Application for authorization to place on the market MON 87427 maize in the European Union, according to Regulation (EC) No 1829/2003 on genetically modified food and feed

Part VII

Summary

1. GENERAL INFORMATION

1.1. Details of application

(a) Member State of application

Belgium

(b) Application number

Not available at the time of submission.

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

The Monsanto development code for this genetically modified maize is MON 87427. Currently, no commercial name has been attributed to this product.

(d) Date of acknowledgement of valid application

Not available at the time of submission.

1.2. Applicant

(a) Name of applicant

Monsanto Company, represented by Monsanto Europe S.A.

(b) Address of applicant

Monsanto Europe S.A.	Monsanto Company
Avenue de Tervuren 270-272	800 N. Lindbergh Boulevard
B-1150 Brussels	St. Louis, Missouri 63167
BELGIUM	U S

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

See above.

1.3. Scope of the application

(a) GM food

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

(b) GM feed

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

(c) GM plants for food or feed use

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

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

No ☑

Yes ☐ (in that case, specify)

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

Yes ☐

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

The protein expression, the composition, the safety, the agronomic and the phenotypic characteristics of MON 87427 have been studied at multiple locations in the US that cover a range of environmental conditions. The risk assessment presented in the MON 87427 application includes data collected from these field trials. A summary of the conclusions of the risk analysis that demonstrate the safety of MON 87427 to humans, animals and to the environment, has been presented in the respective sections throughout this summary.

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

No ☑

Yes ☐ (in that case, specify)

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

No ☐

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

Regulatory submissions for the full range of uses have been made in Canada, Japan, US and are planned for Argentina.
Applications for import approvals have been submited to countries that import significant quantities of maize or food and feed products derived from maize and have regulatory review processes in place. The countries where applications were already submitted are: Australia, Colombia, Indonesia, Korea, Mexico, Philippines, Singapore and Taiwan. Regulatory submissions will also be made in China and Russia.
Also, as appropriate, notifications will be made to countries that import significant quantities of maize and maize products and do not have a formal regulatory review process for biotechnology derived crops.

1.8. 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 MON 87427 maize with tissue-selective glyphosate tolerance to facilitate the production of viable hybrid maize seed. MON 87427 produces the same 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) protein that is produced in commercial Roundup Ready® crop products, via

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the incorporation of a *cp4 epsps* coding sequence. CP4 EPSPS protein confers tolerance to the herbicide glyphosate, the active ingredient in the family of Roundup® agricultural herbicides. Tissue-selective expression of CP4 EPSPS protein in MON 87427 enables an extension of the use of glyphosate tolerant maize as a tool in hybrid maize seed production.

The maize line LH198 × HiII, a proprietary, conventional maize line developed by Monsanto Company, was used as the recipient for the DNA insertion to create MON 87427.

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

The scope of the current application is for authorisation of MON 87427 in the EU for all uses according to Art 3(1) and 15(1) of Regulation (EC) No 1829/2003, with the exception of cultivation. The range of uses of this maize will be identical to the full range of equivalent uses of conventional maize.

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

MON 87427 will be traded and used in the EU in the same manner as current conventional commercial maize and by the same operators currently involved in the trade and use of maize.

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

With the exception of its tissue-selective tolerance to glyphosate MON 87427 is not different in composition, nutritional and agronomic characteristics from it's conventional counterpart and is equivalent to the conventional commercial reference varieties with a history of safe use.Therefore, MON 87427 and its derived products will be stored, packaged, transported, handled and used in the same manner as current commercial maize products. No specific instructions and/or recommendations are warranted or required for the placing on the market of MON 87427 for import, processing and all uses in the EU as specified in Section 1.8(b) above.

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

MON 87427 is suitable for use throughout the EU as any other maize. The scope of this application covers the import, processing and all uses of MON 87427, excluding cultivation.

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

MON 87427 is suitable for use throughout the EU as any other maize. The scope of this application covers the import, processing and all uses of MON 87427, excluding cultivation.

(g) Any proposed packaging requirements

MON 87427 is not different from conventional commercial maize, except for the tissue-selective tolerance to glyphosate. Therefore, MON 87427 and derived products will be used in the same manner as other maize and no specific packaging is required.

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

In accordance with Regulations (EC) No 1829/2003 and 1830/2003, a labelling threshold of 0.9 % is applied for the placing on the market of MON 87427 and derived products.

Operators shall be required to label products containing or consisting of MON 87427 with the words "genetically modified maize" or "contains genetically modified maize", and shall be required to declare the unique identifier 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 87427 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 87427 and derived foods and feeds in the EU shall be required to be aware of the legal obligations regarding traceability and labelling of these products. Given that explicit requirements for the traceability and labelling of GMOs and derived foods and feeds are laid down in Regulations (EC) No 1829/2003 and 1830/2003, and that authorised foods and feeds shall be entered in the EU Register for genetically modified food and feed, operators in the food/feed chain will be fully aware of the traceability and labelling requirements for MON 87427. Therefore, no further specific measures are to be taken by the applicant.

(i) Estimated potential demand

(i) In the Union

The EU is a big producer of maize. In 2011/2012, the EU-27 produced about 64.64 MMT[1] of grain[2].

(ii) In export markets for EU supplies

Maize imports in EU mainly come from US, Argentina and Brazil. In 2011/2012, EU exported 2MMT of grain and imported 6 MMT[3].

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

The unique identifier for this genetically modified maize is MON‑87427‑7.

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

Because this application is for consent to import, process and all uses of MON 87427 as any other maize, not including the cultivation in the EU, the only potential means of environmental release would be more likely to occur during import, storage and processing of MON 87427.

[1] Million metric tones

[2] http://www.fas.usda.gov/psdonline/psdreport.aspx?hidReportRetrievalName=BVS&hidReportRetrievalID=459&hidReportRetrievalTemplateID=7 – Accessed June 2012

[3] http://www.fas.usda.gov/psdonline/psdgetreport.aspx?hidReportRetrievalName=BVS&hidReportRetrievalID=455&hidReportRetrievalTemplateID=7 – Accessed June 2012

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 87427 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 killed by frost or could be easily controlled by the use of selective herbicides or by mechanical means. Moreover, the information presented in this application established that MON 87427 is not different in composition, nutritional and agronomic characteristics relative to the conventional counterpart, except for the tissue-selective tolerance to glyphosate, and therefore, it is unlikely to pose any threat to the EU environment or to require special measures for its containment. Therefore, no special measures are considered to be required in case of misuse or unintended release.

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

2.1. Complete name

(a)	**Family name**	Poaceae (formerly Gramineae)
(b)	**Genus**	*Zea*
(c)	**Species**	*mays* (2n = 20)
(d)	**Subspecies**	N/A
(e)	**Cultivar/breeding line or strain**	LH198 × HiII
(f)	**Common name**	maize or corn

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

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.

Significant 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.

2.3. Information concerning reproduction (for environmental safety aspects)

(a) Mode(s) of reproduction

Maize (*Zea mays* L.) reproduced sexually. It is an annual, wind-pollinated, monoecious species with separate staminate (tassels) and pistillate (silk) flowers which encourages the natural outcrossing between maize plants. Wind movement across maize fields causes pollen from the tassel to fall on the silks of the same or adjoining plants. Self-pollination leads to homogeneity of the genetic characteristics within a single plant while cross-pollination combines the genetic traits of many plants

(b) 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. Under conditions of high temperature and desiccation maize pollen viability is measured in minutes; these conditions may even destroy the tassel before any viable pollen is shed

(c) Generation time

Maize is an annual crop with cultural cycle ranging from as short as 60 to 70 days to as long as 43 to 48 weeks from grainling emergence to maturity. The different relative maturities occurring depend on prevailing weather patterns, topography, large bodies of water, and soil types.

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

Outcrossing with cultivated Zea varieties

Maize is wind pollinated, and the distance that viable pollen can travel depends on prevailing wind patterns, humidity, and temperature.Once in the atmosphere, pollen grains must remain viable long enough to be able to reach a viable silk to complete the pollination process. In average maize pollen looses 100% viability after two hours of atmospheric exposure.

All maize will inter-pollinate, except for certain popmaize varieties and varieties that have one of the gametophyte factors (GaS, Ga, and ga allelic series on chromosome 4). Pollen of a specific variety can be carried by wind to pollinate other dent maize varieties, sweet maize and popmaize, if the popmaize does not carry the dent-sterile gametophyte factor (Hallauer, 1995). Maize pollen, therefore, moves freely within an area, lands on silks of the same variety or different varieties, germinates almost immediately after pollination, and within 24 hours completes fertilisation.

It has to be noted, however, that the scope of the current application does not include cultivation of MON 87427 in the E U therefore any outcrossing between MON 87427 and cultivated *Zea* varieties is highly unlikely.

Outcrossing with wild Zea species

Gene flow in maize (*Zea mays* L.) is closely associated with the biology of the staminate and pistillate inflorescences. Gene flow between maize and its closest relative, teosinte (*Zea* ssp.) is specific to Mexico and Central America. In the Central Plateau and Valley of Mexico, maize can grow sympatrically with teosinte (*Zea* ssp.) providing the opportunity for hybridization.

There are no compatible wild relatives of maize in Europe.

2.5. Survivability (for environmental safety aspects)

(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.

2.6. Dissemination (for environmental safety aspects)

(a) Ways and extent of dissemination

In general, dissemination of maize may occur by means of seed 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 87427 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.

However, the current application does not include the environmental release of MON 87427 in the E U.

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

There are no sexually compatible wild relatives of maize in Europe.

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

Not applicable, as maize is grown in Europe.

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

Like other plants, cultivated 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.

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. Maize has been a staple of the human diet for centuries, and its processed fractions are consumed in a multitude of food and animal feed products.

3. MOLECULAR CHARACTERISATION

3.1. Information relating to the genetic modification

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

MON 87427 was developed through *Agrobacterium*-mediated transformation of immature maize embryos using plasmid vector PV-ZMAP1043

(b) Nature and source of the vector used

.PV-ZMAP1043 was used in the transformation of maize to produce MON 87427.

PV-ZMAP1043 is approximately 8.9 kb and contains one T-DNA that is delineated by Left and Right Border sequences. The T-DNA contains one expression cassette consisting of the *cp4 epsps* coding sequence under the regulation of the *e35S* promoter, the *hsp70* intron, the *CTP2* targeting sequence, and the *nos* 3′ non-translated region.

The backbone region of PV-ZMAP1043, located outside of the T-DNA, contains two origins of replication for maintenance of the plasmid vector in bacteria (*or*I *V*, *or*I-*pBR322*), a bacterial selectable marker gene (*aadA*), and a coding sequence for repressor of primer protein for maintenance of plasmid vector copy number in *Escherichia coli E. coli*.

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

PV-ZMAP1043 is a binary plasmid vector containing a T-DNA which hosts the a *cp4 epsps* expression cassette The *cp4 epsps* coding sequence in MON 87427 is under the regulation of the *e35S* promoter, the *hsp70* intron, the *CTP2* targeting sequence, and the *nos* 3′ non-translated region. The *e35S* promoter, which directs transcription in plant cells, contains the duplicated enhancer region from the cauliflower mosaic virus (CaMV) *35S* RNA promoter. The *hsp70* intron is the first intron from the maize heat shock protein 70 gene.

The *CTP2* targeting sequence is the targeting sequence from the *ShkG* gene encoding the chloroplast transit peptide region of *Arabidopsis thaliana* EPSPS that directs transport of the CP4 EPSPS protein to the chloroplast. The *nos* 3' *non-translated* region is the 3' non-translated region of the *nopaline synthase* (nos) gene from *Agrobacterium tumefaciens* that terminates transcription and directs polyadenylation. The genetic elements intended for insertion in MON 87427 are summarized in Table 1.

Table 1 Summary of genetic elements intended for insertion in MON 87427

Genetic element[1]	Size (kb)	Source	Function
B[1]-Left Border Region	0.25	*Agrobacterium tumefaciens*	Left border region used for transfer of the T-DNA
P[2]-*e35S*	0.62	Cauliflower mosaic virus (CaMV) 35S RNA	Promoter
I[3]-*hsp70*	0.8	Maize heat shock protein 70 gene	Intron
TS[4]-*CTP2*	0.23	*Arabidopsis thaliana*	Targeting sequence
CS[5]-*cp4 epsps*	1.37	*Agrobacterium* sp. strain CP4	Coding sequence for the CP4 EPSPS protein
T[6]-*nos*	0.25	*Agrobacterium tumefaciens*	Transcription termination sequence
B-Right Border Region	0.035	*Agrobacterium tumefaciens*	Right border region used for transfer of the T-DNA

[1] B, Border; [2] P, Promoter; [3] I, Intron; [4] TS, Targeting Sequence; [5] CS, Coding Sequence
[6] T, Transcription Termination Sequence;

3.2. Information relating to the GM plant

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

Monsanto Company has developed biotechnology-derived MON 87427 maize with tissue-selective glyphosate tolerance to facilitate the production of viable hybrid maize seed. MON 87427 produces the same protein (CP4 EPSPS) that is produced in commercial Roundup Ready® crop products, via the incorporation of a *cp4 epsps* coding sequence. CP4 EPSPS protein confers tolerance to the herbicide glyphosate, the active ingredient in the family of Roundup® agricultural herbicides.

MON 87427 utilizes a specific promoter and intron combination (*e35S-hsp70*) to drive CP4 EPSPS protein expression in vegetative and female reproductive tissues, conferring tolerance to glyphosate in the leaves, stalk, and root tissues and tissues that develop into seed or grain and silks. This specific promoter and intron combination also results in limited or no production of CP4 EPSPS protein in two key male reproductive tissues: pollen microspores, which develop into pollen grains, and tapetum cells that supply nutrients to the pollen. Thus, in MON 87427, male reproductive tissues critical for male gametophyte (pollen) development are not tolerant to glyphosate. Tissue-selective expression of CP4 EPSPS protein in MON 87427 facilitates an extension of the use of glyphosate tolerant maize to enable its use as a tool for hybrid maize seed production.

3.2.2. *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 87427 contains a single copy of the *cp4 epsps* expression cassette, *i.e.* the T-DNA that is stably integrated at a single locus of the maize genome and is inherited according to Mendelian principles over multiple generations.

Southern blot analyses assayed the entire maize genome for the presence of DNA derived from PV-ZMAP1043, and demonstrated that only a single copy of the T-DNA was inserted at a single site and no plasmid vector backbone sequences were detected in MON 87427.

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

No deletion was intended, however there is a 140 base pair deletion (and a 41 base pair insertion) at the 5′ insert-to-flank junction (and a 24 base pair insertion at the 3′ insert-to-flank junction) of MON 87427.

Minor 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/inserted regions.

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

The presence of MON 87427 insert in the nuclear genome is best shown by the Chi square analysis of the segregation results.The Chi square analysis of the segregation pattern, according to Mendelian genetics, was consistent with a single site of insertion into maize nuclear DNA.

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

Molecular analysis was conducted to characterize the insert in MON 87427. Genomic DNA was analyzed using Southern blot to determine the insert number (number of insertions of the integrated DNA within the maize genome), the copy number (the number of copies of the integrated DNA within one locus), the integrity and organization of the inserted *cp4 epsps* expression cassette and the presence or absence of plasmid backbone sequences.

DNA sequence analyses confirmed the sequence identity between the MON 87427 insert and the corresponding insert from the plasmid PV-ZMAP1043. The results of PCR and sequence analyses further confirmed the organisation of the genetic elements within the *cp4 epsps* expression cassette of MON 87427, which were identical to that in plasmid PV-ZMAP1043.

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

Not applicable

3.2.3. *Information on the expression of the insert*

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

The expression levels of the CP4 EPSPS protein in various tissues of MON 87427 collected from a field trial conducted in the US during 2010 were assessed by validated enzyme-linked immunosorbent assay (ELISA). Tissues were collected from each replicated plot at eight field sites. Both glyphosate treated and glyphosate untreated samples were analyzed.

The mean CP4 EPSPS protein level in treated MON 87427 across sites was 41 µg/g fwt in forage and 4.3 µg/g fwt in grain while the mean CP4 EPSPS protein level in untreated MON 87427 across sites was 22 µg/g fwt in forage and 4.9 µg/g fwt in grain.

The CP4 EPSPS protein expressin levels determined from treated tissues of MON 87427 were comparable to those determined from untreated MON 87427 tissues showing that glyphosate application in MON 87427 does not alter nor have any negative effects on the expression of the CP4 EPSPS protein in the plant.

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

MON 87427 utilizes a specific promoter and intron combination (*e35S-hsp70*) to drive CP4 EPSPS protein expression in vegetative and female reproductive tissues, conferring tolerance to glyphosate in the leaves, stalk, and root tissues and tissues that develop into grain or grain and silks. This specific promoter and intron combination also results in limited or no production of CP4 EPSPS protein in two key male reproductive tissues: pollen microspores, which develop into pollen grains, and tapetum cells that supply nutrients to the pollen. Thus, in MON 87427, male reproductive tissues critical for male gametophyte (pollen) development are not tolerant to glyphosate.

In terms of food and feed safety assessment of MON 87427 grain and forage are the most relevant tissues.

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

MON 87427 contains a single copy of the T DNA sequence that was integrated into a single locus of the maize genome. The inserted DNA is inherited in a Mendelian fashion and is stably maintained through multiple generations of breeding. This has been confirmed by Southern blot analyses.

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

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

Phenotypic and agronomic characterization as well as environmental interaction data were collected from eight sites at field trials in major maize-growing areas of US during the 2010 field season. Randomized complete block design with four replicates at each field site was used. In each of the assessments MON 87427, either treated or not with glyphosate, was compared to an appropriate maize conventional counterpart (control) which has a genetic background similar to MON 87427 but does not possess the *cp4 epsps* expression cassette. In addition, multiple commercial hybrids (references) were employed to provide a range of baseline values that are common to the existing commercial maize hybrids for each measured phenotypic, agronomic, and ecological interaction characteristic.

Results of this field study demonstrate that the assessed characteristics of MON 87427 were within the range expected for maize. The statistical analyses of the field evaluations support a conclusion of no unexpected changes in the phenotype indicative of increased plant weed/pest potential of MON 87427 compared to conventional maize. Furthermore, the results demonstrate that in-crop applications of glyphosate herbicide do not alter the phenotypic and agronomic characteristics of MON 87427 compared to conventional maize.

Based on the study described above, it is possible to conclude that no differences in the mode or rate of reproduction, dissemination, survivability or other agronomic, phenotypic or ecological characteristics are expected in MON 87427 and that MON 87427 is similar to conventional maize in its phenotypic and agronomic behaviour, except for the glyphosate-tolerance trait.

(b) Dissemination

See Section 3.2.5(a) above.

(c) Survivability

See Section 3.2.5(a) above.

(d) Other differences

See Section 3.2.5(a) above.

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

(a) Plant to bacteria gene transfer

None of the genetic elements inserted in MON 87427 has a genetic transfer function. Therefore, no changes are expected in the ability of this maize to transfer genetic material to bacteria.

(b) Plant to plant gene transfer

Not applicable. The scope of the current application does not include the cultivation of MON 87427 varieties in the EU.

4. COMPARATIVE ANALYSIS

4.1. Choice of the conventional counterpart and additional comparators

MON 87427 was compared to a conventional maize counterpart with a genetic background similar to MON 87427, as well as with other commercially available maize varieties.

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

MON 87427 and the conventional counterpart were grown in 2010 in eight US field sites. Additionally, several conventional commercial reference varieties were used to provide reference substances representative for their respective growing regions. At each field site, the test, the conventional counterpart and reference seed were planted in a randomized complete block design with four replicates per block. Field locations were acceptable environments for maize growth and are distributed across a wide geographical area to provide a variety of agronomic practices, soils and climatic factors. All the plants were grown under normal agronomic field conditions for their respective geographic regions. The test MON 87427 was either treated or untreated with glyphosate herbicide.

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

4.3. Selection of material and compounds for analysis

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

4.4. Comparative analysis of agronomic and phenotypic characteristics

An assessment of the phenotypic, agronomic and environmental interactions of MON 87427 compared to conventional maize has been performed in the field. It was guided by the OECD concept of familiarity by scientists who are familiar with the production and evaluation of maize.

Results of this field study showed that there are no unexpected changes in the phenotype or ecological interactions indicative of increased pest or weed potential of MON 87427 compared to the maize conventional counterpart.

4.5. Effect of processing

With the exception of the glyphosate-tolerance trait, MON 87427 is not different from the conventional counterpart. Therefore, the processing of MON 87427 is not expected to be any different from that of conventional maize.

5. TOXICOLOGY

(a) Toxicological testing of newly expressed proteins

The CP4 EPSPS protein, as expressed in MON 87427, has been assessed for its potential toxicity according to the recommendations of Codex. The inserted *cp4 epsps* gene in MON 87427 results in the expression of CP4 EPSPS.

The conclusion of safety to humans of the CP4 EPSPS protein was based upon the following considerations:

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

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

It is therefore possible to conclude that the CP4 EPSPS protein is safe and poses no concerns for humans, animals and the environment.

(a) 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 87427 was shown to be compositionally similar to conventional maize, no testing of any constituent other than the introduced protein is indicated.

(b) Information on natural food and feed constituents

Maize is known to contain a number of natural anti-nutritional analytes, such as phytic acid and raffinose. These antinutrients were evaluated in MON 87427 compositional analyses and their levels were demonstrated to be not different in MON 87427 and in conventional maize. Therefore the levels of food and feed constituents in MON 87427 have not been altered

(c) Testing of the whole GM food/feed

The safety assessment demonstrates that MON 87427 is as safe as conventional maize for food and feed use through the compositional assessment of MON 87427 harvested grain and forage to harvested grain and forage from conventional maize already on the market. The safety for humans and animals of the CP4 EPSPS 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 87427 is as as safe as conventional maize from a food and feed perspective and therefore it can be concluded that there was no evidence of any adverse effects on human or animal health.

6. ALLERGENICITY

(a) Assessment of allergenicity of the newly expressed protein

It is unlikely that CP4 EPSPS protein will cause allergenic concerns due to the following considerations:

- The CP4 EPSPS protein was obtained from a non-allergenic source (*Agrobacterium* sp. Strain CP4;
- The CP4 EPSPS the protein does not share structural similarities to known allergens, as demonstrated by bioinformatics analyses;
- The CP4 EPSPS the protein constitue a very small portion of the total protein present in MON 87427;
- The CP4 EPSPS the protein is rapidly digested in simulated gastric fluid;

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

(b) Assessment of allergenicity of the whole GM plant

Maize is not considered a common allergenic food. Food allergies to maize are of low frequency and mainly occur in populations of specific geographic areas. Rare cases of occupational allergy to maize dust have been reported. There is no reason to expect that the use of MON 87427 will significantly increase the intake and exposure to maize. Therefore a possible overexpression of any endogenous protein, which is not known to be allergenic, would be unlikely to alter the overall allergenicity of the whole plant or the allergy risk for consumers.

As MON 87427 is comparable and as safe as conventional maize, there is no reason to expect that the use of MON 87427 will significantly increase the potential for allergenicity. Further, as the introduced proteins in MON 87427 do not have any allergenic potential, it was concluded that the use of MON 87427 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. Therefore, an assessment of the allergenicity of the whole MON 87427 plant is not considered necessary.

7. NUTRITIONAL ASSESSMENT

(a) Nutritional assessment of GM food

The introduced trait in MON 87427 is of agronomic interest, and is not intended to change any nutritional aspect of this maize. The presence of this trait is not expected to alter patterns or volumes of maize consumption.

Results of the extensive compositional analyses indicate that observed differences fell within the range of natural variability for maize with a history of safe usage, and the grain and forage composition of MON 87427 is not different to the grain and forage composition of the conventional counterpart.

Overall, MON 87427 reveals comparable nutritional characteristics to the conventional counterpart maize, as well as to maize varieties in commerce. 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, and no nutritional imbalances are expected as a result of the presence of MON 87427 in the maize supply.

(b) Nutritional assessment of GM feed

See Section 7 (a).

8. EXPOSURE ASSESSMENT – ANTICIPATED INTAKE/EXTENT OF USE

The exposure assessment in humans and animals indicates that there is minimal dietary exposure to CP4 EPSPS protein from consumption of foods and feed derived from MON 87427.
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 87427 to the maize supply. MON 87427 is expected to replace a portion of current maize such that its intake or use will represent some fraction of the total products derived from maize.

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

Based on the information provided in this application, it can be concluded that MON 87427 is as safe as conventional maize. The molecular characterization of MON 87427 did not raise any safety concern and did not show any evidence of unintended changes in MON 87427. Detailed compositional comparisons of MON 87427, its conventional counterpart and conventional commercial reference varieties demonstrated that MON 87427 is compositionally similar to the conventional maize counterpart and that MON 87427 is not a contributor to compositional variability in maize. The assessed phenotypic and agronomic characteristics of MON 87427 were within the range expected for maize and did not show any phenotypic changes indicative of increased plant weed/pest potential of MON 87427 compared to conventional maize. An extensive characterisation of the CP4 EPSPS protein expressed in MON 87427 confirmed that the protein is safe for human and animal consumption. Additionally, the exposure assessment in humans and animals did not indicate any safety concerns.

In summary, there are no signs of adverse or unanticipated effects observed in a number of safety studies and the pre-market risk characterisation for food and feed use of MON 87427. The consumption of food and feed derived from GM plants is as safe as the consumption of its respective comparators. It can be concluded that the food derived from a GM plant is not nutritionally disadvantageous for the consumer compared to the food which is intended to replace. Finally, it can be also concluded that the feed derived from a GM plant does not harm or mislead the consumer by impairing distinctive features of the animal products compared to conventionally produced feed.

10. POST-MARKET MONITORING ON GM FOOD/FEED

Based on the information provided in this application, it is reasonable to conclude that MON 87427 is as safe as conventional maize. There are no intrinsic hazards related to MON 87427 indicating that MON 87427 is less safe than its conventional counterpart. The pre-market risk characterisation for food and feed use of MON 87427 demonstrates that the risks of

consumption of MON 87427 or its derived products are not different from the risks associated with the consumption of conventional maize or its derived products. As a consequence, specific risk management measures are not indicated and post-market monitoring of the use of this maize for food and feed is not considered necessary.

11. ENVIRONMENTAL ASSESSMENT

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

According to the EFSA ERA Guidance, the primary focus for the assessment on target organisms is the development of resistance to the insect or pathogen tolerance traits expressed by the GM plant. The scope of his application covers the import, processing and all uses as any other maize, but excludes the cultivation of MON 87427 in the EU. Hence, no deliberate release of viable plant material in the EU environment is expected and no target organisms are associated with this event. Therefore an assessment of the potential resistance development in target organisms resulting from import, processing and all uses as any other maize, but excluding the cultivation of MON 87427 in the EU is not relevant for this submission.

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

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

Results from the assessment support a conclusion that the abilities of MON 87427, that receive the trait to persist in agricultural fields or invade non-agricultural habitats, are comparable to those of conventional maize in the EU. Thus, MON 87427 is not more likely to represent an agronomic problem in agricultural fields or become more invasive in natural habitats and no adverse effects on ecological functions within agricultural production fields or on biodiversity is expected as a result of the import, processing and all uses as any other maize. Given the negligible hazard and the low levels of environmental exposure that could arise from the import, processing and all uses as any other maize of this products and the fact that any exposure would be limited spatially and temporally, the uncertainties associated with this risk characterization and the probability of long-term adverse environmental effects are negligible

(b) Selective advantage or disadvantage

Compared with conventional commercial maize, the introduced trait in Mon 87427 would confer a selective advantage, only under specific conditions (i.e. following treatment with glyphosate). The selective advantage is only relevant in agricultural habits (i.e. in maize fields) and is short in duration.When viewed in the context of today's baseline agronomic practices for the production of maize, this advantage is no likely to pose any risk to the agricultural environment.

Tissue-selective expression of CP4 EPSPS protein in MON 87427 enables an extension of the use of glyphosate tolerant maize as a tool in hybrid maize seed production. This trait is of purely agronomic interest and presents negligible risk to the nonagricultural environments, because of the poor survival characteristics of maize under most European conditions.

Therefore, the risk of adversely impacting the receiving environment is negligible under the intended use for food, feed or processing.

(c) Potential for gene transfer

The scope of this application covers the import, processing, and all uses of MON 87427 as any other maize in the EU. Therefore, no deliberate release of viable plant material in the EU environment is expected, and interactions of MON 87427 with the biotic environment will be limited. Given the low likelihood of occurrence of horizontal gene transfer and lack of adverse consequences if it were to occur, the import, processing, and food and feed use of MON 87427 in the EU is not likely to pose any risk to human and animal health or the environmental.

Considering the low exposure and lack of hazard from horizontal gene transfer of the *cp4 epsps* gene from MON 87427 to micro-organisms, resulting from the import,processing and all uses of MON 87427, the risk that this would result in adverse effects on human or animal health or the environment is negligible. Thus, no risk management strategies are considered necessary.

(d) Interactions between the GM plant and target organisms

The scope of this application covers the import, processing and all uses of MON 87427 as any other maize, but excludes the cultivation of MON 87427 in the EU. No deliberate release of viable plant material in the EU environment is expected and no target organisms are associated with this event. Therefore an assessment of the potential resistance development in target organisms resulting from the import, processing and all uses as any other maize of MON 87427 in the EU is not relevant for this submission.

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

The scope of this application covers the import, processing and all uses of MON 87427 as any other maize, but excludes the cultivation of MON 87427 in the EU. Therefore, no deliberate release of viable plant material in the EU environment is expected and interactions of MON 87427 with the biotic environment will be limited. Importantly, CP4 EPSPS is heat inactivated during processing for feed and CP4 EPSPS can also be inactivated in the digestive tract of animals. Given the low levels of environmental exposure combined with low hazard from exposure of MON 87427 to NTOs, the likelihood of adverse effects from the import of MON 87427 to NTO communities that perform in-field ecological functions and NTO communities outside of the field from import of MON 87427, is negligible.

The conclusion from the risk characterization is that the probability that direct or indirect interactions between MON 87427 and NTOs that could lead to direct or indirect, immediate or delayed environmental harm as a result of import, processing and use of MON 87427 in the EU (excluding cultivation) is negligible. Thus, no risk management strategies are necessary.

(f) Effects on human and animal health

This application is for the import, processing and all uses as any other maize, but excludes the cultivation of MON 87427 in the EU. Therefore, no deliberate release of viable plant material in the EU environment is expected and interactions of MON 87427 with humans and animal health will be limited to the occupational hazards associated with the cultivation, storage, handling and processing of MON 87427. Given the low levels of environmental exposure combined with the negligible hazard occurring from the contact of workers with MON 87427 grain, the likelihood of adverse effects on workers handling MON 87427 import and processing in the EU is negligible.

(g) Effects on biogeochemical processes

The scope of this application covers the import, processing and all uses of MON 87427 in the EU as any other maize (excluding the cultivation of MON 87427). Therefore, no deliberate release of viable plant material in the EU environment is expected, and interactions of MON 87427 with the biotic environment will be very limited. Importantly, CP4 EPSPS protein is heat inactivated during processing for feed, and CP4 EPSPS can also be inactivated in the digestive tract of animals thereby limiting any exposure via faeces of animals fed processed or unprocessed MON 87427 grain. Given the low level of environmental exposure combined with a lack of hazard, the import, processing, and food and feed use of MON 87427 in the EU is not likely to adversely impact soil micro-organisms that perform ecological functions in-field or in non-agricultural habitats, and therefore poses negligible environmental risk.

The conclusion from the risk characterization is that the probability that direct or indirect interactions between MON 87427 and soil micro-organisms that could lead to immediate or delayed harm to human and animal health or the environment as a result of import, processing, or food and feed use in the EU is negligible. Thus, no risk management strategies are considered necessary.

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

Cultivation of MON 87427 in the EU is not included in the scope of this application. An assessment of the impacts of specific cultivation, management and harvesting techniques of MON 87427 is therefore not relevant for this application.

11.3. Potential interactions with the abiotic environment

Although the CP4 EPSPS protein is introduced in maize, it already has a safe history of use and it has no known negative interactions with the abiotic environment.

Overall results of the comparative analysis of MON 87427 with respect to its conventional counterpart indicate that observed differences in composition and agronomic and phenotypic characteristics, fell within the range of natural variability for maize with a history of safe usage. Therefore, there is no evidence that this maize would be any different from conventional maize with regard to its baseline interactions with the abiotic environment.

In addition, because this application is for import, processing and all uses as any other maize in the EU, interactions of MON 87427 with the environment will be limited. Moreover no negative impact of MON 87427 on the abiotic environment is expected to result from the import, processing and all uses as any other maize in the EU.

11.4. Risk characterisation for the environmental risk assessment

Results from the environmental risk assessment which takes into consideration the risk characterization and includes results described above addressing risk hypotheses for the specific areas of assessment lied down in 2010 EFSA guidance, support a conclusion that the import, processing and all uses (excluding cultivation) of MON 87427, as any other maize, in the EU represents negligible risk to human and animal health and the environment, and poses no greater risk than the import and processing of conventional maize. Because no immediate adverse effects are expected, the probability of long-term adverse effects is also negligible.

12. ENVIRONMENTAL MONITORING PLAN

(a) General (risk assessment, background information)

As required by Article 5(5)(b) and 17(5)(b) of Regulation (EC) No. 1829/2003 the proposed monitoring plan for MON 87427 has been developed according to the principles and objectives outlined in Annex VII of Directive 2001/18/EC and Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC. The monitoring plan also takes into account the Scientific Opinion on guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants[4].

(b) Interplay between environmental risk assessment and monitoring

The scope of this application is the authorisation of MON 87427 for import, processing, and the use of food and feed produced from MON 87427 in the European Union (EU) under Regulation (EC) No. 1829/2003. The scope of the application does not include authorisation for the cultivation of MON 87427 seed products in the EU.

An environmental risk assessment (ERA) was carried out for MON 87427 according to the principles laid down in Annex II to Directive 2001/18/EC, the Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC and the Guidance Document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed[5]. The scientific evaluation of the characteristics of MON 87427 in the ERA (*see* Section E of Part II of this application) has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses of MON 87427 relative to:

- Persistence and invasiveness including plant to plant gene flow
- Plant to micro-organisms gene transfer
- Interactions between the GM plant and target organisms
- Interactions of the GM plant with non-target organisms
- Impacts of the specific cultivation, management and harvesting techniques
- Effects on biochemical processes
- Effects on human and animal health.

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

As discussed in Section E.4.2 of Part II of this application, the scientific evaluation of the characteristics of MON 87427 in the ERA has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses of MON 87427. It is therefore considered that there is no need for case-specific monitoring.

[4] www.efsa.europa.eu/en/efsajournal/doc/2316.pdf -Accessed June 2012.
[5] www.efsa.europa.eu/en/scdocs/doc/1879.pdf -Accessed June 2012

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

Any potential adverse effects of MON 87427 on human health and the environment, which were not anticipated in the ERA, can be addressed under the general surveillance. General surveillance is largely based on routine observation and implies the collection, scientific evaluation and reporting of reliable scientific evidence, in order to be able to identify whether unanticipated, direct or indirect, immediate or delayed adverse effects have been caused by the placing on the market of a genetically modified (GM) crop in its receiving environment.

In order to allow detection of the broadest possible scope of unanticipated adverse effects, general surveillance is performed by either selected, existing networks, or by specific company stewardship programmes, or by a combination of both. The consent holder will ensure that appropriate technical information on MON 87427 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 EU, the consent holder will approach key stakeholders and key networks of stakeholders of the product (including international grain traders, maize processors and users of maize 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 maize, 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 maize 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 87427 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 87427 and the observed effect. The evaluation should consider the consequence of the observed effect and remedial action, if necessary, should be proportionate to the significance of the observed effect.

(e) Reporting the results of monitoring

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

If information that confirms an adverse effect of MON 87427 and that alters the existing risk assessment becomes available, the authorisation holder will immediately investigate and inform the European Commission. The authorisation holder, in collaboration with the European Commission and based on a scientific evaluation of the potential consequences of the observed adverse effect, will define and implement management measures to protect human and animal health or the environment, as necessary. It is important that the remedial action is proportionate to the significance of the observed effect.

The authorisation holder will submit an annual monitoring report including results of the general surveillance in accordance with the conditions of the authorisation. The report will contain information on any unanticipated adverse effects that have arisen from handling and use of viable MON 87427.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of MON 87427 and, as appropriate, the measures that were taken to ensure the safety of human and animal health or the environment.

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

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

The presence of the *cp4 epsps* gene and the CP4 EPSPS protein in maize or in maize derived products can be identified by employing different techniques. Southern blot or PCR techniques can identify the inserted nucleotide sequence, while the CP4 EPSPS protein can be detected in all tissues of MON 87427, by optimised tissue extraction, standardised electrophoretic blotting and immunodetection methodologies.

A MON 87427-specific PCR-based assay allowing the identification and quantification of MON 87427 has been provided to the Joint Research Centre (JRC)[6], acting as the European Union Reference Laboratory for GM Food and Feed (EURL-GMFF).

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

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

(a) Notification number

There is no history of field realease of MON 87427 in EU.

(b) Conclusions of post-release monitoring

Not applicable

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

Not applicable

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

(a) Release country

MON 87427 has been field tested in the U.S. (2005-2011), Argentina (2007/2008 and 2009/2010), Chile (2009/2010 and 2011/2012), Canada (2010) and Japan (2010).

[6] http://gmo-crl.jrc.ec.europa.eu/ Accessed June 2012

(b) Authority overseeing the release

US and Puerto Rico: 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)
Japan: Ministry of Agriculture, Forestry and Fisheries/Ministry of Environment (MAFF/MOE)

(c) Release site

US: in major maize growing states (Arkansas, Hawaii, Illinois, Indiana, Iowa, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Ohio, Pennsylvania, Puerto Rico, Kansas, South Dakota, Tennessee, Texas, Oklahoma, Maryland, and Wisconsin)
Argentina: Buenos Aires and San Luis
Chile: Rancagua, Codegua, and Chimbarongo
Canada: Ontario and Quebec
Japan: Ibaraki

(d) Aim of the release

US/Argentina/Chile/Puerto Rico/Canada/Japan: regulatory trials, efficacy, yield, product development, and demonstration.

(e) Duration of the release

US/Argentina/Chile/Puerto Rico/Canada/Japan: One growing season.

(f) Aim of post-releases monitoring

US/Argentina/Chile/Puerto Rico/Canada/: Assessment of volunteers.

(g) Duration of post-releases monitoring

US/Argentina/Puerto Rico/Canada/: 12 months.
Chile: six months.

(h) Conclusions of post-release monitoring

US/Argentina/Chile/Puerto Rico/Canada/: In general, no volunteers have been observed since maize 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 87427 would be the cause of any adverse effects to human health or to the environment.