Application for authorization of MON 88017 x MON 810 maize in the European Union, according to Regulation (EC) No 1829/2003 on genetically modified food and feed

Part II
Summary

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

A. GENERAL INFORMATION

1. Details of application

a) Member State of application

Czech Republic

b) Notification number

Not available at the time of application.

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

The Monsanto development code for this genetically modified maize is: MON 88017 x MON 810. In countries where MON 88017 x MON 810 will be cultivated, packages of this maize will be marketed under the name of the hybrid variety, in association with a trademark, indicating clearly to growers that the hybrid is tolerant to glyphosate[1] and protected from specific coleopteran and lepidopteran insect pests.

d) Date of acknowledgement of notification

Not available at the time of application.

2. Applicant

a) Name of applicant

Monsanto Company, represented by Monsanto Europe S.A.

b) Address of applicant

Monsanto Europe S.A.
Avenue de Tervuren 270-272
B-1150 Brussels
BELGIUM

Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63167
U.S.A

c) Name and address of the person established in the Community who is responsible for the placing on the market, whether it be the manufacturer, the importer or the distributor, if different from the applicant (Commission Decision 2004/204/EC Art 3(a)(ii))

MON 88017 x MON 810 will be traded and used in the E.U. in the same manner as current commercial maize varieties and by the same operators currently involved in the trade and use of conventional maize.

[1] Active ingredient of Monsanto's Roundup range of agricultural herbicides. Roundup® is a registered trademark of Monsanto Technology LLC.

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 or containing ingredients 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 (x)	**No ( )**
If *no*, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC	

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

In more than a third country outside the E.U., application for the full range of uses have been made in the U.S.A, but approval has not been obtained. The status of other pending regulatory reviews, which are currently in progress in numerous countries around the world, typically depend on the country and its local regulatory framework.

8. General description of the product

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

MON 88017 x MON 810 was obtained by traditional breeding of two inbred lines, one derived from MON 88017 and the other one derived from MON 810.

MON 88017 x MON 810, as well as the genetically modified parental lines containing either the MON 88017 or MON 810 insert, have been developed by Monsanto Company.

MON 88017 produces the CP4 EPSPS and the MON 88017 Cry3Bb1[2] proteins that confer tolerance to glyphosate[3] and protection against certain coleopteran pests (*Diabrotica* spp.), respectively. MON 88017 was produced by *Agrobacterium*-mediated transformation of maize cells with plasmid vector PV-ZMIR39.

MON 810 produces the protein Cry1Ab, which confers protection against certain lepidopteran insect pests (*Ostrinia nubilalis* and *Sesamia* spp.). MON 810 was produced by genetic modification using particle acceleration transformation methods.

As MON 88017 x MON 810 inherits the introduced traits from its parental single-trait maize inbreds, it is tolerant to glyphosate as well as protected from the targeted coleopteran and lepidopteran insect pests.

The use of MON 88017 x MON 810 enables the farmer to effectively control the targeted coleopteran and lepidopteran insect pests in maize, ensuring maximum realization of yield potential, while removing the environmental burden of the production, packaging and transport of insecticides, previously used to control *Diabrotica* spp., *Ostrinia nubilalis* and *Sesamia* spp. In addition, growers will have the ability to apply glyphosate over the top of maize for broad-spectrum weed control.

[2] The Cry3Bb1 protein expressed in MON 88017.

[3] Active ingredient of Monsanto's Roundup family of agricultural herbicides. Roundup® is a registered trademark of Monsanto Technology LLC.

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

The scope of the current application is for import, processing and all uses of MON 88017 x MON 810 for food and feed. The range of uses of this maize for food and feed will be identical to the full range of equivalent uses of conventional maize.

c) Intended use of the product and types of users

MON 88017 x MON 810 will be traded and used in the E.U. in the same manner as current commercial maize varieties and by the same operators currently involved in the trade and use of conventional maize.

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

No specific conditions or instructions are warranted or required for the placing on the market of MON 88017 x MON 810 for import, processing, and use as or in food and feed. MON 88017 x MON 810 is substantially equivalent to other maize varieties except for its tolerance to glyphosate and its protection from target coleopteran and lepidopteran pests, which are traits of agronomic interest. This maize was shown to be as safe and as nutritious as conventional maize. Therefore MON 88017 x MON 810 and derived products will be stored, packaged, transported, handled and used in the same manner as the commercial maize products.

e) Any proposed packaging requirements

MON 88017 x MON 810 is substantially equivalent to conventional maize varieties (except for its tolerance to glyphosate and its protection from targeted coleopteran and lepidopteran insect pests). Therefore, MON 88017 x MON 810 and derived products will be used in the same manner as other maize and no specific packaging is foreseen. (For the labelling, *see* question A.8.(f)).

f) Any proposed labelling requirements in addition to those required by Community law (Annex IV of Directive 2001/18/EC; Regulation 1829/2003 art. 13 and 25)

In accordance with Regulations (EC) No 1829/2003 and 1830/2003, a labelling threshold of 0.9 % is applied for the placing on the market of MON 88017 x MON 810 grain and derived products.

Operators shall be required to label products containing or consisting of MON 88017 x MON 810 with the words “genetically modified maize” or “contains genetically modified maize”, and shall be required to declare the unique identifier MON-88Ø17-3 x MON-ØØ81Ø-6 in the list of GMOs that have been used to constitute the mixture that contains or consists of this GMO.

Operators shall be required to label foods and feeds derived from MON 88017 x MON 810 with the words "produced from genetically modified maize". In the case of products for which no list of ingredients exists, operators shall 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 88017 x MON 810 grain and derived foods and feeds in the E.U. are 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 88017 x MON 810. Therefore, no further specific measures are to be taken by the notifier.

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)

MON-88Ø17-3 x MON-ØØ81Ø-6

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

MON 88017 x MON 810 is suitable for food and feed use throughout the E.U.

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

Because this application is for consent to import and use MON 88017 x MON 810 as any other maize, not including the cultivation of varieties of MON 88017 x MON 810 in the E.U., environmental release would be more likely to occur during import, storage and processing of MON 88017 x MON 810. However, modern methods of grain handling minimize losses of grain, so there is little chance of germination of spilt grain resulting in the development of mature plants of MON 88017 x MON 810 in the E.U. Moreover, in the event of incidental spillage, the establishment of volunteer plants would be unlikely, since maize cannot survive without human assistance and is not capable of surviving as a weed. Although maize seed can over-winter in mild conditions and can germinate the following year, the appearance of maize in rotational fields is rare under European conditions. Maize volunteers, if they occurred, would be likely to be killed by frost or could be easily controlled by the use of selective herbicides. Moreover, the information presented in this application established that MON 88017 x MON 810 is unlikely to be different

from other maize and, therefore, is unlikely to pose any threat to the environment or to require special measures for its containment.

No specific conditions are warranted or required for the placing on the market of MON 88017 x MON 810 for import, processing, or use for food and feed.

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

1. Complete name

a) Family name

Poaceae (formerly Gramineae)

b) Genus

Zea

c) Species

mays (2n=20)

d) Subspecies

Mays

e) Cultivar/breeding line

MON 88017 x MON 810

f) Common name

Maize; Corn

2. a) Information concerning reproduction

(i) Mode(s) of reproduction

Maize (*Zea mays*) is an annual, wind-pollinated, monoecious species with separate staminate (tassels) and pistillate (silk) flowers, Self- and cross-pollination are generally possible, with frequencies of each normally determined by proximity and other physical influences on pollen transfer.

(ii) Specific factors affecting reproduction

Tasselling, silking, and pollination are the most critical stages of maize development and, consequently, grain yield may ultimately be greatly impacted by moisture and fertility stress.

(iii) Generation time

Maize is an annual crop with a cultural cycle ranging from as short as 60 to 70 days to as long as 43 to 48 weeks from seedling emergence to maturity.

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

Out-crossing with cultivated *Zea* varieties

The scope of the current application does not include cultivation of MON 88017 x MON 810 varieties in the E.U. Outcrossing with cultivated *Zea* varieties is therefore not expected.

Out-crossing with wild *Zea* species

Closely related wild relatives of maize do not exist in Europe.

3. Survivability

a) Ability to form structures for survival or dormancy

Maize is an annual crop and seeds are the only survival structures. Natural regeneration from vegetative tissue is not known to occur.

b) Specific factors affecting survivability

Maize cannot survive without human assistance and is not capable of surviving as a weed due to past selection in its evolution. Volunteer maize is not found growing in fencerows, ditches or roadsides as a weed. Although maize seed from the previous crop year can over-winter in mild winter conditions and germinate the following year, it cannot persist as a weed. The appearance of "volunteer" maize in fields following a maize crop from the previous year is rare under European conditions. Maize volunteers are killed by frost or, in the unlikely event of their occurrence, are easily controlled by current agronomic practices including cultivation and the use of selective herbicides.

Maize grain survival is dependent upon temperature, moisture of seed, genotype, husk protection and stage of development. Freezing temperatures have an adverse effect on maize seed germination and have been identified as being a major risk in seed maize production. Temperatures above 45° C have also been reported as injurious to maize seed viability.

4. Dissemination

a) Ways and extent of dissemination

In general, dissemination of maize may occur by means of seed dispersal and pollen dispersal. Dispersal of the maize grain is highly restricted in domesticated maize due to the ear structure including husk enclosure. For maize pollen, the vast majority is deposited in the same field due to its large size (90 to 100 μm) with smaller amounts of pollen deposited usually in a downwind direction. However, the current application does not include the environmental release of MON 88017 x MON 810 in the E.U.

b) Specific factors affecting dissemination

Dispersal of maize seeds does not occur naturally because of the structure of the ears of maize. Dissemination of isolated seeds may result from mechanical harvesting and transport as well as insect or wind damage, but this form of dissemination is highly infrequent. Genetic material can be disseminated by pollen dispersal, which is influenced by wind and weather conditions. Maize pollen is the largest of any pollen normally disseminated by wind from a comparably low level of elevation. Dispersal of maize pollen is limited by its large size and rapid settling rate.

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

Because of its many divergent types, maize is grown over a wide range of climatic conditions. The bulk of the maize is produced between latitudes 30° and 55°, with relatively little grown at latitudes higher than 47° latitude anywhere in the world. The greatest maize production occurs where the warmest month isotherms range between 21° and 27° C and the freeze-free season lasts 120 to 180 days. A summer rainfall of 15 cm is approximately the lower limit for maize production without irrigation with no upper limit of rainfall for growing maize, although excess rainfall will decrease yields.

There are no close wild relatives of maize 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

Maize is widely grown in the E.U. and represents a significant portion of global maize production. The most important areas of maize production in Europe include the Danube Basin, from southwest Germany to the Black Sea, along with southern France through the Po Valley of northern Italy.

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

There are no known toxic effects of the maize plant to humans, animals or livestock; it has a history of safe use for human food and animal feed. However, maize is known to interact with other organisms in the environment including insects, birds, and mammals. It is susceptible to a range of fungal diseases and nematode, insect and mite pests.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification

MON 88017 × MON 810 was produced by crossing single-trait inbred plants of MON 88017 and MON 810 using traditional breeding methods.

The single-trait parental lines were both produced by genetic modification, *Agrobacterium*-mediated transformation of maize cells for MON 88017 and particle acceleration transformation methods for MON 810.

2. Nature and source of the vector used

MON 88017 x MON 810 has been obtained by traditional breeding of MON 88017 and MON 810 and no vector has been used to produce this maize hybrid.

The plasmid vector PV-ZMIR39 was used for the transformation of maize cells to produce MON 88017. It was constructed using standard molecular biology techniques. It is a disarmed, binary *Agrobacterium tumefaciens* transformation vector that contains both left and right transfer-DNA (T-DNA) border sequences to facilitate transformation. The T-DNA region contains the *cp4 epsps* and *MON 88017 cry3Bb1* gene expression cassettes, and is the portion of plasmid PV-ZMIR39 that is integrated into the maize genome during the transformation process.

MON 810 was generated by the integration of sequences from the plasmid vector PV-ZMBK07, containing the *cry1Ab* coding sequence of interest, which was derived from *Bacillus thuringiensis* subsp. *kurstaki*.

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

MON 88017 × MON 810 results from a single traditional cross of the inbred parental lines MON 88017 and MON 810, which are made homozygous for their respective inserted sequences.

By crossing MON 88017 and MON 810, MON 88017 × MON 810 inherits the inserted DNA fragments from both its parental maize lines as they were present in the parental line.

The individual components and the function of these inherited DNA sequences are given in Tables 1 and 2.

Table 1. Components of the inserted DNA fragment inherited from MON 88017

Sequence	Size (Kb)	Source	Function
LB (portion of the left border)	0.02	Octopine Ti plasmid, pTi15955	Portion of the left border sequence involved in transfer of T-DNA from the octopine Ti plasmid, pTi15955
***cp4 epsps* gene cassette**			
P-ract1	0.93	Rice actin gene	Promoter
ract1 intron	0.46	Rice actin gene	Intron
CTP2	0.23	*Arabidopsis thaliana*	DNA sequence coding for the N-teminal chloroplast transit peptide
cp4 epsps	1.37	*Agrobacterium* sp. Strain CP4	DNA sequence coding for the native CP4 EPSPS protein
NOS 3'	0.26	*Agrobacterium tumefaciens*	3' nontranslated region of the nopaline synthase (NOS) gene which terminates transcription and directs polyadenylation
***MON 88017 cry3Bb1* gene cassette**			
P-e35S	0.61	Cauliflower mosaic virus	Promoter with the duplicated enhancer region
wt CAB leader	0.07	Wheat	5' untranslated leader of the wheat chlorophyll a/b-binding protein
ract1 intron	0.46	Rice actin gene	Intron
MON 88017 cry3Bb1	1.96	*Bacillus thuringiensis* subsp. k*umamotoensis*	DNA sequence coding for a synthetic variant of Cry3Bb1 protein
tahsp17 3'	0.23	Wheat heat shock protein	3' nontranslated region of the DNA sequence coding for wheat 17.3 kDa heat-shock protein, which ends transcription and directs polyadenylation

Table 2. Components of the inserted DNA fragment inherited from MON 810

Sequence	Size (Kb)	Source	Function
P-e35S	0.32	Cauliflower mosaic virus	DNA sequence derived from cauliflower mosaic virus (CaMV) containing a portion of the CaMV promoter with the duplicated enhancer region and 5' untranslated region.
***Zm*hsp70**	0.81	Maize (*Zea mays* L.)	DNA sequence derived from corn containing the intron sequence from the maize *hsp* 70 gene (heat-shock protein) present to stabilize the level of gene transcription.
cry1Ab	2.45	*Bacillus thuringiensis* subsp. *kurstaki*	DNA sequence containing synthetic linker and a portion of the synthetic coding sequence for a variant of Cry1Ab1 protein from *Bacillus thuringiensis* subsp. *kurstaki*.

D. INFORMATION RELATING TO THE GM PLANT

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

MON 88017 x MON 810 consists of varieties developed using traditional methods of maize breeding, which express:

1. the CP4 EPSPS protein, derived from *Agrobacterium* sp. strain CP4 which provides tolerance to glyphosate.
2. the modified Cry3Bb1 protein, derived from *Bacillus thuringiensis* subsp. *kumamotoensis*, which provides protection from certain coleopteran pests (*Diabrotica* spp.),
3. the Cry1Ab protein, derived from *Bacillus thuringiensis* subsp. *kurstaki*, which provides protection from certain lepidopteran insect pests (including *Ostrinia nubilalis* (European corn borer) and *Sesamia* spp).

Commercialization of MON 88017 x MON 810 will therefore provide substantial benefits to growers by limiting weed pressure while at the same time reducing the risk from insecticide use to humans and the environment and by limiting yield losses from insects feeding damage.

2. Information on the sequences actually inserted or deleted

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

MON 88017 and MON 810 each contains a single DNA insert containing a single copy of the introduced DNA fragment, and this at different loci in the maize genome.

In the progeny of MON 88017 and MON 810, each fragment is inherited as a single gene in a Mendelian fashion.

As the parental maize lines used in the traditional cross to produce MON 88017 × MON 810 are inbred lines that are homozygous in the MON 88017 or MON 810, both of the inserted fragments are inherited by the MON 88017 × MON 810. The presence of these inserts in the hybrid was confirmed through Southern blot analysis.

Therefore, MON 88017 × MON 810 contains both of the parental inserts, as they were present in the parental MON 88017 and MON 810.

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

Not applicable.

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

The traditionally bred F_1 MON 88017 x MON 810 contains both of the parental inserts on separate chromosomes in the nuclear genome, as they were present in the parental MON 88017 and MON 810 lines, respectively. The presence of the inserts from MON 88017 and MON 810 in MON 88017 x MON 810 was confirmed by Southern blot analyses.

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

The molecular comparison of MON 88017 x MON 810 to the parental lines, MON 88017 and MON 810, indicates that the inserts are preserved in MON 88017 x MON 810. Note that there is no scientific basis to support the fact that those inserts would be intrinsically more unstable when combined together by traditional breeding. The molecular characteristics of the respective introduced DNA sequences, present in the single-trait MON 88017 and MON 810, also apply to MON 88017 × MON 810, including the structural organisation and integrity of the inserts, as well as the characteristics of the sites of insertion and the flanking sequences, immediately adjacent to the introduced sequences.

A schematic representation of MON 88017 and MON 810 inserts is given in Figures 1 and 2.

Figure 1. Schematic representation of the MON 88017 insert

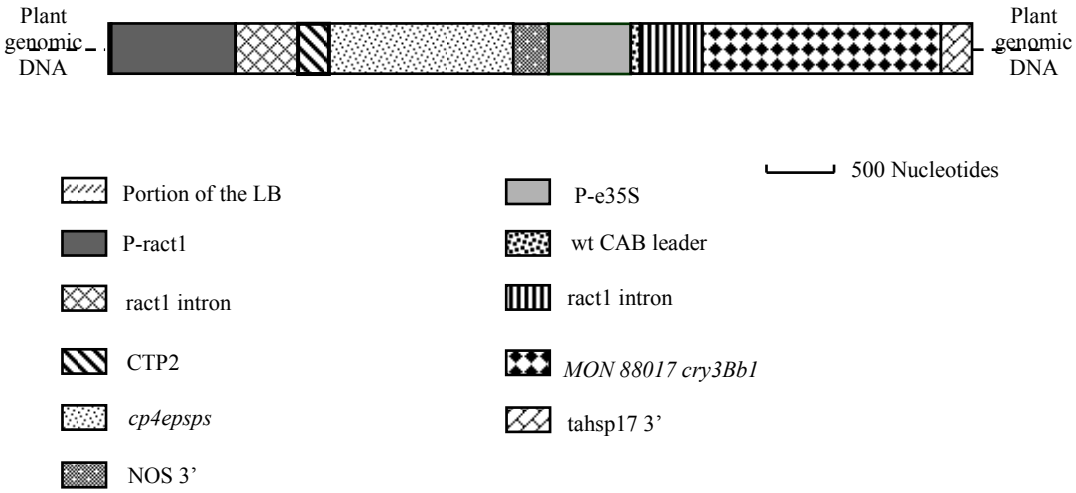
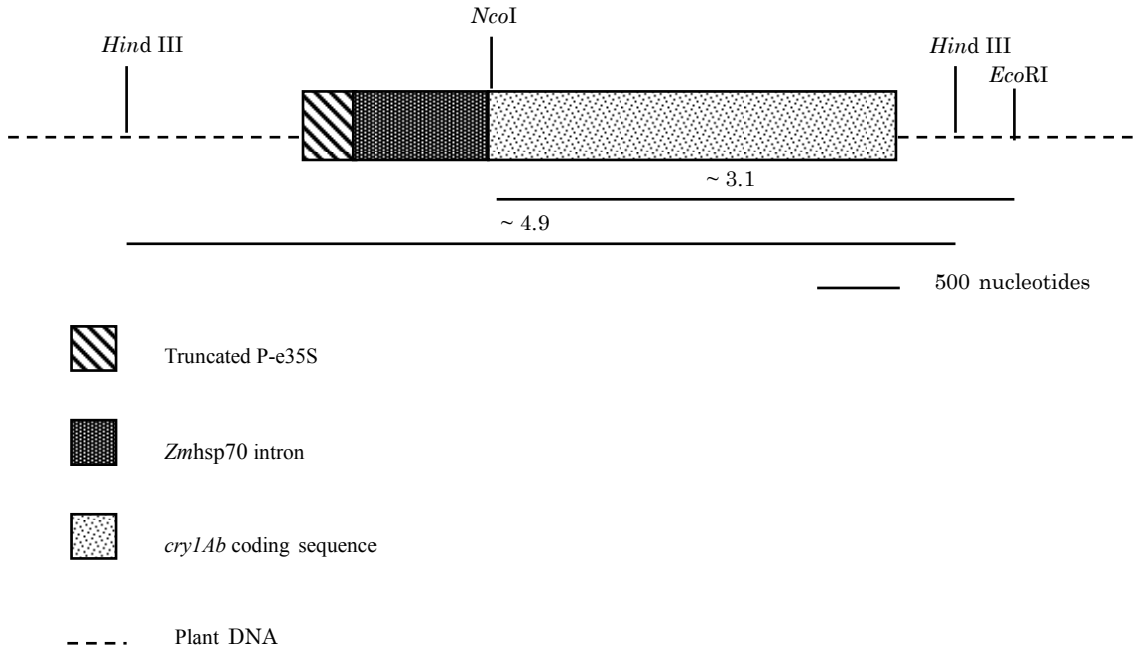


Figure 2. Schematic representation of the MON 810 insert



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 CP4 EPSPS, MON 88017 Cry3Bb1 and Cry1Ab proteins were measured in various tissues collected from MON 88017 × MON 810 plants produced in three field trials in the U.S.A. during the 2002 growing season. These field sites were located within the major corn-growing region of the U.S.A. and provided a variety of environmental conditions. At each site, three replicated plots of plants containing MON 88017 × MON 810, as well as the control hybrids H1200902, MON 88017, and MON 810, were planted using a randomized complete block field design.

CP4 EPSPS, MON 88017 Cry3Bb1 and Cry1Ab protein levels were estimated in forage and grain because these tissues are most relevant to food and animal feed product safety. Since protein levels are relevant to the insect control performance of the maize plants, and are also necessary to assess exposure of non-target species where the maize is planted, protein levels were also measured in additional maize tissues. Levels of MON 88017 Cry3Bb1 protein were measured in young leaf, root, pollen and forage root, while levels of Cry1Ab protein were measured in leaf and pollen.

Enzyme-linked immunosorbent assay (ELISA) methods were developed and validated for each protein. All protein values are reported as micrograms (µg) of the specific protein per gram (g) of tissue on a fresh weight (fw) and a dry weight (dw) basis.

Overall, the ranges across three sites for the CP4 EPSPS, MON 88017 Cry3Bb1 and Cry1Ab protein levels in MON 88017 × MON 810 were comparable to the corresponding ranges in either MON 88017 or MON 810.

b) Parts of the plant where the insert is expressed

Levels of proteins are summarized in Table 3. (CP4 EPSPS), Table 4. (MON 88017 Cry3Bb1) and Table 5. (Cry1Ab). The CP4 EPSPS and MON 88017 Cry3Bb1 protein levels in MON 88017 x MON 810 were compared to MON 88017, whereas, the Cry1Ab protein levels in MON 88017 x MON 810 were compared to MON 810.

CP4 EPSPS

The mean CP4 EPSPS level was 4.3 µg/g dw (SD 1.6 µg/g dw) in MON 88017 x MON 810 grain samples, as compared to 5.8 µg/g dw (SD 0.97 µg/g dw) in grain from MON 88017. The mean CP4 EPSPS level was 51 µg/g dw (SD 9.2 µg/g dw) in MON 88017 x MON 810 forage samples, as compared to 57 µg/g dw (SD 7.6 µg/g dw) in forage from MON 88017.

MON 88017 Cry3Bb1

The mean MON 88017 Cry3Bb1 level was 9.3 µg/g dw (SD 3.4 µg/g dw) in MON 88017 x MON 810 grain samples, as compared to 15 µg/g dw (SD 3.6 µg/g dw) in grain from MON 88017. The mean MON 88017 Cry3Bb1 level was 100 µg/g dw (SD 23 µg/g dw) in MON 88017 x MON 810 forage samples, as compared to 95 µg/g dw (SD 19 µg/g dw) in forage from MON 88017.

Cry1Ab

The mean Cry1Ab level was 0.39 µg/g dw (SD 0.13 µg/g dw) in MON 88017 x MON 810 grain samples, as compared to 0.43 µg/g dw (SD 0.091 µg/g dw) in grain from MON 810. The mean Cry1Ab level was 14 µg/g dw (SD 2.1 µg/g dw) in MON 88017 x MON 810 forage samples, as compared to 14 µg/g dw (SD 3.4 µg/g dw) in forage from MON 810.

Overall, the ranges across three sites for the CP4 EPSPS, MON 88017 Cry3Bb1 and Cry1Ab protein levels in MON 88017 x MON 810 were comparable to the corresponding ranges in either MON 88017 or MON 810.

Table 3. Summary of CP4 EPSPS protein levels in maize tissues collected from MON 88017 × MON 810 and MON 88017[1] produced in U.S. field trials conducted in 2002

	MON 88017 × MON 810		MON 88017[3]	
Tissue Type[2]	**Mean (SD) Range (µg/g fw)[4]**	**Mean (SD) Range (µg/g dw)[5]**	**Mean (SD) Range µg/g fw**	**Mean (SD) Range µg/g dw**
Grain	3.8 (1.5)[6] 1.9 – 5.5[7]	4.3 (1.6) 2.2 – 6.2	5.1 (0.89) 3.7 – 6.3	5.8 (0.97) 4.1 – 7.1
Forage	15 (2.8) 11 – 21	51 (9.2) 38 – 70	16 (2.1) 12 – 19	57 (7.6) 42 – 69

1. The levels of CP4 EPSPS protein in tissue samples from the control hybrid H1200902 were below the LOQ for grain tissue (0.28 µg/g fw). The levels of CP4 EPSPS protein in tissue samples from the control hybrid H1200902 were below the LOD for forage tissue (0.18 µg/g fw).
2. Tissues were collected at the following growth stages:
   a. Grain: R6 (physiological maturity)
   b. Forage: early dent (R4 - R6)
3. The analyses of MON 88017 tissue samples were conducted at the same time and are reported in a separate study.
4. Protein levels are expressed as microgram (µg) of protein per gram (g) of tissue on a fresh weight (fw) basis and are corrected for method bias.
5. Protein levels are expressed as µg/g on a dry weight (dw) basis. The dry weight values were calculated by dividing the fw values by the dry weight conversion factors obtained from moisture analysis data.
6. The mean and standard deviation were calculated across sites (n=9).
7. Minimum and maximum values were determined for each tissue type across sites.

Table 4. Summary of MON 88017 Cry3Bb1 protein levels in maize tissues collected from MON 88017 × MON 810 and MON 88017[1] produced in U.S. field trials conducted in 2002

Tissue Type[2]	MON 88017 × MON 810 Mean (SD) Range (µg/g fw)[4]	MON 88017 × MON 810 Mean (SD) Range (µg/g dw)[5]	MON 88017[3] Mean (SD) Range µg/g fw	MON 88017[3] Mean (SD) Range µg/g dw
OSR-1	37 (16)[6] 8.8 – 56[7]	350 (150) 88 – 560	39 (8.1) 24 – 51	370 (80) 240 – 510
OSL-1	90 (18) 65 – 120	670 (130) 550 – 920	76 (23) 28 – 110	570 (170) 230 – 820
Pollen	16 (3.5) 0.020[8] – 19	27 (5.7) N/A[9] – 34	14 (2.5) 11 – 20	25 (4.2) 17 – 32
Grain	8.2 (3.0) 3.3 – 12	9.3 (3.4) 3.9 – 13	13 (3.1) 8.7 – 19	15 (3.6) 10 – 22
Forage	29 (6.8) 20 – 43	100 (23) 71 – 150	27 (5.5) 22 – 39	95 (19) 75 – 130
Forage Root	21 (2.3) 16 – 24	140 (29) 89 – 180	21 (3.1) 17 – 27	130 (29) 98 – 170

1. The levels of MON 88017 Cry3Bb1 protein in tissue samples from the control hybrid H1200902 were below the LOQ for OSL-1, grain, forage, and forage root tissues (0.044, 0.051, 0.047, and 0.040 µg/g fw, respectively) and below the LOD for OSR-1 and pollen tissues (0.032 and 0.020 µg/g fw, respectively).
2. Tissues were collected at the following growth stages:
    a. OSR-1: V2 - V3
    b. OSL-1: V2 – V3
    c. Pollen: R1
    d. Forage: early dent (R4 - R6)
    e. Grain: R6 (physiological maturity
    f. Forage Root: early dent (R4 - R6)
3. The analyses of MON 88017 tissue samples were conducted at the same time and are reported in a separate study.
4. Protein levels are expressed as microgram (µg) of protein per gram (g) of tissue on a fresh weight (fw) basis and are corrected for method bias.
5. Protein levels are expressed as µg/g on a dry weight (dw) basis. The dry weight values were calculated by dividing the fw by the dry weight conversion factors obtained from moisture analysis data.
6. The mean and standard deviation were calculated across sites (n=9).
7. Minimum and maximum values were determined for each tissue type across sites.
8. The level of Cry3Bb1 for one of the nine replicates was below the LOD (0.020 µg/g fw).
9. Protein levels ≤ LOD on a fw basis are not reported on a dw basis.

Table 5. Summary of Cry1Ab protein levels in maize tissues collected from MON 88017 × MON 810 and MON 810[1] produced in U.S. field trials conducted in 2002

Tissue Type[2]	MON 88017 × MON 810 Mean (SD) Range (µg/g fw)[4]	MON 88017 × MON 810 Mean (SD) Range (µg/g dw)[5]	MON 810 Mean (SD) Range µg/g fw	MON 810 Mean (SD) Range µg/g dw
OSL-1	15 (2.5)[5] 10 – 18[6]	110 (17) 85 – 140	14 (1.4) 11 – 16	100 (12) 89 – 130
Pollen	0.090[7] N/A	N/A N/A	0.090[7] N/A	N/A N/A
Grain	0.34 (0.11) 0.13 – 0.54	0.39 (0.13) 0.16 – 0.63	0.38 (0.078) 0.24 – 0.48	0.43 (0.091) 0.27 – 0.54
Forage	3.9 (0.65) 3.2 – 5.0	14 (2.1) 11 – 17	4.2 (1.0) 2.3 – 5.5	14 (3.4) 8.4 – 19

1. The levels of Cry1Ab protein in tissue samples from the control hybrid H1200902 were below the LOD for OSL-1, pollen, forage and grain tissues (1.1, 0.090, 0.26, and 0.13 µg/g fw, respectively).
2. Tissues were collected at the following growth stages:
   a. OSL-1: V2 – V3
   b. Pollen: R1
   c. Grain: R6 (physiological maturity)
   d. Forage: early dent (R4 - R6)
3. Protein levels are expressed as microgram (µg) of protein per gram (g) of tissue on a fresh weight (fw) basis and are corrected for method bias.
4. Protein levels are expressed as µg/g on a dry weight (dw) basis. The dry weight values were calculated by dividing the fw values by the dry weight conversion factors obtained from moisture analysis data.
5. The mean and standard deviation were calculated across sites (n=9).
6. Minimum and maximum values were determined for each tissue type across sites.

The level of Cry1Ab for all samples from all sites was below the LOD (0.090 µg/g fw).

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

a) Reproduction

Agronomic data collected from trials performed with MON 88017 x MON 810 have demonstrated that MON 88017 × MON 810 has not been altered in survival, multiplication or dissemination characteristics when compared to its parental maize lines (MON 88017 and MON 810) or compared to conventional maize varieties. The introduced traits for glyphosate tolerance and insect-protection have no influence on maize reproductive morphology and hence no changes in seed dissemination would be expected.

b) Dissemination

The introduced traits have no influence on maize reproductive morphology and hence no changes in seed dissemination are to be expected.

c) Survivability

Maize is known to be a weak competitor in the wild, which cannot survive outside cultivation without the aid of human intervention. Field observations have demonstrated that MON 88017 x MON 810 has not been altered in its survivability when compared to conventional maize.

d) Other differences

Comparative assessments in the field did not reveal any biologically significant differences between MON 88017 x MON 810 and conventional maize hybrids, except for the introduced traits that are of agronomic interest.

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

MON 88017 × MON 810 hybrid seed (F_1) is produced by a single cross of the MON 88017 and MON 810 parental inbred lines (made homozygous for MON 88017 or MON 810, respectively) by traditional breeding. Thereby, each parental line passes on its inserted DNA sequence to the resulting MON 88017 × MON 810 F_1 hybrid seed, which is sown by the grower.

The single-trait modified maize lines MON 88017 and MON 810 each contain one insert with a single copy of the respective transformed DNA, which is stably integrated into the nuclear maize genome. Each trait is inherited as a single dominant gene in a Mendelian fashion. This has been confirmed by Southern blot analyses.

The harvested (F2) grain of MON 88017 × MON 810 is marketed by the grower for food, feed or industrial use and is not used for further breeding. Therefore, since MON 88017 × MON 810 hybrid maize seed exists only for a single generation, there is no opportunity for its stability to be compromised.

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

a) Plant to bacteria gene transfer

No changes are expected in the ability of MON 88017, MON 810 or MON 88017 x MON 810 to transfer genetic material to bacteria since none of the genetic elements inserted in MON 88017 and MON 810 has a genetic transfer function.

b) Plant to plant gene transfer

Not applicable. The scope of the current application does not include the cultivation of MON 88017 x MON 810 varieties in the E.U.

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 88017 x MON 810 was compared with control lines that had not been genetically modified and with commercial hybrids. This MON 88017 x MON 810 F_1 was used for the studies and its self-pollination produced the respective F_2 seed generations, which was the grain material tested.

7.2 Production of material for comparative assessment

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

MON 88017 x MON 810 and the conventional control maize were grown at four replicated field sites in major maize-growing areas of the U.S.A. (Iowa, Illinois, Nebraska and Ohio) during the 2002 field season. Four commercially available maize hybrids were grown also at each of the same field sites to provide a total of 12 different reference substances. At each field site, the test, control and reference seed were planted in a randomized complete block design with three replicates per block

b) the baseline used for consideration of natural variations

The compositional study compared MON 88017 x MON 810 to the control. Reference hybrids were grown in the same field locations and under the same conditions as the test and control. Where statistical differences occurred, the measured analyte was compared to a confidence interval developed from the reference hybrids. Differences were also compared to historical ranges and ranges reported in literature.

7.3 Selection of material and compounds for analysis

The numerous compounds that were selected for analysis in the compositional study were chosen on the basis of internationally accepted guidance provided by the OECD (*See* consensus document for compositional analysis of maize), in addition to other selected compounds.

Based on the positive results of these extensive, compositional analyses conducted for MON 88017 x MON 810 compared to conventional maize hybrids (*see* Section D.7.1), there is no indication to further analyse other selected compounds in this maize.

7.4 Agronomic traits

Field trials with MON 88017 x MON 810 were performed and the set of agronomic observations supports a conclusion that from an agronomic and phenotypic (morphological) point of view, MON 88017 x MON 810 is equivalent to conventional maize, except for the introduced glyphosate tolerance and insect-protection traits.

7.5 Product specification

MON 88017 x MON 810 will be imported into the E.U. in mixed shipments of maize grain and products, produced in other world areas, for use by operators that have conventionally been involved in the commerce, processing and use of maize and maize derived products in the E.U.

7.6 Effect of processing

Using both wet and dry milling processes, maize is converted into a diverse range of food and feed products and derivatives used as food and feed ingredients or additives. As MON 88017 x MON 810 is substantially equivalent and as safe and as nutritious as conventional maize, the use of MON 88017 x MON 810 for the production of foods and feeds is no different from that of conventional maize. Consequently, any effects of the production and processing of MON 88017 x MON 810 are not expected to be any different from the production and processing of the equivalent foods and feeds, originating from conventional maize.

7.7 Anticipated intake/extent of use

There are no anticipated changes in the intake and/or extent of use of maize or derived products for use as or in food or feed as a result of the addition of MON 88017 x MON 810 to the conventional maize supply. MON 88017 x MON 810 is expected to replace a portion of current maize hybrids such that its intake or use will represent some fraction of the total products derived from maize.

7.8 Toxicology

7.8.1 Safety evaluation of newly expressed proteins

MON 88017 × MON 810 is produced by a single traditional cross of two genetically modified parental inbred maize lines, *i.e.* one derived from MON 88017 and one derived from MON 810. Both of the introduced traits in the single-trait, parental lines are inherited by the MON 88017 × MON 810 progeny. This results in the combined expression of the CP4 EPSPS, MON 88017 Cry3Bb1 and the Cry1Ab proteins in the same plant, MON 88017 × MON 810. These introduced proteins are present at low levels in the plant and have previously been demonstrated as safe for animal and human health.

The conclusion of safety to humans of the CP4 EPSPS, MON 88017 Cry3Bb1 and Cry1Ab proteins was based upon the following considerations:

(1) no amino acid sequence similarity to known toxins, other than *B.t.* proteins in the case of MON 88017 Cry3Bb1 and Cry1Ab, and no immunologically relevant sequence similarity with known allergens, (2) rapid degradation under conditions which simulate mammalian digestive systems, (3) no indications of acute toxicity in mice administered CP4 EPSPS, MON 88017 Cry3Bb1 or Cry1Ab protein by oral gavage, (4) very low dietary exposure, and (5) a history of safe use.

7.8.2 Testing of new constituents other than proteins

Since maize is known as a common source of food and feed with a centuries-long history of safe use and consumption around the world, and as MON 88017 x MON 810 was shown to be substantially equivalent to conventional maize, no testing of any constituent other than the proteins produced by the introduced genes is indicated.

7.8.3 Information on natural food and feed constituents

Maize is known as a common source of food and feed with a centuries-long history of safe use and consumption around the world. No particular natural constituents of maize are considered to be of significant concern to require additional information or further risk assessment.

7.8.4 Testing of the whole GM food/feed

The compositional and nutritional equivalence of grain and forage from MON 88017 x MON 810 and conventional maize have been established by compositional analysis. Additionally, the wholesomeness of MON 88017 x MON 810 grain has been confirmed by a feeding study in broiler chickens using MON 88017 x MON 810-containing diets.

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

Absence of any allergenic potential associated with the introduced CP4 EPSPS, MON 88017 Cry3Bb1 and Cry1Ab proteins expressed in MON 88017 × MON 810 has previously been demonstrated for the single-trait parental lines containing either MON 88017 or MON 810.

These proteins were assessed for their potential allergenicity by a variety of tests, including a) whether the genes came from allergenic or non-allergenic sources, b) sequence similarity to known allergens, and c) pepsin stability of the protein in an *in vitro* digestion assay. In all cases, the proteins did not exhibit properties characteristic of allergens.

7.9.2 Assessment of allergenicity of the whole GM plant or crop

As the introduced proteins do not have any allergenic potential, it was concluded that the use of MON 88017 x MON 810 for food or feed does not lead to an increased risk for allergenic reactions compared to the equivalent range of food and feed uses of conventional maize.

7.10 Nutritional assessment of GM food/feed

7.10.1 Nutritional assessment of GM food

The introduced traits in MON 88017 x MON 810 are of agronomic interest, and are not intended to change any nutritional aspects of this maize. Hence this maize is not expected to be more or less attractive for use as food (or feed), for processing, or as a food (or feed) ingredient. Therefore, anticipated dietary intake of maize-derived foods and feeds is not expected to be altered upon commercialisation of MON 88017 x MON 810, and no nutritional imbalances are expected as a result of the use of MON 88017 x MON 810.

7.10.2 Nutritional assessment of GM feed

A confirmatory feeding study in broiler chickens was conducted to compare the nutritional value of MON 88017 × MON 810 grain and non-transgenic control grain as well as additional commercial maize hybrids, and to provide confirmation of the safety of this hybrid maize. The results of this study show that there were no biologically relevant differences in the parameters tested between broilers fed the MON 88017 × MON 810 diet and the non-transgenic control diet. The MON 88017 × MON 810 diet was as wholesome as its corresponding non-transgenic control diet and commercially available reference diets regarding its ability to support the rapid growth of broiler chickens. This conclusion was consistent with the evaluation of the composition of the MON 88017 × MON 810, which showed that there were no biologically relevant differences in nutritional and compositional properties relative to control and reference maize hybrids. These data confirm and support the conclusion that the MON 88017 × MON 810 is as safe and nutritious as conventional maize.

7.11 Post-market monitoring of GM food/feed

The assessment of the human and animal safety of MON 88017 x MON 810 was conducted on the basis of its substantial equivalence to conventional maize (except for the introduced traits) and by extensive characterisation of the introduced traits, which are of agronomic interest, resulting in the expression of the CP4 EPSPS, MON 88017 Cry3Bb1 and Cry1Ab proteins.

There are no intrinsic hazards related to MON 88017 × MON 810 as no signs of adverse or unanticipated effects have been observed in a number of safety studies, including an animal feeding study using doses of administration that are orders of magnitude above expected consumption levels. The pre-market risk characterisation for food and feed use of MON 88017 x MON 810 demonstrates that the risks of consumption of MON 88017 x MON 810 or its derived products are consistently negligible and no different from the risks associated with the consumption of conventional maize and maize-derived products.

As a consequence, specific risk management measures are not indicated, and post-market monitoring of the use of this maize for food, feed or processing is neither warranted, nor appropriate.

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

The MON 88017 Cry3Bb1 protein present in MON 88017 and MON 88017 x MON 810 confers protection against certain economically damaging coleopteran insect pests, in particular the larvae of *Diabrotica* spp. (corn rootworm). The Cry1Ab protein present in MON 810 and MON 88017 × MON 810 confers protection against certain lepidopteran insect pests, including the European Corn Borer (*Ostrinia nubilalis*) and pink borers (*Sesamia* spp.).These species may be considered the target organisms which interact with MON 88017 × MON 810. The Cry3Bb1 and Cry1Ab proteins are known to provide protection to maize in the field against their specific target organisms and not to have synergistic effects.

The Cry3Bb1 and Cry1Ab proteins must be ingested by the relevant, susceptible insect to produce their insecticidal effect. Following ingestion, Cry1Ab and Cry3Bb1 proteins are solubilized and are relatively proteolytically stable, but unlike Cry1A proteins, Cry3 proteins do not have a large C-terminal domain that is processed to the active core protein. The active form of the respective Cry protein must traverse the insect midgut peritrophic membrane and selectively bind to specific receptors to exert its insecticidal activity. Cation-selective pores are formed by the Cry protein, disrupting cell homeostasis and ultimately leading to the death of the specific insect.

Any significant interactions of MON 88017 × MON 810 with its target pest organisms are limited to those countries where the cultivation of this maize has been authorized. The cultivation of MON 88017 × MON 810 varieties in the E.U. is not within the scope of this application. The likelihood that the import and use of MON 88017 × MON 810 for food, feed or processing will result in plants of this maize being present in the environment is negligible.

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

9.1 Persistence and invasiveness

Like for conventional maize, the likelihood of MON 88017 x MON 810 spreading in the environment is negligible, as maize is neither persistent nor invasive and these parameters are unaltered in MON 88017 x MON 810 when compared to conventional maize. Hence the risk of establishment and spreading of MON 88017 x MON 810 in the environment is negligible.

9.2 Selective advantage or disadvantage

Compared with conventional maize, the presence of the introduced traits in a MON 88017 x MON 810 volunteer would only confer a meaningful advantage where plants would be treated with glyphosate herbicide or where target coleopteran and/or lepidopteran pest species would be present in high numbers, and if no other more important factors limiting its establishment in the environment would be present. The risk of the glyphosate-tolerance and the coleopteran and lepidopteran pest protection traits in MON 88017 x MON 810 to be the cause of any competitive advantage or disadvantage impacting the environment is negligible, as maize is unlikely to establish outside cultivation under European conditions (*see* Section D.9.1).

9.3 Potential for gene transfer

There is no potential for gene transfer from MON 88017 x MON 810 to wild plant species in the E.U. and negligible likelihood for gene transfer to other maize crops, as this application is not for consent to cultivate MON 88017 x MON 810 varieties in the E.U. The environmental risk of potential gene transfer is negligible.

9.4 Interactions between the GM plant and target organisms

The MON 88017 Cry3Bb1 protein present in MON 88017 and MON 88017 x MON 810 confers protection against certain economically damaging coleopteran insect pests, in particular the larvae of *Diabrotica* spp. (corn rootworm). The Cry1Ab protein present in MON 810 and MON 88017 × MON 810 confers protection against certain lepidopteran insect pests, including the European Corn Borer (*Ostrinia nubilalis*) and pink borers (*Sesamia* spp.).These species may be considered the target organisms which interact with MON 88017 × MON 810. The Cry3Bb1 and Cry1Ab proteins are known to provide protection to maize in the field against their specific target organisms and not to have synergistic effects.

Any significant interactions of MON 88017 × MON 810 with its target pest organisms are limited to those countries where the cultivation of this maize has been authorized. The cultivation of MON 88017 × MON 810 varieties in the E.U. is not within the scope of this application. The likelihood that the import and use of MON 88017 × MON 810 for food, feed or processing will result in plants of this maize being present in the environment is negligible.

9.5 Interactions of the GM plant with non-target organisms

Given the scope of the current application, which does not include the cultivation of MON 88017 x MON 810 varieties in the E.U., the likelihood for direct or indirect interactions of this maize with non-target organisms is considered to be negligible.

In addition, the introduced CP4 EPSPS, MON 88017 Cry3Bb1 and Cry1Ab proteins present a negligible hazard to non-target organisms, even if incidental spillage of MON 88017 x MON 810 grains during import, storage, transport or use would lead to the brief survival of MON 88017 x MON 810 plants in the environment. It is established that Cry3Bb1 exhibits specific toxicity towards Coleoptera and Cry1Ab to specific Lepidoptera, but not to other families of beetles, other insect orders or other non-target organisms. Based on the ubiquitous occurrence of natural EPSPSs in the environment and the history of safe use of CP4 EPSPS-expressing crops such as Roundup Ready soyabean, it is highly unlikely that the introduced CP4 EPSPS in MON 88017 x MON 810 would possess biological activity towards any non-target organisms.

As a consequence, there is negligible risk for harmful effects of MON 88017 x MON 810 on non-target organisms, either through direct or indirect interactions with this maize or through contact with the newly expressed proteins.

Furthermore, no evidence of any adverse effects was found since the commercial introduction of NK603, MON 863, MON 810, MON 863 x MON 810, MON 863 × NK603, NK603 x MON 810 and MON 863 x MON 810 x NK603 expressing similar proteins, in North America. No evidence has been brought forward by the many farmers and operators handling these products of any harmful or undesirable effects associated with this maize or with the introduced proteins.

9.6 Effects on human health

The likelihood for any adverse effects, occurring in humans as a result of their contact with this maize, is no different from conventional maize. MON 88017 x MON 810 contains the CP4 EPSPS, MON 88017 Cry3Bb1 and Cry1Ab proteins, which have negligible potential to cause any toxic or allergenic effects in man. Therefore, the risk of changes in the occupational health aspects of this maize is negligible.

9.7 Effects on animal health

The likelihood of potential adverse effects in animals fed on MON 88017 x MON 810 and in humans, consuming those animals, is negligible (*see* Sections D.7.8, D.7.9, D.7.10). Therefore, the risk of MON 88017 x MON 810 for the feed/food chain is also negligible.

9.8 Effects on biogeochemical processes

In the event of an incidental release of MON 88017 x MON 810 in the environment, the risk for direct or indirect, immediate or delayed adverse effects on biogeochemical processes can be considered as negligible. There is no evidence that MON 88017 x MON 810 plants would be any different from conventional maize regarding their direct influence on biogeochemical processes or nutrient levels in the soil, as MON 88017 x MON 810 is compositionally equivalent and has equivalent growth and development, morphology, yield, plant health and survival characteristics to non-transgenic maize (*see* Sections D.4, D.7.1 and D.7.4). Furthermore, any indirect interactions of the GMO and target or non-target 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. The MON 88017 Cry3Bbl and Cry1Ab proteins are subjected to rapid degradation in soil and the CP4 EPSPS protein belongs to the safe class of EPSP synthases that are ubiquitous in the environment.

9.9 Impacts of the specific cultivation, management and harvesting techniques

Not applicable. This application is for consent to import MON 88017 x MON 810 in the E.U. and for the use of this maize as any other maize, excluding the cultivation of varieties in the E.U.

10. Potential interactions with the abiotic environment

No adverse impact of MON 88017 x MON 810 on the abiotic environment is expected to result from the import, processing or use of this product for food and feed in the E.U. Although CP4 EPSPS, MON 88017 Cry3Bb1 and Cry1Ab are introduced proteins in maize, they already have a safe history of use and have no known negative interactions with the abiotic environment. The MON 88017 Cry3Bbl and Cry1Ab proteins are subjected to rapid degradation in soil and are therefore not expected to negatively affect soil or water. The CP4 EPSPS protein in MON 88017 x MON 810 is innocuous and belongs to a large class of EPSPS proteins that are ubiquitous in nature.

11. Environmental monitoring plan (not if application concerns only food and feed produced from GM plants, or containing ingredients produced from GM plants)

11.1 General (risk assessment, background information)

As required by Article 5(5)(b) of Regulation (EC) No 1829/2003, a general surveillance 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.) was conducted for MON 88017 x MON 810 according to the principles laid down in Annex II to Directive 2001/18/EC. The e.r.a. was undertaken in the context of the scope of this application under Regulation (EC) No 1829/2003, that is, for import, processing and food and feed use of MON 88017 x MON 810 in the E.U., but excluding the cultivation MON 88017 x MON 810 varieties in the E.U. Analysis of the characteristics of MON 88017 x MON 810 has shown that the risk for potential adverse effects on human or animal health and on the receiving environment, resulting from the import and use of MON 88017 x MON 810 in the E.U., is consistently negligible. Therefore, the overall environmental risk posed by this genetically modified higher plant is negligible, and no specific strategies for risk management and no case-specific post-market monitoring actions are considered required.

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

As the overall environmental risk posed by this genetically modified higher plant is negligible, and as the conclusions of this environmental risk assessment are derived from the results of scientific studies, rather than major assumptions, no case-specific post-market monitoring actions, typically aimed at testing assumptions made in this assessment, would be warranted or required.

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

Any potential adverse effects of MON 88017 x MON 810 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 notifier will ensure that appropriate technical information on MON 88017 x MON 810 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 maize in the E.U., Monsanto will approach key stakeholders and key networks of stakeholders of the product (including international grain traders, maize processors and users of maize grain for animal feed) and inform them that the product has been

authorised and may be present in grain shipments. Monsanto will request key stakeholders and networks for their participation in the general surveillance of the placing on the market of this maize. Key stakeholders and networks will be requested to be aware of their use of this maize and to inform Monsanto 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 88017 x MON 810 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 88017 x MON 810 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 the monitoring

Monsanto will submit a General Surveillance Report containing information obtained from participating networks, and/or in case of an effect that was confirmed. If information that confirms an adverse effect which alters the existing risk assessment becomes available, Monsanto will submit a Report, consisting of a scientific evaluation of the potential adverse effect and a conclusion on the safety of the product. The report will also include, where appropriate, the measures that were taken to ensure the safety of human or livestock health and/or the environment.

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

As MON 88017 × MON 810 is the result of a traditional cross of MON 88017 and MON 810, they contain both transformation events in combination. Therefore, MON 88017 × MON 810 is detectable using either the event-specific PCR method for detecting the introduced DNA present in MON 88017 or the equivalent method for MON 810. However, as for all plants in which one or more events are combined by traditional breeding, the unambiguous detection of MON 88017 × MON 810 in mixed consignments of grain will require single grains to be subjected to detection methods for both MON 88017 and MON 810, and to test positive for both.

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** B/FR/05/04.02
b)	**Conclusions of post-release monitoring** No field trials performed in 2005.
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)** No field trials performed in 2005.

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

a)	**Release country** MON 88017 x MON MON 810 has been field tested in the USA since 2002. It has also been tested in Argentina in 2004-5.
b)	**Authority overseeing the release** Argentina: Secretary of Agriculture (SAGPyA) - CONABIA. USA: United States Department of Agriculture and Environmental Protection Agency.
c)	**Release site** U.S.A.: mainly in the states of the corn belt. Argentina: Perico (Jujuy) , Reconquista (Santa Fe), Rafaela (Santa Fe).
d)	**Aim of the release** U.S.A./Argentina: assess the performances: efficacy, yield, breeding, …
e)	**Duration of the release** U.S.A./Argentina: 12 months.
f)	**Aim of post-releases monitoring** U.S.A./Argentina: assess for volunteers.
g)	**Duration of post-releases monitoring** U.S.A./Argentina: 12 months.

h) Conclusions of post-release monitoring

U.S.A.: volunteers have been eliminated to prevent persistence in the environment. Argentina: nothing to report.

i) Results of the release in respect to any risk to human health and the environment

All countries: no evidence that MON 88017 x MON 810 is likely to cause any adverse effects to human or animal health and 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 website[8] provides information related to the applications submitted under Regulation (EC) No 1829/2003 on genetically modified food and feed.

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

A notification for MON 88017 x MON 810 according to Directive 2001/18/EC has not been submitted by Monsanto.

c) EFSA opinion

An EFSA opinion, specifically for MON 88017 x MON 810, was not available at the time of submission of this application. Favourable Scientific opinions have been issued, however, for the NK603, MON 863 and MON 810, expressing similar proteins and were posted on the EFSA and European Commission websites[9].

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

The authorised food and feed are entered in the Community Register of GM food and feed[10].

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

Information on detection protocols can be found on the JRC website[11].

8 http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html

9 http://www.efsa.eu.int/science/gmo/gmo_opinions/catindex_en.html; http://europa.eu.int/comm/food/fs/sc/scp/out02_en.html

10 http://europa.eu.int/comm/food/dyna/gm_register/index_en.cfm

11 http://gmo-crl.jrc.it/statusofdoss.htm

f)	**Biosafety Clearing-House (Council Decision 2002/628/EC)** The publicly accessible portal site of the Biosafety Clearing-House (BCH) can be found at http://bch.biodiv.org/
g)	**Summary Notification Information Format (SNIF) (Council Decision 2002/812/EC)** A notification and SNIF according to Directives 2001/18/EC and 2002/812/EC, respectively, have not been submitted for MON 88017 x MON 810. The EFSA website[12] does provide a link to this summary of the application for MON 88017 x MON 810 under Regulation (EC) No 1829/2003.

[12] http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html