pollen comes naturally in contact with the stigma during the process of anthesis. Anthesis normally occurs in late morning (usually between 10.00 and 11.00 am, depending on the environmental conditions). The pollen usually remains viable for 2-4 hours, after which it germinates and o viable pollen can be detected by late afternoon. Natural or artificial cross-pollination can only take place during the short time of the day that the pollen is viable.
(ii) Specific factors affecting reproduction Soybean is a quantitative short day plant and hence flowers more quickly under short days. As a result, photoperiodism and temperature response are important in determining areas of cultivar adaptation. During the reproductive stages of development, soybean plants are particularly sensitive to hydric and thermal (low temperature) stress which can cause significant flower abortion and yield loss. Soybean does not yield well on acid soils and the addition of limestone may be required.

(iii) Generation time

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

Soybean grows most rapidly when air temperatures are between 25°C and 35°C. The length of the cultural cycle is approximately 100 to 160 days, depending on the variety and the region in which it is cultivated.

2 b) Sexual compatibility with other cultivated or wild plant species

Outcrossing with cultivated soybean species

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

It has to be noted, however, that the scope of the current application does not include the cultivation of MON 87708 varieties in the EU. Therefore, any outcrossing between MON 87708 and cultivated *Glycine* varieties is highly unlikely.

Outcrossing with wild soybean species

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

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

The wild annual species *G. soja*, can hybridise naturally with the cultivated soybean, *G. max*, since they are both members of the subgenus *Soja*. Therefore, gene transfer between cultivated soybean and wild species of subgenus *Soja* may occur, but not in Europe, where the wild relatives of subgenus *Soja* are not present.

3. Survivability

a) Ability to form structures for survival or dormancy

Cultivated soybean plants are annuals and they reproduce solely by means of seeds. Mature soybean seeds have no innate dormancy and 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 (other herbicide than dicamba).

b) Specific factors affecting survivability

See Section B.3.a.

4. Dissemination

a) Ways and extent of dissemination

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

Soybean pollen may also be considered as a vehicle for dissemination, but the pollen viability outside of the soybean flower is limited by the fact that soybean is predominantly a self-pollinated species. The major barrier that prevents dissemination of soybean pollen and therefore cross-pollination, is the enclosure of both the stigma and anthers within the flower, even during maturation of the pollen. As a consequence, the potential for the pollen to become disseminated is reduced and the chance for self-pollination greatly increases. However, natural cross-pollination may occur to a certain extent as discussed in B.2.a.

b) Specific factors affecting dissemination

See Section B.4.b.

5. Geographical distribution and cultivation of the plant, including the distribution in Europe of the compatible species

Soybean was domesticated in the eastern half of northern China around the 11th century B.C. or earlier and its cultivation subsequently extended throughout south-east Asia. From the first century A.D. to approximately the 15th to 16th centuries, soybean were introduced into several countries, with land races eventually developing in Japan, Indonesia, Philippines, Vietnam, Thailand, Malaysia, Myanmar, Nepal and northern India. Soybean cultivation was probably introduced in Europe starting in the late 16th and throughout the 17th century and in the US in the 18th century. Today, the major producers of soybeans are the US, Brazil, Argentina and China. The largest soybean producers in the European Union are Italy and Romania, followed by France and Hungary.

There are no compatible species for cultivated soybean in Europe.

6. In the case of plant species not normally grown in the Member State(s), description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts

Not applicable, as soybean is grown in Europe.

7. Other potential interactions, relevant to the GM plant, of the plant with organisms in the ecosystem where it is usually grown, or used elsewhere, including information on toxic effects on humans, animals and other organisms

Soybean is known to interact with other organisms in the agricultural environment. Soybean is sensitive to a number of economically important diseases and insect predators and is susceptible to competition from surrounding weeds, which commonly compete with soybean for light, water and nutrients. 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, stachyose, raffinose and phytic acid. Some of these anti-nutrients relate to their impact on human nutrition, while others relate to animal nutrition in general including livestock.

Soybean is one of the eight food groups that are known to elicit food allergic responses in humans. It contains several endogenous proteins that have been shown to elicit an allergenic response when ingested. Relatively few of the specific soybean proteins involved in allergenic reactions in soybean have been uniquely identified or characterised. Allergic responses to soybean are experiences by a very small percentage

of the human population, but are considered clinically important. Allergy to soybean is more prevalent in children than adults and is considered a transient allergy of infancy/childhood.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification

MON 87708 was developed through *Agrobacterium*-mediated transformation of conventional soybean A3525 meristem tissue using the 2T-DNA plasmid vector PV-GMHT4355.

2. Nature and source of the vector used

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.

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

The genetic elements of PV-GMHT4355 intended for insertion into the soybean genome comprised between the T-DNA I borders are, from the right border region, the *PC1SV* promoter (P-*PC1SV)*, 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.

Each individual components and the function of the DNA sequences in MON 87708 are given in Table 1.

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

Genetic Element	Size (kp)	Function and source (Reference)
T-DNA I		
B[1]-Right Border Region	0.36	DNA region from *Agrobacterium tumefaciens* containing the Right Border sequence used for transfer of the T-DNA
P[2]-*PC1SV*	0.43	Promoter for the Full-Length Transcript (FLt) of peanut chlorotic streak caulimovirus that directs transcription in plant cells
L[3]-*TEV*	0.13	5′ non-translated region from the Tobacco Etch virus genome that is involved in regulating gene expression
TS[4]-*RbcS*	0.24	Sequences encoding the transit peptide and the first 24 amino acids of the mature protein of the *RbcS* gene from *Pisum sativum* (pea) that directs transport to the DMO precursor protein to the chloroplast
CS[5]-*dmo*	1.02	Coding sequence for the dicamba mono-oxygenase derived from *Stenotrophomonas maltophilia*
T[6]-*E9*	0.64	3′ non-translated region from the *RbcS2* gene of *Pisum sativum* (pea) encoding the Rubisco small subunit, which functions to direct polyadenylation of the mRNA
B-Left Border Region	0.44	DNA region from *Agrobacterium tumefaciens* containing the Left Border sequence used for transfer of the T-DNA

[1] B - border.
[2] P - promoter.
[3] L - leader.
[4] TS - targeting sequence.
[5] CS - coding sequence.
[6] T - 3' non-translated transcriptional termination sequence and polyadenylation signal sequences.

D. INFORMATION RELATING TO THE GM PLANT

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

MON 87708 contains a gene from *Stenotrophomonas maltophilia* that 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.

MON 87708 offers growers an expanded use of dicamba in soybean production from the current preplant and preharvest labeled uses. The tolerance of MON 87708 to dicamba facilitates a wider window of application in soybean, allowing preemergence application up to the day of crop emergence and postemergence in-crop applications through the early reproductive growth stage. Dicamba provides effective control of over 95 annual and biennial weed species, and suppression of over 100 perennial broadleaf and woody plant species. Dicamba is efficacious on broadleaf weeds that are hard-to-control with glyphosate, such as common lambsquarters, hemp sesbania, morning glory species, nightshade, Pennsylvania smartweed, prickly sida, and wild buckwheat. Additionally, dicamba provides effective control of herbicide-resistant broadleaf weeds, including glyphosate-resistant weeds such as marestail, common ragweed, giant ragweed, palmer pigweed, and waterhemp.

2. Information on the sequences actually inserted or deleted

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

The molecular analysis shows that MON 87708 contains one single copy of the *dmo* expression cassette integrated into a single locus of the soybean genome. No additional elements from the transformation vector PV-GMHT4355, linked or unlinked to the expression cassette, were detected in the genome of MON 87708. Additionally, no element of the PV-GMHT4355 backbone sequence was detected in MON 87708.

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

No deletion was intended, however there was an 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 in MON 87708. Deletions and/or insertions of DNA due to double-strand break repair mechanisms in the plant during *Agrobacterium*-mediated transformation process are not uncommon. Further analyses revealed that there is no known function associated with this deleted region.

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

The presence of the MON 87708 insert in the soybean nuclear genome is best shown by the Chi square (χ^2) analysis of the segregation data. The results of the χ^2 analysis indicate that a single insert is integrated in the plant nuclear genome and is stably inherited as a single locus, following a Mendelian one-locus model.

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

Molecular analysis was conducted to characterize the insert in MON 87708. Genomic DNA was analyzed using Southern blot to determine the insert number (number of insertions of the integrated DNA within the soybean genome), the copy number (the number of copies of the integrated DNA within one locus), the integrity and organization of the inserted *dmo* expression cassette and the presence or absence of any other elements of plasmid vector PV-GMHT-4355. DNA sequence analyses confirmed the sequence identity between the MON 87708 insert and the corresponding insert from the plasmid PV-GMHT-4355. The results of PCR and sequence analyses further confirmed the organisation of the genetic elements within the *dmo* expression cassette of MON 87708, which were identical to that in plasmid PV-GMHT-4355.

The MON 87708 insert consists of the *dmo* expression cassette containing the *PC1SV* promoter, the *TEV* leader, the *RbcS* targeting sequence, the *dmo* coding sequence and the *E9* 3' non-translated sequence.

3. Information on the expression of the insert

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

MON 87708 contains a *dmo* expression cassette that upon translation results in two forms of the DMO protein; referred to as MON 87708 DMO protein and MON 87708 DMO+27 protein. The active form of these proteins, necessary to confer dicamba tolerance, is a trimer comprised of three DMO monomers. In MON 87708, the trimer can be comprised of MON 87708 DMO protein, MON 87708 DMO+27 protein, or a combination of both. Therefore, MON 87708 DMO will refer to both forms of the protein and all forms of the trimer.

MON 87708 DMO levels were determined in over-season leaf (OSL), seed, root and forage tissues derived from MON 87708 plants produced in replicated field trials across eight US locations during the 2009 growing season.

MON 87708 DMO was detected in all tissue types ranging from 1.3-120 µg/g dry weight (dwt). The mean levels of the MON 87708 DMO across the eight sites were highest in leaf (ranging from OSL-1 at 29 µg/g dwt to OSL-4 at 53 µg/g dwt), followed by seed (40 µg/g dwt), forage (32 µg/g dwt), and root (5.3 µg/g dwt).

b) Parts of the plant where the insert is expressed

The *dmo* transgene in MON 87708 is driven by the *PC1SV* promoter and results in detectable DMO protein levels in all tissue types.

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

a) Reproduction

Phenotypic and agronomic data were collected from trials conducted with MON 87708 in 2008 and 2009 US major soybean producing geographies. In each of these assessments, MON 87708 was compared to an appropriate conventional soybean control, A3525, with genetic background similar to MON 87708, but lacking the introduced trait. In addition, multiple commercial soybean varieties (references) were included to provide a range of comparative values that are representative of existing commercial soybean varieties for each measured phenotypic, agronomic, and environmental interaction characteristic.

Results from the phenotypic and agronomic assessments showed that there are no unexpected changes in the phenotype or ecological interactions indicative of increased pest or weed potential of MON 87708 compared to the conventional soybean control.
On the basis of those 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 and that MON 87708 is equivalent to conventional soybean in its phenotypic and agronomic behaviour.

b) Dissemination

See Section D.4.a); the introduced trait has no influence on soybean reproductive morphology and, hence, no changes in seed dissemination are to be expected in MON 87708 compared to conventional soybean.

c) Survivability

See Section D.4.a); soybean is known to be a weak competitor in the wild, which cannot survive outside cultivation without human intervention. Field observations have demonstrated that MON 87708 has not been altered in its survivability when compared to conventional soybean.

d) Other differences

See Section D.4.a); comparative assessments in the field did not reveal any biologically significant differences between MON 87708 and conventional soybean.

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

MON 87708 contains a single copy of the T-DNA I sequence that was integrated into a single locus of the soybean genome. The insert is inherited in a Mendelian fashion. This has been confirmed by Southern blot analyses.

6. Any change to the ability of the GM plant to transfer genetic material to other organisms

a) Plant to bacteria gene transfer

None of the genetic elements inserted in MON 87708 has a genetic transfer function. Therefore, no changes are expected in the ability of this soybean to transfer genetic material to bacteria.

b) Plant to plant gene transfer

Based on the observation that reproductive morphology in MON 87708 is unchanged compared to conventional soybean and that pollen production and pollen viability were unaffected by the genetic modification, the out-crossing frequency to other soybean varieties or to wild relatives (which are not present in the EU) would be unlikely to be different for MON 87708, when compared to conventional soybean varieties.

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

7. Information on any toxic, allergenic or other harmful effects on human or animal health arising from the GM food/feed

7.1 Comparative assessment

Choice of the comparator

MON 87708 was compared to A3525, a conventional soybean variety with background genetics similar to MON 87708, but lacking the introduced trait.

7.2 Production of material for comparative assessment

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

Compositional analyses were conducted on MON 87708 and conventional control soybean, A3525, seed and forage, grown at eight sites in major soybean-growing areas of the US in 2009.

Commercially available conventional soybean varieties were also grown at each of the field sites to provide a total of 14 different reference substances. At each field site, the MON 87708 test, control and reference seeds were planted in a randomised complete block design with four replicates per block. All the plants were grown under normal agronomic field conditions for their respective geographic regions.

b) the baseline used for consideration of natural variations

Levels of the components in seed and forage of MON 87708 were compared to the corresponding levels in the control. Reference varieties were grown in the same field locations and under the same conditions as the MON 87708 test and conventional soybean control to provide data for the development of a 99% tolerance interval for each analyte evaluated. Where statistical differences occurred, the measured analyte was compared to the tolerance interval developed from these references. Differences were also compared to ranges reported in the ILSI Crop Composition Database and ranges reported in literature.

7.3 Selection of material and compounds for analysis

The key nutrients and other nutritionally important components that were selected for analysis of MON 87708 in the compositional study were chosen on the basis of internationally accepted guidance provided by the OECD consensus document on compositional considerations for new varieties of soybean.

7.4 Agronomic traits

Field trials with MON 87708 were conducted and the set of agronomic observations supports the conclusion that from an agronomic and phenotypic (morphological) point of view, MON 87708 is equivalent to conventional soybean, except for the introduced dicamba-tolerance trait (*see* Section D.4.).

7.5 Product specification

The tolerance to dicamba herbicide in MON 87708 soybean is achieved through the expression of the *dmo* coding sequence.

The presence of the *dmo* gene and/or the MON 87708 DMO protein in soybean or in soybean derived products can be identified by using different techniques. Southern blot or PCR techniques can identify the inserted nucleotide sequence, while the MON 87708 DMO protein can be detected in all tissues of MON 87708, by optimised tissue extraction, standardised electrophoretic blotting and immunodetection methodologies.

7.6 Effect of processing

MON 87708 was shown to be substantially equivalent to conventional soybean, except for the dicamba-tolerance trait. Therefore, the processing of MON 87708 is not expected to be any different from that of conventional soybean.

7.7 Anticipated intake/extent of use

There are no anticipated changes in the intake and/or extent of use of soybean or derived products for use as or in food or feed as a result of the addition of MON 87708 to the soybean supply. MON 87708 is expected to replace a portion of current soybean such that its intake or use will represent some fraction of the total products derived from soybean.

7.8 Toxicology

7.8.1 Safety assessment of newly expressed proteins

MON 87708 contains the *dmo* expression cassette that produces the MON 87708 DMO protein. Therefore, the safety assessment of newly expressed protein is based on the characterization and safety of the MON 87708 DMO produced by MON 87708. The conclusion of safety to humans of the MON 87708 DMO was based upon the following considerations:

- The MON 87708 DMO has a history of safe use and is homologous to proteins present in the human diet;
- The MON 87708 DMO protein has no structural similarity to known toxins or other biologically active proteins that could cause adverse effects in humans or animals;
- The MON 87708 DMO does not exert any acute toxic effects on mammals;
- The MON 87708 DMO has a large margin of exposure (MOE).

In addition, MON 87708 DMO low levels in tissues that are consumed and its rapid digestibility in simulated digestive fluids provide additional assurance of its safety.

It is therefore possible to conclude that MON 87708 DMO protein is safe and poses no concerns for humans, animals and the environment.

7.8.2 Testing of new constituents other than proteins

Soybean has a long history of safe use and consumption around the world. MON 87708 has been shown to be substantially equivalent to conventional soybean except for the dicamba-tolerance trait. Therefore, no testing of any constituent other than the introduced protein is required.

7.8.3 Information on natural food and feed constituents

Soybean is known to contain a number of natural anti-nutritional components, such as trypsin inhibitors, lectins, isoflavones (daidzein, genistein and glycitein), stacchyose, raffinose and phytic acid, which are inactivated when the beans are toasted or heated during processing. Nonetheless, these anti-nutrients were evaluated in MON 87708 compositional analyses and their levels were demonstrated to be comparable in MON 87708 and in conventional soybean.

7.8.4 Testing of the whole GM food/feed

The safety assessment demonstrates that MON 87708 is as safe as conventional soybean for food and feed use through the compositional equivalence of MON 87708 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 protein 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 protein and the familiarity of the host organisms from which the gene is derived have been demonstrated.

Based on this weight of evidence, no more data is required to demonstrate that MON 87708 is as as safe as conventional soybean from a food and feed perspective. However, a repeat-dose animal feeding study in rat has been generated using MON 87708 soybean meal containing diets. This study found no adverse effects related to the consumption of diets containing MON 87708.

The dietary safety of MON 87708 was further confirmed by an animal feeding study in broiler chickens using MON 87708 containing diets. This study confirms the absence of any toxic effects associated to the introduced protein and the absence of any unanticipated or pleiotropic effects linked to the genetic modification.

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

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

The assessment of the MON 87708 DMO protein allergenic potential compares the biochemical characteristics of this protein to characteristics of known allergens, according to the recommendations of Codex Alimentarius Commission.

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

- It was obtained from a non-allergenic source (*S. maltophilia*)
- It lacks structural similarity to known allergens, as demonstrated by bioinformatics analyses
- It is rapidly digested in simulated gastric fluid
- It constitutes a very small portion of the total protein present in the seed of MON 87708.

Based on the weight of evidence, it can be concluded that the allergenic potential of MON 87708 DMO protein is negligible and therefore, this protein does not pose a significant allergenic risk.

7.9.2 Assessment of allergenicity of the whole GM plant or crop

To assess whether MON 87708 has altered endogenous allergenic potential compared to conventional soybean, the potential allergenicity of MON 87708 against conventional soybean was performed. Results of this assessment support the conclusion that MON 87708 is comparable to conventional soybean in terms of allergenicity potential. Thus, it is concluded that MON 87708 has no greater allergenic potential than soybean varieties that are currently on the market.

7.10 Nutritional assessment of GM food/feed

7.10.1 Nutritional assessment of GM food

The inserted dicamba-tolerance trait in MON 87708 is of agronomic interest, and is not intended to change any nutritional aspects of this soybean. The presence of this trait is not expected to alter patterns or volumes of soybean consumption.

In addition to the extensive compositional analyses, which demonstrated the equivalence of MON 87708 to conventional soybean (except for the introduced dicamba-tolerance trait), a confirmatory feed performance study was conducted in rapidly growing broiler chickens. This study confirms the nutritional equivalence of MON 87708 for use as food or feed, and demonstrates the absence of any pleiotropic or unanticipated effects from the introduced trait. The dietary safety of MON 87708 was further confirmed by repeat-dose animal feeding studies in rat. In conclusion, MON 87708 is nutritionally equivalent to conventional control soybean, as well as to soybean varieties in commerce. Hence, it would not be 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 would not be expected to be altered, and no nutritional imbalances would be expected as a result of the presence of MON 87708 in the soybean supply.

7.10.2 Nutritional assessment of GM feed

MON 87708 was demonstrated to be compositionally equivalent to conventional soybean. The safety assessment of MON 87708 showed that this dicamba-tolerant soybean does not pose any adverse effects for humans and animals. As described above (Section 7.8.4), the nutritional value of MON 87708 was assessed by a feed performance study conducted in rapidly growing broiler chickens. Broilers were fed diets containing soybean meal produced from MON 87708. There were no biologically relevant differences in broiler performance, carcass yield or meat composition between broilers fed diets containing meal from MON 87708 and those fed diets containing genetically similar conventional control or reference soybean meal. Therefore, diets containing meal from MON 87708 were as wholesome as the diets formulated with conventional control or reference soybean meal regarding their ability to support the rapid growth of broiler chickens. These data support the conclusion that soybean meal from MON 87708 is as nutritious as conventional soybean meal.

In conclusion, MON 87708 is nutritionally equivalent to conventional control soybean, as well as to soybean varieties in commerce.

7.11 Post-market monitoring of GM food/feed

There are no intrinsic hazards related to MON 87708 as no signs of adverse or unanticipated effects have been observed in a number of safety studies, including animal feeding studies using doses of administration that are orders of magnitude above expected consumption levels.

The pre-market risk characterization for food and feed use of MON 87708 demonstrates that the risks of consumption of MON 87708 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 appropriate.

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

Not applicable. MON 87708 is tolerant to dicamba and, as such, does not have any target organisms.

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

This application under Regulation (EC) No. 1829/2003 is for the authorization of MON 87708 for import, processing and all uses as any other soybean, excluding the cultivation of MON 87708 in the EU.

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

9.1 Persistence and invasiveness

Based on centuries of experience with conventional, domesticated soybean in Europe, there is no potential for soybean to be invasive of natural habitats or persist in the environment without the aid of human intervention.

Extensive characterization of MON 87708 (which, in part, includes molecular, expression, composition, and phenotypic data) demonstrated that the only meaningful differences between MON 87708 and conventional soybean is the dicamba-tolerance trait conferred by the MON 87708 DMO protein.

This application is limited to import of MON 87708 seed into the EU and use thereof as any other soybean commodity seed. As such, exposure to the environment will be rare. In the event MON 87708 seed is spilt in the environment, its introduced trait would have negligible consequences for the environment. Hence the risk to the environment from MON 87708 through increased persistence and invasiveness of this soybean is negligible.

9.2 Selective advantage or disadvantage

It was previously demonstrated that the introduced genetic sequences in MON 87708 did not lead to any biologically meaningful alterations of the phenotypic characteristics, such as plant growth and development, morphology, agronomic performance, composition, nutritional value or safety characteristics, when compared to conventional soybean. Therefore, it was concluded that MON 87708 is not meaningfully different from conventional soybean, with the exception of the intentionally introduced dicamba-tolerance trait.

Compared with conventional soybean, the presence of the dicamba tolerance trait would only confer a selective advantage to MON 87708, where its control was attempted using dicamba alone and if no other, more important factors limiting the survival of soybean in the receiving environment were present. In practice, however, this advantage would be of short duration and of limited consequence because of the poor survival characteristics of soybean under most European conditions.

Therefore, the likelihood is negligible for the introduced trait in MON 87708 to confer any meaningful competitive advantage or disadvantage of relevance to the environment.

9.3 Potential for gene transfer

There is no potential for gene transfer from MON 87708 to wild plant species in the EU since soybean is not sexually compatible with any indigenous or introduced wild plant species present in European countries. Furthermore, there is negligible likelihood for gene transfer from MON 87708 to other soybean crops since this application is not for consent to cultivate MON 87708 varieties in the EU but limited to import of MON 87708 seed into the EU and use thereof as any other soybean commodity seed.

As the likelihood of accidentally spilt MON 87708 seed to germinate, establish, mature and flower is very low (soybeans are predominantly self-pollinated), and the majority of soybean pollen is largely confined to short distances from the source plant, the transfer of the introduced trait to neighbouring soybean plants through cross-pollination is negligible.

In the case that an introduced gene outcrossed to other soybean, its transfer would only confer a selective advantage under specific conditions (*i.e.* upon applications of dicamba herbicide), as discussed in Section 9.2.

In the highly unlikely event that the introduced gene would outcross to another soybean plant, its transfer would, in any event, have negligible consequences for the environment. The environmental risk posed by this transfer, and hence by the intended import, processing and all uses of MON 87708 is negligible.

9.4 Interactions between the GM plant and target organisms

MON 87708 is tolerant to dicamba and, as such, has no target organisms with which to interact, either directly or indirectly.

9.5 Interactions of the GM plant with non-target organisms

The only meaningful difference between MON 87708 and conventional soybean is the dicamba-tolerance trait conferred by the MON 87708 DMO protein. Thus, the baseline interaction of MON 87708 with other organisms in the environment is considered no different from conventional soybean, except for the additional direct exposure of pests and animals that feed on soybean seeds to the MON 87708 DMO protein newly produced in the plant. Additionally, through trophic interactions and decomposition processes predators and prey of soybean pests could be exposed to very low levels of MON 87708 DMO protein. Potential exposure of non-target organisms in the receiving environment to the MON 87708 DMO protein produced in MON 87708 is the characteristic of the GMHP that may, theoretically, cause an adverse environmental effect. However, as the scope of the current application does not include planting of MON 87708 varieties in the EU, any meaningful exposure of non-target organisms to this soybean is highly unlikely.

Furthermore, no adverse effects were observed in field trials conducted since 2008 across a broad geographic range of environments involving MON 87708.

9.6 Effects on human health

MON 87708 was shown to be compositionally equivalent to conventional soybean with the exception of the dicamba-tolerance trait. No substantial differences from conventional soybean were found with respect to safety characteristics and agronomic and phenotypic characteristics.

The likelihood for any adverse effects occurring in humans as a result of their contact with this soybean is no different from that of conventional soybean, as MON 87708 expresses MON 87708 DMO protein, which has negligible potential to cause any toxic or allergenic effects in humans. Therefore, the risk of changes in the occupational health aspects of this soybean is negligible.

9.7 Effects on animal health

Based on centuries of experience with conventional, domesticated soybean in Europe, there is negligible potential for soybean to cause any adverse health effects in animals, especially considering that soybean is processed to deactivate anti-nutritional factors before feeding it to animals.

MON 87708 was shown to be compositionally equivalent to conventional soybean with the exception of the dicamba-tolerance trait. No substantial differences from conventional soybean were found with respect to safety characteristics and agronomic and phenotypic characteristics.

The likelihood of potential adverse effects in animals fed on MON 87708 and in humans, consuming those animals, is no different from conventional soybean, as MON 87708 expresses MON 87708 DMO protein, which has negligible potential to cause any toxic or allergenic effects in humans. Therefore, the risk of MON 87708 for the feed/food chain is also negligible.

9.8 Effects on biogeochemical processes

The scope of the current application does not include cultivation of MON 87708 in the EU. As such, exposure to the environment will be rare, occurring only through incidental release during shipment and handling. As for conventional soybean, spillage of MON 87708 during transport or storage of grain could cause some seed to fall to the ground. Although such seed could eventually germinate if the local soil and environmental conditions are favourable, this soybean is a poor competitor and cannot persist as a weed. Environmental conditions at the sites of handling are, however, unlikely to be conducive to germination, growth and reproduction of soybean seed that is incidentally released.

Soybean production in general is known to have indirect impacts on biogeochemical processes through tillage, fertilizer application, and establishment of a monoculture in a defined area. As MON 87708 was shown to be compositionally equivalent to conventional soybean with no

biologically meaningful differences in agronomic and phenotypic characteristics, except for the inherited trait, there is no evidence that this soybean would be any different from conventional soybean regarding its influence on biogeochemical processes and nutrient levels in the soil. Furthermore, any indirect interactions of the GMO with other organisms in the vicinity of an incidental release of the grain are not likely to cause hazardous effects on the biogeochemical processes in the soil. As previously discussed, DMO is widely present in the environment.

Therefore, in the event of an incidental release of MON 87708 in the environment, the risk for direct or indirect, immediate or delayed adverse effects on biogeochemical processes can be considered as negligible.

9.9 Impacts of the specific cultivation, management and harvesting techniques

Not applicable. This application is for consent to import MON 87708 in the EU and for the use of this soybean as any other soybean, excluding the cultivation of MON 87708 varieties in the EU.

10. Potential interactions with the abiotic environment

MON 87708 was shown to be substantially equivalent to conventional soybean, except for the introduced dicamba-tolerance trait, imparted by the production of the MON 87708 DMO protein. Although DMO is a newly introduced protein in soybean, it has a history of safe use and has 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 with the environment will be limited. Moreover no negative impact of MON 87708 on the abiotic environment is expected to result from the import, processing and all uses as any other soybean in the EU.

11. Environmental monitoring plan (not if application concerns only food and feed produced from GM plants, or containing ingredients produced from GM plants and if the applicant has clearly shown that environmental exposure is absent or will be at levels or in a form that does not present a risk to other living organisms or the abiotic environment)

11.1 General (risk assessment, background information)

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

11.2 Interplay between environmental risk assessment and monitoring

An environmental risk assessment (E.R.A.) for MON 87708 was undertaken in the context of the scope of the application, that is, for import, processing and all uses of MON 87708 as any other soybean, but not including the cultivation of MON 87708 varieties in the EU. The scientific evaluation of the characteristics of MON 87708 in the E.R.A. (Sections D.9 and D.10) has shown that the risk for potential adverse effects on human and animal health or the environment resulting from the proposed use of MON 87708 in the EU is consistently negligible.

11.3 Case-specific GM plant monitoring (approach, strategy, method and analysis)

The scientific evaluation of the characteristics of MON 87708 in the E.R.A. 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 this soybean. It is therefore considered that there is no need for case-specific monitoring.

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

Any potential adverse effects of MON 87708 on human health and the environment, which were not anticipated in the E.R.A., can be addressed under the general surveillance. General surveillance is largely based on routine observation and implies the collection, scientific evaluation and reporting of reliable scientific evidence, in order to be able to identify whether unanticipated, direct or indirect, immediate or delayed adverse effects have been caused by the placing on the market of a genetically modified (GM) crop in its receiving environment.

In order to allow detection of the broadest possible scope of unanticipated adverse effects, general surveillance is performed by either selected, existing networks, or by specific company stewardship programmes, or by a combination of both. The consent holder will ensure that appropriate technical information on MON 87708 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 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 and the observed effect. The evaluation should consider the consequence of the observed effect and remedial action, if necessary, should be proportionate to the significance of the observed effect.

11.5 Reporting the results of monitoring

The consent holder will submit a monitoring report annually, containing information obtained from participating networks, and/or in case of a confirmed adverse effect. 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 animal health and/or the environment.

12. Detection and event-specific identification techniques for the GM plant

The presence of the *dmo* gene and the MON 87708 DMO protein in soybean or in soybean derived products can be identified by employing different techniques. Southern blot or PCR techniques can identify the inserted nucleotide sequence, while the MON 87708 DMO protein can be detected in all tissues of MON 87708, by optimised tissue extraction, standardised electrophoretic blotting and immunodetection methodologies.

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 for GM Food and Feed (EURL-GMFF), formerly named Community reference laboratory (CRL).

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

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

a) Notification number There is no history of release of MON 87708 in the EU.
b) Conclusions of post-release monitoring Not applicable.
c) Results of the release in respect to any risk to human health and the environment (submitted to the Competent Authority according to Article 10 of Directive 2001/18/EC) Not applicable.

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

a) Release country MON 87708 has been field tested in the US since 2005 and in Argentina, Chile, and Canada since 2006, 2007, and 2008, respectively.
b) Authority overseeing the release US: United States Department of Agriculture (USDA) Argentina: Secretary of Agriculture, Livestock, Fisheries, and Food (SAGPyA) Chile: Agriculture and Livestock Service (SAG) Canada: Canadian Food Inspection Agency (CFIA)
c) Release site US/Argentina/Chile/Canada: In major soybean growing regions of the respective countries.
d) Aim of the release US/Argentina/Chile/Canada: regulatory trials, efficacy, yield, breeding, product development, and demonstration.
e) Duration of the release US/Argentina/Chile/Canada: One growing season.
f) Aim of post-releases monitoring US/Argentina/Chile/Canada: Assessment of volunteers.

g) Duration of post-releases monitoring

US/Argentina/Canada: 12 months.

Chile: six months.

h) Conclusions of post-release monitoring

US/Argentina[1]/Chile/Canada: 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 would be the cause of any adverse effects to human, animal health or to the environment.

3. Links (some of these links may be accessible only to the competent authorities of the Member States, to the Commission and to EFSA):

a) Status/process of approval

The EFSA[2] and EURL[3] websites provide publicly accessible links to up-to-date databases on applications under Directive 2001/18/EC and applications under Regulation (EC) No. 1829/2003, including the Monsanto application for MON 87708.

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

A notification for MON 87708 according to Directive 2001/18/EC has not been submitted by Monsanto Company.

c) EFSA opinion

No EFSA opinion is available at the time of submission of this application.

d) Commission Register (Commission Decision 2004/204/EC)

The Commission Register is accessible on the European Commission website[4].

e) Molecular Register of the Community Reference Laboratory/Joint Research Centre

Information on detection protocols is posted on the JRC website[5].

[1] Post-release monitoring is still in progress in Argentina for the 2009/2010 growing season.
[2] http://registerofquestions.efsa.europa.eu/roqFrontend/ (Accessed on January 17, 2011)
[3] http://gmo-crl.jrc.ec.europa.eu/ (Accessed on January 17, 2011)
[4] http://ec.europa.eu/food/dyna/gm_register/index_en.cfm (Accessed on January 17, 2011)

f) Biosafety Clearing-House (Council Decision 2002/628/EC)

Publicly available information can be obtained from the Biosafety Clearing-House website[6].

g) Summary Notification Information Format (SNIF) (Council Decision 2002/812/EC)

EFSA website[7] provides a link to the publicly accessible summary of this application under Regulation (EC) No. 1829/2003.

[5] http://gmo-crl.jrc.ec.europa.eu/ (Accessed on January 17, 2011)
[6] http://bch.biodiv.org/ (Accessed on January 17, 2011)
[7] http://www.efsa.europa.eu/ (Accessed on January 17, 2011)