Application for renewal of the authorization for continued marketing of existing food additives, feed materials and feed additives produced from MON 15985 and MON 15985 × MON 1445 cotton that were notified according to Articles 8(1)(b) and 20(1)(b) of Regulation (EC) No 1829/2003 on genetically modified food and feed

Part II

Summary

April 2007

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

Not applicable

b) Application number

Not known at the time of application

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

The Monsanto development codes for both genetically modified cotton products are: MON 15985 and MON 15985 × MON 1445*. In countries where MON 15985 and MON 15985 × MON 1445 are being cultivated, packages of these cottonseeds are marketed under the name of the varieties, in association with the trademarks Bollgard II® or Bollgard II® with Roundup Ready®, indicating clearly to growers that the cotton is protected from specific lepidopteran insect pests or protected from specific lepidopteran insect pests and tolerant to Roundup® herbicide, containing the active ingredient glyphosate.

d) Date of acknowledgement of valid application

Not known 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))

Food additives, feed materials and feed additives produced from MON 15985 and MON 15985 × MON 1445 will continue to be traded

* This renewal application is for MON 15985, but as the Core Dossier covers both MON 15985 and MON 15985 × MON 1445, these products are both cited throughout this document.

® Bollgard II, Roundup Ready, and Roundup are registered trademarks of Monsanto Technology LLC.

and used in the E.U. in the same manner as the equivalent products derived from current commercial cotton and by the same operators currently involved in the trade and use of cotton.

3. Scope of the application

( ) GM plants for food use
( ) Food containing or consisting of GM plants
(X) Food produced from GM plants or containing ingredients produced from GM plants
( ) GM plants for feed use
( ) Feed containing or consisting of GM plants
(X) Feed produced from GM plants
( ) 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 *ye*s, specify	

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

Yes ( )	**No (x)**
If *n*o, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC *See* following sections	

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 *ye*s, specify An application for MON 15985 and MON 15985 × MON 1445 under Regulation (EC) No 1829/2003 (EFSA-GMO-UK-2005-10) for food and feed use in the European Union, was submitted in December 2004 and is currently under EFSA review.	

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

Yes (x)	No ( )

If *yes*, specify

Cultivation of MON 15985 × MON 1445 is lawful in the U.S.A., Australia/New Zealand and Canada, while importation of derived foods and feeds is approved in Korea, Mexico and the Philippines.

8. General description of the product

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

MON 15985 was developed to produce two *Bacillus thuringiensis* proteins conferring protection against certain lepidopteran pests. This product is the result of the transformation of MON 531, which contains the genetic material necessary to express the Cry1Ac insect protection protein, and the NPTII selectable marker protein. Genetic modification was used in the development of MON 531. The transformation of MON 531 introduced a second genetic modification, resulting in the production of the Cry2Ab2 and GUS proteins; this second genetic modification is referred to as MON 15947. The combination of the genetic material responsible for the Cry1Ac and the Cry2Ab2 production from MON 531 and MON 15947, respectively, is known as MON 15985. Therefore, MON 15985 produces both Cry1Ac and Cry2Ab2 insect protection proteins for the effective control of major lepidopteran insect pests of cotton, including the cotton bollworm, tobacco budworm, and the pink bollworm.

MON 1445 contains the genetic material necessary to express the CP4 EPSPS which imparts tolerance to glyphosate and the NPTII selectable marker protein.

MON 15985 × MON 1445 has been produced by the traditional breeding of MON 15985 and MON 1445. Although genetic modification was used in the development of MON 15985 and MON 1445, no additional genetic modification was involved for the production of MON 15985 × MON 1445.

The use of MON 15985 and MON 15985 × MON 1445 enables farmers to effectively control certain lepidopteran insect pests in cotton, ensuring maximum realization of yield potential, while removing the environmental burden of the production, packaging and transport of insecticides, previously used to control lepidopteran pests. The use of MON 15985 × MON 1445 plants also enables the farmer to use glyphosate for effective control of weeds during the growing season and to take advantage of the favourable environmental and safety characteristics of glyphosate herbicides.

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

The scope of this renewal application includes food additives, feed materials and feed additives produced from MON 15985 and MON 15985 × MON 1445, as listed in the Community Register of GM Food and Feed[1]. The range of uses of both cotton-derived products will be identical to the full range of equivalent uses of current commercial cotton.

c) Intended use of the product and types of users

Food additives, feed materials and feed additives produced from MON 15985 and MON 15985 × MON 1445 will continue to be traded and used in the E.U. in the same manner as equivalent products from current commercial cotton and by the same operators currently involved in the trade and use of conventional cotton.

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

MON 15985 and MON 15985 × MON 1445 are substantially equivalent to other cotton varieties except for the introduced traits, namely protection from target lepidopteran pests or protection from target lepidopteran pests with tolerance to glyphosate, which are traits of agronomic interest. Both were shown to be as safe and as nutritious as conventional cotton. Therefore MON 15985 and MON 15985 × MON 1445-derived food additives, feed materials and feed additives will be stored, packaged, transported, handled and used in the same manner as products derived from current commercial cotton. No specific conditions are warranted or required for the food additives, feed materials and feed additives produced from MON 15985 and MON 15985 × MON 1445.

e) Any proposed packaging requirements

MON 15985 and MON 15985 × MON 1445 are substantially equivalent to conventional cotton varieties (except for the protection from targeted lepidopteran insect pests or the protection from targeted lepidopteran insect pests with tolerance to glyphosate). Therefore, MON 15985 and MON 15985 × MON 1445-derived food additives, feed materials and feed additives will continue to be used in the same manner as other equivalent cotton derived products and no specific packaging is required. [For labeling, *See* question 8.(f)].

[1] http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

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

In accordance with Regulations (EC) N° 1829/2003 and 1830/2003, a labelling threshold of 0.9 % is applied for the placing on the market of MON 15985 and MON 15985 × MON 1445 seed and derived products.

According to Regulation (EC) No. 1829/2003, Articles 13 and 25, the operators placing on the market food and feed products produced from MON 15985 and MON 15985 × MON 1445 shall ensure that those products are labeled with the words "*produced from genetically modified cotton*". 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 this GM plant is transmitted in writing to the operator receiving the product.

Operators handling or using foods and feeds produced from MON 15985 and MON 15985 × MON 1445 in the E.U. are required to be aware of the legal obligations regarding traceability and labeling of these products.

Given that explicit requirements for the traceability and labeling 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 and feed chain will be fully aware of the traceability and labeling requirements for foods and feeds produced from MON 15985 and MON 15985 × MON 1445. Therefore, no further specific measures are to be taken by the applicants.

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)

Not applicable

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 15985 and MON 15985 × MON 1445-derived food additives, feed materials and feed additives are suitable for 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

Misuse of food additives, feed materials and feed additives produced from MON 15985 and MON 15985 × MON 1445 is unlikely, as the proposed uses for both cottons are included in the current food and feed uses of conventional cotton. MON 15985 and MON 15985 × MON 1445 are substantially equivalent to other cotton except for the introduced traits, which are traits of agronomic interest. Both MON 15985 and MON 15985 × MON 1445 have been shown to be as safe and as nutritious as conventional cotton. Therefore, any measures for waste disposal and treatment of MON 15985 and MON 15985 × MON 1445-derived products are the same as those for conventional cotton. No specific conditions are warranted or required for the placing on the market of MON 15985 and MON 15985 × MON 1445-derived food additives, feed materials and feed additives.

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

1. Complete name

a) Family name

Malvaceae

b) Genus

Gossypium

c) Species

spp.

d) Subspecies

N/A

e) Cultivar/breeding line or strain

MON 15985 and MON 15985 × MON 1445

f) Common name

Cotton

2. a) Information concerning reproduction

(i) Mode(s) of reproduction

Cotton production is generally carried out with seeds. Cotton is a perennial plant that is harvested and planted annually. Cross-pollination can occur, but cotton is normally considered to be a

self-pollinating crop.

(ii) Specific factors affecting reproduction

Although natural crossing can occur, cotton is considered to be a self-pollinating crop. The pollen is heavy and sticky and transfer by wind is unlikely. Regardless, there are no morphological barriers to cross-pollination based on flower structure. Pollen is transferred by insects, in particular by various wild bees, bumble bees (*Bombus* sp.), and honeybees (*Apis mellifera*).

(iii) Generation time

The cultural cycle for cotton ranges from 120 to 200 growing days from seedling emergence to maturity. Rainfall, temperature, sunshine and spring warming all impact optimal growth.

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

The scope of this renewal application does not include the environmental release of MON 15985 and MON 15985 × MON 1445.

Gene transfer to cultivated genotypes

In as much as similar cotton genotypes are fully compatible; any pollen that is transferred has the potential to produce a hybrid seed. The degree of out-crossing in a production field is strongly dependent upon the geographic location of the field, which depends upon the crop ecology. Cross-pollination decreased from five to less than one percent from one to seven meters, respectively, away from the source plot.

Regardless, outcrossing with cultivated *Gossypium* varieties is not expected in the context of this renewal application.

Gene transfer to wild plant species

The criterion of sexual compatibility greatly limits the potential of gene flow from cultivated *Gossypium* in the geopolitical boundaries of Spain, Greece or other countries of the E.U. No genera in the *Gossypieae* tribe occur naturally in these countries.

3. Survivability

a) Ability to form structures for survival or dormancy

Cotton is a perennial plant that is harvested and planted annually and is not considered to have weedy characteristics.

b) Specific factors affecting survivability

Cultivated cotton does not possess any of the attributes associated with long term survivability such as seed dormancy, long soil persistence, germination under diverse environmental conditions, rapid vegetative

growth, a short life cycle, high seed output, high seed dispersal or long distance dispersal of seeds. In most cotton growing areas of the E.U. some of the seed remaining in the field following harvest and cultivation may germinate in the autumn if conditions are favorable. The seeds not germinating are likely to rot and die. In cotton growing regions with mild and dry winters, such as in Spain and Greece, cottonseed may over-winter and germinate the following spring. These cotton volunteers can be easily controlled by current agronomic practices including cultivation and the use of appropriate herbicides. However, it should be noted that cultivation or import of cottonseed of MON 15985 and MON 15985 × MON 1445 is not in the scope of this renewal application.

4. Dissemination

a) Ways and extent of dissemination

Cotton is a perennial plant that is harvested and planted annually. Dissemination occurs only by means of seeds. Genetic material can be disseminated by pollen movement. However, the current renewal application does not include the cultivation of MON 15985 and MON 15985 × MON 1445 varieties in the E.U. but only the continued use of existing food and feed products derived from MON 15985 and MON 15985 × MON 1445.

b) Specific factors affecting dissemination

Seed dissemination is impacted by mechanical harvesting and transport as well as wind damage, which may cause some mature bolls to fall to the ground. Pollen dispersal is influenced by insect vectors, particularly, bumble bees (*Bombus* spp.) and honey bees (*Apis mellifera*), with the former being the most efficient pollinator.

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

The major type of cotton being grown commercially around the world is the upland cotton *G. hirsutum*. There are, however, other two minor categories of cotton grown globally: the long staple cotton, *G barbadense* (commonly known as Pima or Egyptian cotton) and the Asiatic cotton, including *G. arboreum* and *G. herbaceum*.

Cotton is grown worldwide between latitudes of 45° north and 30° south, in areas that have at least 160 frost-free days. Cotton is a 'heat loving' plant, however more than 50% of the world crop is grown in temperate zones above 30° N latitude. Additionally, cotton is grown under similar climatic and soil constraints. The majority of cotton is grown in areas that receive between 50 and 150 cm of rainfall per year.

The major cotton producing countries in the world include the United States, Peoples Republic of China, India, Pakistan, and the Republic of Uzbekistan. Brazil, Australia, Egypt, Argentina, Turkey, Greece, Syria, and others produce significant, but lesser amounts.

There are no close wild relatives of cotton in the E.U.

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

In the E.U., cotton is commercially grown in Spain and Greece.

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

Cotton is known to interact with other organisms in the environment including a range of beneficial and pestiferous arthropods, fungal diseases and surrounding weed species. Cotton is cultivated in Spain and Greece and has a history of safe use in those countries. Cotton is not considered harmful or pathogenic to humans; however the plant does produce gossypol and cyclopropenoid fatty acids, which are natural toxicants. Both gossypol and cyclopropenoid fatty acids contents are reduced via processing of the cottonseed into oil or meal.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification

MON 15985
MON 15985 is produced by the transformation of MON 531, which was previously genetically modified via *Agrobacterium tumefaciens* mediated transformation. MON 15985 was generated using the particle acceleration transformation system.

MON 15985 × MON 1445
No novel method of genetic modification is used in the production of MON 15985 × MON 1445. Instead, MON 531 × MON 1445 is produced from a traditional breeding cross between is MON 15985 and MON 1445. Genetic modification was used in the development of MON 15985 and MON 1445.

2. Nature and source of the vector used

MON 15985
The plasmid vector used to generate MON 15985, PV-GHBK11, is an 8.7 kb high copy number, pUC-based plasmid. It contains well-characterized DNA elements for selection (*nptII*) and replication (ori-pUC) of the plasmid in bacteria.

MON 15985 × MON 1445
MON 15985 × MON 1445 results from traditional breeding. Genetic modification was used to generate the parental MON 15985 and MON 1445,

using plasmid vectors PV-GHBK11 and PV-GHGT07, respectively.

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

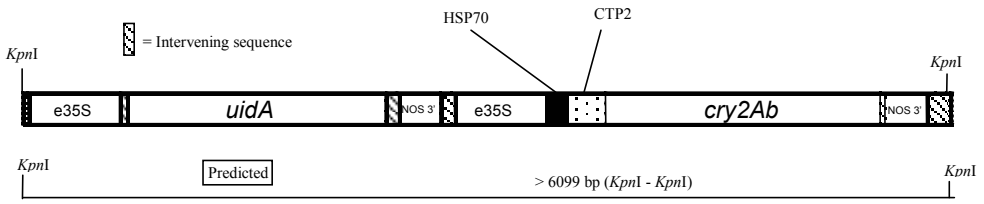
MON 15985

The linearized segment of the vector used in the transformation, PV-GHBK11L**,** contained the two genes to be introduced in MON 531 cotton plant cells, *i.e.*, the chimeric *cry2Ab2* gene (encoding the agronomic trait) and the *uidA* gene (selectable marker). The expression cassettes (Table 1 and Figure 1) corresponding to these two genes consist of respectively: a *cry2Ab2* coding sequence regulated by the *e35S* plant promoter, heat shock protein leader (*HSP70*), *ctp2* and the *NOS 3'* polyadenylation sequence; and the *uidA* coding sequence regulated by the *e35S* plant promoter and the *NOS 3'* polyadenylation sequence.

Table 1. Elements of the transformation fragment PV-GHBK11.

Genetic Element	Approximate Size (kb)	Description/source
uidA cassette		
e35S	0.6	Cauliflower mosaic virus (CaMV) promoter with the duplicated enhancer region used to drive expression of the *uidA* coding sequence.
uidA	1.8	DNA sequence coding for the β-D-glucuronidase (GUS) protein from *E. coli*.
NOS 3'	0.26	3' nontranslated region of the nopaline synthase (*nos*) gene from *Agrobacterium tumifaciens* which terminates transcription and directs polyadenylation.
cry2Ab2 cassette		
e35S	0.6	Cauliflower mosaic virus (CaMV) promoter with the duplicated enhancer region used to drive expression of the *cry2Ab2* gene.
HSP70	0.1	Petunia heat shock protein 70 5' untranslated leader sequence.
ctp2	0.23	DNA sequence coding for the N-terminal chloroplast transit peptide from *Arabidopsis* thaliana *epsps* gene.
cry2Ab2	1.9	DNA sequence coding for a synthetic Cry2Ab2 protein of *Bacillus thuringiensis*.
NOS 3'	0.26	3' nontranslated region of the nopaline synthase (*nos*) gene from *Agrobacterium tumefaciens* which terminates transcription and directs polyadenylation.

Figure 1. Transformation vector: DNA segment PV-GHBK11L



The *Kpn*I DNA segment, PV-GHBK11L was used as transformation vector to generate MON 15985 by particle acceleration technology.

MON 15985 × MON 1445

MON 15985 × MON 1445 has been produced by the traditional breeding of MON 15985 and MON 1445. The inserted DNA fragment from both parental lines are inherited in MON 15985 × MON 1445.

The individual components and the size, source and function of these inherited DNA sequences are given in Tables 2 and 3, while schematic representations of those inserts are shown in Figures 2 and 3.

Table 2. Summary of genetic elements of the inserts in MON 15985.

Genetic Element	Approximate Size (kb)[1]	Description/source
Genetic elements associated to the functional *cry1Ac* insert (MON 531)		
cry1Ac cassette		
7S 3'	0.44	3' nontranslated region from soybean 7S seed storage protein gene which terminates transcription and directs polyadenylation of the *cry1Ac* mRNA
cry1Ac	3.54	DNA sequence coding for a synthetic variant of the Cry1Ac protein of *Bacillus thuringiensis*
e35S	0.6	Cauliflower mosaic virus (CaMV) promoter with the duplicated enhancer region used to drive expression of the *cry1Ac* coding sequence.
aad gene		
aad	0.79	Bacterial gene comprising its own regulatory elements and coding for an aminoglycoside-modifying enzyme, 3'(9)-O-nucleotidyltransferase from the transposon Tn7
nptII cassette		
NOS 3'	0.24	3' nontranslated region of the nopaline synthase (*nos*) gene from *Agrobacterium tumefaciens* which terminates transcription and directs polyadenylation
nptII	0.97	DNA sequence isolated from the bacterial transposon Tn5 coding for neomycin phosphotransferase type II. Expression of this sequence in plant cells confers resistance to kanamycin and serves as a selectable marker for transformation. The *nptII* cassette also contains a 153 bp portion of the 378 bp (*ble*) gene encoding the bleomycin binding protein.
35S	0.32	Cauliflower mosaic virus (CaMV) promoter
ori-V	0.39	Origin of replication for *Agrobacterium* derived from the broad host range plasmid RK2.

[1] Sizes of the same genetic element may differ slightly between the *cry1Ac* and *cry2Ab2* coding regions due to revisions in the annotation of the Monsanto proprietary sequence database.

Table 2. Summary of genetic elements of the inserts in MON 15985 – continued.

Genetic Element	Approximate Size (kb)[1]	Description/source
Genetic elements associated to the *cry2Ab2* insert (MON 15947) [2]		
uidA cassette		
e35S	0.3	Cauliflower mosaic virus (CaMV) promoter with a duplicated enhancer region used to drive expression of the *uidA* coding sequence.
uidA	1.8	DNA sequence coding for the ß-D-glucuronidase (GUS) protein from *E. coli*
NOS 3'	0.26	3' nontranslated region of the nopaline synthase (*nos*) gene from *Agrobacterium tumefaciens* which terminates transcription and directs polyadenylation
cry2Ab2 cassette		
e35S	0.6	Cauliflower mosaic virus (CaMV) promoter with the duplicated enhancer region used to drive expression of the *cry2Ab2* gene.
HSP70	0.1	Petunia heat shock protein 70 5' untranslated leader sequence.
ctp2	0.23	DNA sequence coding for the N-terminal chloroplast transit peptide from *Arabidopsis thaliana epsps* gene.
cry2Ab2	1.9	DNA sequence coding for a synthetic Cry2Ab2 protein of *Bacillus thuringiensis*.
NOS 3'	0.26	3' nontranslated region of the nopaline synthase (NOS) gene from *Agrobacterium tumefaciens* which terminates transcription and directs polyadenylation.

[1] Sizes of the same genetic element may differ slightly between the *cry1Ac* and *cry2Ab2* coding regions due to revisions in the annotation of the Monsanto proprietary sequence database.

[2] Newly inserted fragment discussed in Section D.2. of this document.

Table 3. Summary of genetic elements of the insert in MON 1445.

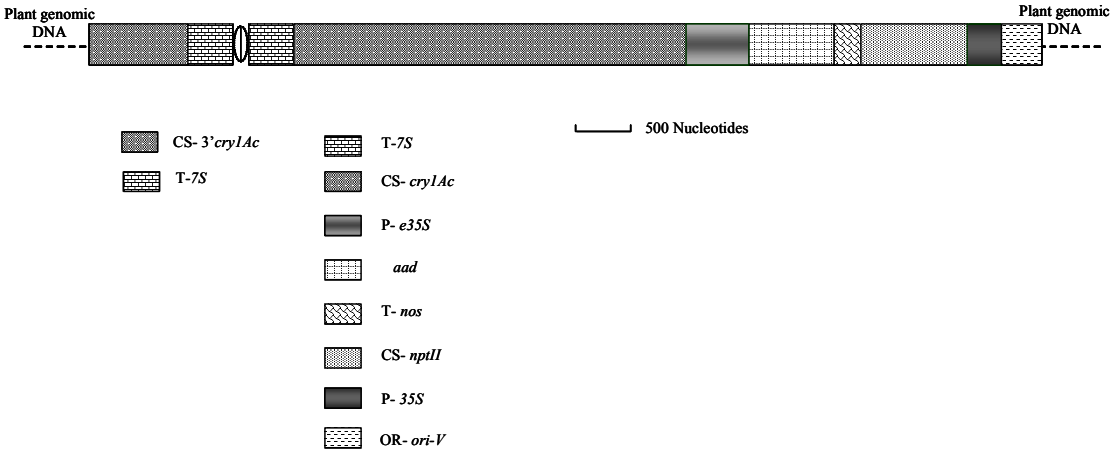
Genetic Element	Approximate Size (kb)	Description/source (Reference)
Right Border	0.02	DNA sequence derived from *Agrobacterium* containing the right border essential for transfer of the T-DNA.
cp4 epsps cassette		
E9 3'	0.64	3' nontranslated region of the pea ribulose-1,5-bisphosphate carboxylase small subunit (rbcS) E9 gene, terminates transcription and directs polyadenlyation of the mRNA.
cp4 epsps	1.37	DNA sequence coding for the synthetic CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) from *Agrobacterium* sp. strain CP4 (*aroA* gene).
ctp2	0.29	DNA sequence coding for the N-terminal chloroplast transit peptide from *Arabidopsis thaliana* EPSPS gene.
FMV	0.56	35S promoter derived from figwort mosaic virus.
aad gene		
aad	0.83	Bacterial gene comprising its own regulatory elements and coding for an aminoglycoside-modifying enzyme, 3'(9)-O-nucleotidyltransferase from the transposon Tn7

Table 3. Summary of genetic elements of the inserts in MON 1445 – continued.

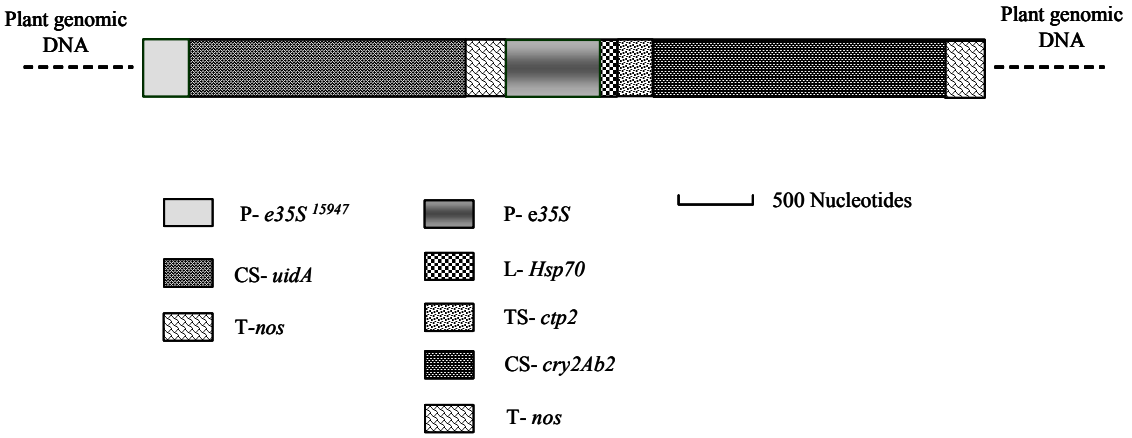
Genetic Element	Approximate Size (kb)	Description/source (Reference)
nptII cassette		
NOS 3'	0.25	3' nontranslated region of the nopaline synthase (NOS) gene from *Agrobacterium tumefaciens* which terminates transcription and directs polyadenylation.
nptII	0.79	DNA sequence isolated from the bacterial transposon Tn5 (Beck *et al*., 1982) coding for neomycin phosphotransferase type II. Expression of this sequence in plant cells confers resistance to kanamycin and serves as a selectable marker for transformation.
35S	0.32	Cauliflower mosaic virus (CaMV) promoter.
ori-V	0.22	Origin of replication for *Agrobacterium* derived from the broad host range plasmid RK2.

Figure 2. Schematic representation of the inserts in MON 15985

a) <u>MON 531 insert</u>

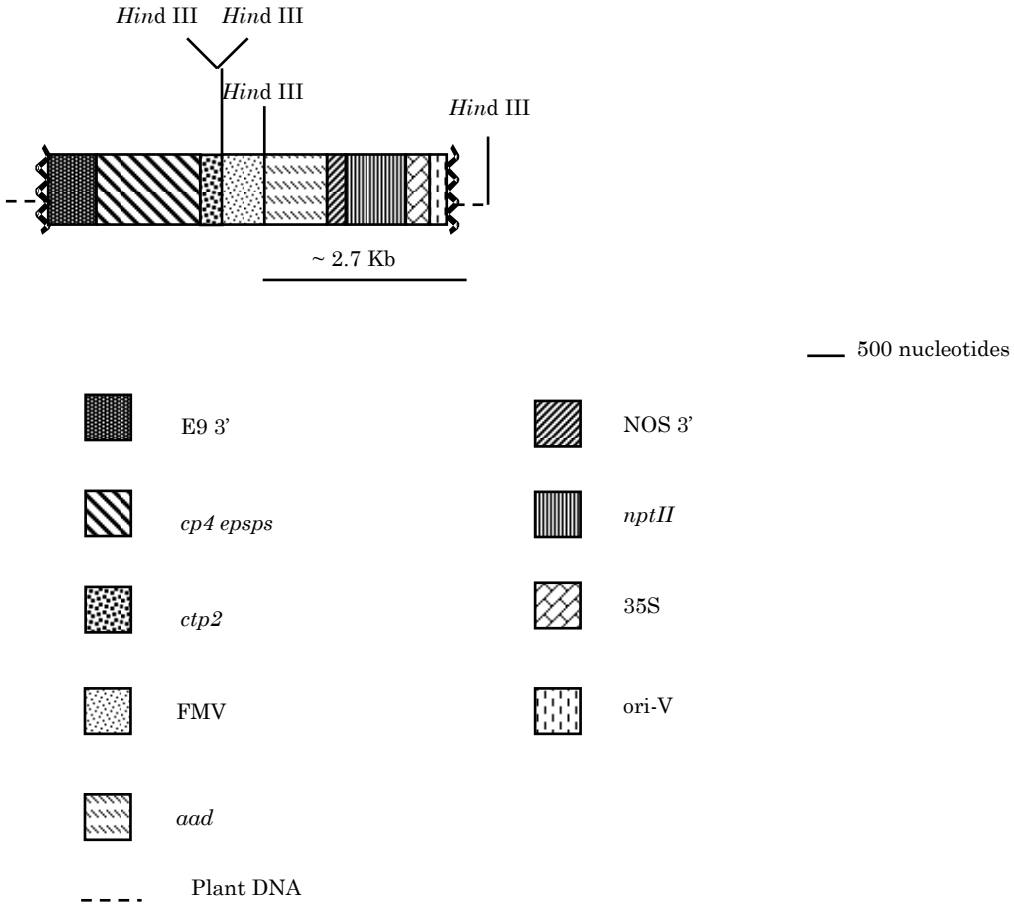


b) MON 15947 insert*



* Newly inserted fragment discussed in Section D.2. of this document

Figure 3. Schematic representation of the *cp4 epsps* insert in MON 1445.



indicate junctions between truncated genetic elements and the plant genomic DNA

D. INFORMATION RELATING TO THE GM PLANT

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

MON 15985
MON 15985 plants produce the Cry1Ac and Cry2Ab2 insect protection proteins, derived from the common soil bacterium *Bacillus thuringiensis* subsp. *Kurstaki*, which provide effective control of cotton bollworm (CBW, *Helicoverpa armigera*), pink bollworm (PBW, *Pectinophora gossypiella*) and tobacco budworm (TBW, *Heliothis virescens*) in cotton. Previously, MON 531 was found to have value beyond a replacement for insecticide applications for specific pests. The other direct benefits of MON 531, continued in MON 15985, and supported by data in the current literature, are improved control of agricultural pests, improved yield, reduced production costs, improved grower profitability, reduced occupational risk, improved opportunity to grow cotton, and improved economic outlook for the cotton industry. There also are a number of indirect benefits associated with the reduction in insecticide use, which include improved beneficial insect and wildlife populations, reduced runoff of insecticides, reduced air pollution, and reduction of chemical handling for farm workers.

MON 15985 is also expected to provide an additional tool to delay the development of lepidopteran resistance in cotton, because MON 15985 produces both the Cry1Ac and Cry2Ab2 proteins. MON 15985 provides equivalent or increased control of the major insect pests of cotton (tobacco budworm, pink bollworm, and cotton bollworm) compared to MON 531, with additional control of secondary lepidopteran insect pests such as beet and fall armyworm.

MON 15985 × MON 1445
MON 15985 × MON 1445 has been produced by the traditional breeding of MON 15985 and MON 1445. MON 15985 × MON 1445 expresses the Cry1Ac and Cry2Ab2 insect protection proteins, found in MON 15985, as well as the CP4 EPSPS protein which confers tolerance to glyphosate. The insect protection trait provides effective control of lepidopteran insects which are economically damaging pests in most cotton growing regions (*see* above). The glyphosate tolerance trait provides a novel, highly efficacious weed control option for farmers, and allows the farmer to take advantage of the favorable environmental properties exhibited by Roundup®.

2. Information on the sequences actually inserted or deleted

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

MON 15985
MON 15985 genomic DNA was analyzed by Southern blotting to determine the number of insertions and the copy number of the inserted DNA from MON 15947 and MON 531 genetic elements in MON 15985. It has been demonstrated that MON 15947 DNA contains one single insert made of one copy of the genetic elements of the

transformation vector PV-GHBK11L. MON 531 contains a functional insert made of two linked T-DNA insertions arranged in a head-to-tail configuration.

MON 15985 × MON 1445
To confirm that the DNA inserts in MON 15985 × MON 1445 are the same as those that occur in MON 15985 and MON 1445, a Southern blot analysis was conducted to confirm the presence of the product-specific fingerprints for both MON 15985 and MON 1445 in MON 15985 × MON 1445.

The fingerprint analyses indicate that each of the parental inserts is present in MON 15985 × MON 1445.

Tables 2 and 3 and figures 2 and 3 summarize the genetic elements of the DNA inserts in MON 15985 and MON 1445.

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

MON 15985
In addition to the MON 531 insert, MON 15985 contains in its nuclear genome an insert with one single copy of the elements present in transformation vector PV-GHBK11L. This insert is defined as MON 15947 insert. The presence of MON 15947 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 was consistent with a single site of insertion into the cotton DNA and segregation according to Mendelian genetics. This result is therefore consistent with the stable integration and maintenance of the insert into nuclear DNA.

MON 15985 × MON 1445
The traditionally bred MON 15985 × MON 1445 contains the DNA inserts from both MON 15985 and MON 1445 at separate sites in the nuclear genome, as they were inherited from the MON 15985 and MON 1445 single trait material. The presence of these inserts in the combined-trait product was confirmed through Southern blot analysis.

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

MON 15985
Genomic DNA from MON 15985 was analyzed by Southern blotting to determine the integrity of the inserted promoters, coding regions, and polyadenylation sequences, and the presence or absence of plasmid backbone sequences associated with the second insert MON 15947. In addition, the 5' and 3' junctions between the insert and the plant DNA

were confirmed by PCR.

MON 15985 contains one complete copy of the *cry2Ab2* cassette linked to one copy of the *uidA* cassette, which is missing approximately 260 bp at the 5' end of the enhanced CaMV 35S promoter. MON 15985 also contains one copy of the *cry1Ac* cassette, consisting of two linked T-DNA insertions arranged in a head-to-tail configuration. MON 15985 does not contain any detectable plasmid backbone sequence.

MON 15985 × MON 1445
As MON 15985 × MON 1445 is the result of traditional breeding of MON 15985 and MON 1445 and no additional genetic modification methods have been applied, and as the inherited DNA fragments have negligible potential to interact with one another, it is highly likely that MON 15985 × MON 1445 contains each of the inserts as they were present in the parental MON 15985 and MON 1445 lines. Therefore, the molecular characteristics of the introduced DNA sequences, known for the parental MON 15985 and MON 1445 products, also apply to MON 15985 × MON 1445. Furthermore, there is no indication that the location of the inserts and the 5' and 3' flanking sequences have been altered during the breeding process. The molecular analysis of MON 15985 × MON 1445 confirms the presence of each insert.

3. Information on the expression of the insert

MON 15985
A study was conducted to measure the amount of Cry2Ab2, Cry1Ac, GUS, NPTII, and AAD proteins in various tissue types collected from MON 15985 and control cotton grown in U.S. field trials in 1998. There were two types of controls used for this study including: DP50, a conventional variety, and MON 531, which expresses Cry1Ac and NPTII proteins. The background genetics of the test and control cotton were similar.

Enzyme-Linked Immunosorbent Assay (ELISA) methods were developed and validated to quantify the Cry2Ab2, Cry1Ac, GUS, NPTII and AAD levels in cotton tissues. Mean level of Cry2Ab2, Cry1Ac, GUS and NPTII proteins in seed samples of MON 15985 were: 43.2, 3.35, 58.8 and 10.8 µg/g fresh weight, respectively. The AAD protein level was below the limit of detection.

In conclusion, the Cry1Ac and NPTII protein levels are similar in MON 15985 compared to MON 531. Additionally, the Cry1Ac and NPTII proteins levels are below the limit of detection in the conventional cotton. As expected, the AAD protein was not detected in MON 15985, MON 531 or in the conventional control. The results also confirm that MON 15947 did not affect the levels of Cry1Ac and NPTII proteins expressed in MON 15985, as compared to MON 531. The measured Cry2Ab2 and Cry1Ac protein levels are sufficient to confer protection from cotton pest feeding damage.

MON 15985 × MON 1445
A study was conducted to measure the amount of Cry1Ac, Cry2Ab2, CP4 EPSPS, NPTII, and GUS proteins in various tissues collected from test and control cotton varieties grown in U.S. field trials conducted in 2001. The test for this study was MON 15985 × MON 1445, expressing the Cry1Ac, Cry2Ab2, CP4 EPSPS, NPTII, and GUS proteins. There were three types of

controls used for this study consisting of 1) MON 15985 expressing Cry1Ac, Cry2Ab2, NPTII, and GUS proteins; 2) MON 1445 expressing CP4 EPSPS and NPTII proteins; and 3) a conventional cotton control. The background genetics of the test and controls were similar.

Enzyme-Linked Immunosorbent Assay (ELISA) methods were developed and validated to quantify the Cry1Ac, Cry2Ab2, CP4 EPSPS, NPTII, and GUS protein levels in cotton tissues. Mean level of Cry1Ac, Cry2Ab2, CP4 EPSPS, NPTII and GUS proteins in seed samples of MON 15985 were: 1.5, 45, 160, 17 and 45 µg/g fresh weight, respectively.

The Cry1Ac levels in MON 15985 were similar to those found in MON 15985 × MON 1445. Additionally, the Cry2Ab2 and GUS protein levels in MON 15985 were similar to those found in MON 15985 × MON 1445. CP4 EPSPS protein levels were slightly higher in MON 15985 × MON 1445 compared to MON 1445. The levels of Cry1Ac, Cry2Ab2, CP4 EPSPS, NPTII and GUS proteins were below the limits of detection in the conventional cotton control.

b) Parts of the plant where the insert is expressed

MON 15985

The levels of Cry2Ab2 and Cry1Ac proteins were analyzed in leaf, seed, whole plant and pollen, while the levels of NPTII and GUS proteins were estimated in leaf and seed samples. Results for seed tissue are the most relevant for the evaluation of the food and feed safety of MON 15985 and are, therefore, presented in this summary.

MON 15985 × MON 1445

The levels of Cry1Ac, Cry2Ab2, CP4 EPSPS, NPTII, and GUS proteins were measured in seed and leaf tissues. Results for seed tissue are the most relevant for the evaluation of the food and feed safety of MON 15985 × MON 1445 and are, therefore, presented in this summary.

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

a) Reproduction

Comparative assessments of the phenotypic and agronomic characteristics of MON 15985 and MON 1445 and conventional cotton have been conducted at multiple sites in the U.S.A. since development of these products began. The extensive experience from commercial use of these products has demonstrated that, except for the insect protection and glyphosate tolerance traits, there are no biologically significant differences in the reproductive capability, dissemination or survivability of MON 15985 and MON 1445 compared to conventional cotton.

Based on the conclusions established for each single trait cotton, no differences are anticipated in the reproduction, dissemination or survivability of MON 15985 × MON 1445 compared to MON 15985 or MON 1445.

Regardless, it should be noted that the scope of the current renewal application does not include the cultivation of MON 15985 or MON 15985 × MON 1445 varieties in the E.U. but only the renewal of the authorisation for the continued marketing of existing MON 15985 and MON 15985 × MON 1445-derived food additives, feed materials, and feed additives, entered in the Community Register of GM Food and Feed, in the E.U.

b) Dissemination

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

c) Survivability

Cotton is known to be a weak competitor in the wild, which cannot survive outside cultivation without human intervention. Field observations have demonstrated that MON 15985 and MON 15985 × MON 1445 have not been altered in its survivability when compared to conventional cotton.

d) Other differences

Comparative assessments in the field did not reveal any biologically significant differences between MON 15985 and MON 15985 × MON 1445 and conventional cotton, except for the introduced traits that are of agronomic interest.

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

No increased hazard is to be expected from potential recombination

Recombination is unlikely to occur. This fact is supported by the stability of the genetic elements over generations. Due to the safety properties associated with the introduced protein, the hazard arising from a hypothetical recombination event is negligible.

Molecular stability of the insert

MON 15985
A Southern blot analysis was conducted to demonstrate the stability of the inserted elements from MON 531 that are responsible for the expression of the Cry1Ac protein in MON 15985 across four generations. The results indicate that the primary, functional insert of MON 531 is stably maintained across the four generations of MON 15985.

Additionally, the genetic stability of the MON 15947 insert in MON 15985 has been demonstrated, by Southern blot analysis across five plant breeding generations.

To determine the phenotypic stability of MON 15985 across generations, a series of progeny tests were conducted based on a qualitative Cry2Ab2

enzyme-linked immunosorbent assay (ELISA) of four generations. The data confirm that the MON 15985 contains a DNA insert at a single locus that segregates according to Mendelian genetics and therefore remains stably integrated in the plant genome over selfed generations and over successive backcross generations.

MON 15985 × MON 1445

The presence of the parental inserts in MON 15985 × MON 1445 was demonstrated using DNA material extracted at the 8th generation (BC_2F_6) of the plant expressing the combined traits. The fact that the two inserts are still present after this high number of generations indicate that, as expected, each of them is stable even when combined over multiple generations.

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

a) Plant to bacteria gene transfer

None of the genetic elements introduced in MON 15985 and MON 15985 × MON 1445 carries a genetic transfer function. Therefore, no changes are expected in the ability of this cotton to transfer genetic material to bacteria.

b) Plant to plant gene transfer

The scope of the current renewal application does not include the cultivation of MON 15985 or MON 15985 × MON 1445 varieties in the E.U. but only the renewal of the authorisation for continued marketing of existing MON 15985 or MON 15985 × MON 1445-derived food additives, feed materials and feed additives, entered in the Community Register of GM Food and Feed, in the E.U. Therefore, plant to plant gene transfers would have no opportunity to occur. However, based on the fact that pollen production and pollen viability as measured by yield and germination of progeny are unchanged by the genetic modification, the outcrossing frequency to other cotton varieties or to wild relatives (which are not present in the E.U.) is unlikely to be different for MON 15985, MON 1445 or MON 15985 × MON 1445 when compared to other cotton.

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 15985 and MON 15985 × MON 1445 were compared with a conventional cotton control and other commercially available cotton.

7.2 Production of material for comparative assessment

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

MON 15985

Materials for the compositional analysis were produced from a total of 14 U.S. field sites over two years (1998 and 1999). The test, MON 15985, and the conventional cotton control, had similar background genetics and were planted in eight sites in 1998 and in six sites in 1999. In 1998, the test and control cotton were planted in a single block with two 4.5 m row plots in LA, SC, MS and TX; in a single block with one 9 m row plot in MS; and in four replicate blocks at MS, AL, LA and AZ[2]. In 1999, all locations included four replicate blocks. Eight commercial reference varieties were included for the seed composition comparisons in 1998, four commercial cotton varieties were planted as reference lines in 1999. Additionally, compositional analysis of the cottonseed oil and cottonseed meal from the test variety compared to the control and three reference varieties were reported.

MON 15985 × MON 1445

A study was conducted on the compositional analysis of cottonseed from the test, MON 15985 × MON 1445, and a control cotton. The control cotton was a conventional cotton variety. Additionally, eleven different conventional cotton varieties were included as reference varieties to provide data for the development of a 99% tolerance interval for each component analyzed. The study was conducted at five sites across the U.S.A. during the 2001 field season. All sites were replicated using a randomized complete block design, with each site having four blocks or replicates of the control, test and reference substance.

b) the baseline used for consideration of natural variations

MON 15985

The study compared MON 15985 to the control. Reference varieties 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 varieties. Differences were also compared to historical ranges and ranges reported in literature.

MON 15985 × MON 1445

The test MON 15985 × MON 1445 was compared to a conventional, non-transgenic control. Eleven different non-transgenic commercial varieties were included as reference lines to provide data for the development of a 99% tolerance interval for each component analyzed. Where statistical differences occurred,

[2] AL: Alabama; AZ: Arizona; LA: Louisiana; MS: Mississippi; SC: South Carolina; TX: Texas

the measured analyte was compared to a confidence interval developed from the reference varieties. Differences were also compared to historical ranges and ranges reported in literature.

7.3 Selection of material and compounds for analysis

The compounds that were selected for analysis in the compositional studies were chosen on the basis of internationally accepted guidance, and animal feed manufacturers specifications.

The results of the compositional analyses conducted for MON 15985 and MON 15985 × MON 1445 in comparison to control cotton demonstrate equivalence and do not indicate a need for further analysis of selected compounds in these cotton products.

7.4 Agronomic traits

The scope of this application is limited to the renewal of the authorisation for continued marketing of existing MON 15985 and MON 15985 × MON 1445-derived food additives, feed materials and feed additives in the E.U., but does not include the cultivation of MON 15985 or MON 15985 × MON 1445 varieties in the E.U. The results from field trials and the experience from commercial planting in North America has provided a weight of evidence that when compared with conventional cotton varieties, MON 15985 and MON 15985 × MON 1445 have:

- equivalent growth, developmental and morphological characteristics;
- equivalent plant health, vigor and pest susceptibility (except for predation by specific leptidopteran insect pests);
- equivalent agronomic performance, including yield potential.

These results also infer that MON 15985 and MON 15985 × MON 1445 have equivalent biological fitness, dissemination and survival characteristics (*i.e.* similar lack of persistence in the field and lack of invasiveness into natural environments) as any other cotton.

7.5 Product specification

MON 15985 and MON 15985 × MON 1445-derived food additives, feed materials and feed additives are currently imported into the EU in mixed shipments of cotton products, produced in other world areas. These products are handled by operators that have traditionally been involved in the commerce, processing and use of cotton and cotton derived products in the European Union.

MON 15985

MON 15985 comprises all traditionally bred progeny that express the MON 15985 traits. MON 15985 contains the MON 15947 insert, and produces the Cry2Ab2 protein. Therefore, MON 15985 is detectable using the product-specific PCR method for detecting the introduced DNA present from MON 15947.

MON 15985 × MON 1445

As MON 15985 × MON 1445 is the result of a conventional cross of MON 15985 and MON 1445, it contains all the respective DNA inserts from both single trait cotton products. Therefore, MON 15985 × MON 1445 is detectable using either the product-specific PCR method for detecting the introduced DNA present in MON 15985 or the equivalent method for MON 1445. However, as for all plants in which one or more genetically modified traits are combined by traditional breeding, unambiguous detection of MON 15985 × MON 1445 can only occur with seeds from the MON 15985 × MON 1445 , by using a combination of the provided PCR methods on a single seed.

7.6 Effect of processing

As MON 15985 and MON 15985 × MON 1445 are substantially equivalent and as safe and nutritious as conventional cotton, the use of MON 15985 and MON 15985 × MON 1445 seed for the production of foods and feeds is no different from that of conventional cotton. Consequently, any effects of the production and processing of MON 15985 and MON 15985 × MON 1445 foods and feeds are not expected to be any different from the production and processing of the equivalent foods and feeds, originating from conventional cottonseed.

7.7 Anticipated intake/extent of use

Food additives, feed materials and feed additives produced from MON 15985 and MON 15985 × MON 1445 were first placed on the E.U. market in 2003. In 2004, these products were notified to the European Commission, following Articles 8(1)(b) and 20(1)(b) of Regulation (EC) No 1829/2003, in order to allow for their continued marketing in the E.U. given that they had been lawfully placed on the market before Regulation (EC) No 1829/2003 came into force, on 18 April 2004.

MON 15985 and MON 15985 × MON 1445-derived food additives, feed materials and feed additives replace a portion of current commercial cotton products, such that the dietary intake and/or extent of use of current commercial cotton products is not expected to be altered upon renewal of the authorisation of existing MON 15985 and MON 15985 × MON 1445-derived products.

7.8 Toxicology

7.8.1 Safety assessment of newly expressed proteins

MON 15985

MON 15985 produces the Cry2Ab2 and GUS proteins as well as the Cry1Ac and NPTII proteins Several studies, including characterization of the introduced proteins, digestion in simulated gastric and intestinal fluids, and bioinformatics analyses, were performed with Cry2Ab2 and GUS. Additionally, acute oral toxicity studies have been conducted in mice using the

Cry2Ab2 and GUS proteins. Analyses from these multiple studies support the conclusion that the Cry2Ab2 and GUS proteins are not toxic to mammals and present no unacceptable risk to human safety. Finally, exposure to the introduced proteins were also considered to be extremely reduced, if at all existing; expression studies show that those proteins are present at very low levels in MON 15985 cottonseed and are unlikely to remain in highly processed cotton food products.

Regarding the potential interactivity of Cry2Ab2 with the Cry1Ac protein, which is also expressed in MON 15985, to date, there is no evidence to support the hypothesis that the presence of the Cry1Ac protein would affect the activity of the Cry2Ab2 protein in MON 15985, and thus affect the safety assessment of the Cry2Ab2 protein.

MON 15985 × MON 1445
MON 15985 × MON 1445 was produced by the traditional crossing of MON 15985 and MON 1445. The introduced traits present in MON 15985 and MON 1445 are inherited in MON 15985 × MON 1445. The safety of the introduced traits present in MON 15985 × MON 1445 was demonstrated on the basis of a) an extensive characterization of each protein, b) comparison of these proteins to known protein toxins and allergens, c) their digestion in simulated gastric and intestinal fluids, and d) the assessment of each protein for evidence of any acute toxicity in oral gavage studies in rodents. All these studies confirmed the absence of any toxic effects associated to the introduced proteins and confirmed the absence of any unanticipated or pleiotropic effects of the genetic modification. The introduced proteins in MON 15985 and MON 1445 have shown no evidence of adverse effects on human or animal safety.

In conclusion, no evidence of toxic or other harmful effects on human health have been identified and no risks specific to the expression of the new proteins in the same plant can be anticipated since the proteins have specific and independent targets.

7.8.2 Testing of new constituents other than proteins

Since cotton is known as a common source of food and feed products with a long history of safe use and consumption around the world, and as MON 15985 and MON 15985 × MON 1445 were shown to be substantially equivalent to conventional cotton, no toxicological testing of any constituents, other than the introduced proteins is not indicated.

7.8.3 Information on natural food and feed constituents

Cotton is known as a common source of human food and feed products, with a long history of safe use and consumption around the world. All cotton contains cyclopropenoid fatty acids

(CPFA) and gossypol, natural compounds that are considered to be undesirable and anti-nutritional. The steps taken during cottonseed processing, in order to produce cottonseed oil, detoxify gossypol and greatly reduce the CPFA content. No other particular natural constituents of cotton 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

Compositional analyses and comparative phenotypic assessments have demonstrated that MON 15985 and MON 15985 × MON 1445 are substantially equivalent to conventional cotton, with the exception of the introduced insect-protection or the introduced insect-protection and glyphosate-tolerance traits.

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

The scope of the current renewal application covers food additives, feed materials and feed additives produced from MON 15985 and MON 15985 × MON 1445.

Absence of any allergenic potential associated with the introduced Cry1Ac, Cry2Ab2 and CP4 EPSPS proteins expressed in MON 15985 and MON 15985 × MON 1445 has previously been demonstrated.

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 food additives, feed materials and feed additives produced from MON 15985 and MON 15985 × MON 1445 do not pose an increased risk for allergenic reactions compared to the equivalent range of food and feed uses of conventional cotton.

7.10 Nutritional assessment of GM food/feed

7.10.1 Nutritional assessment of GM food

MON 15985 and MON 15985 × MON 1445 express the introduced trait(s) of insect-protection or of insect-protection and glyphosate tolerance, which are agronomic traits, and are not intended to change any nutritional aspects of this cotton. Hence both cottons are not expected to be more or less attractive for the production of food products. Therefore, anticipated dietary

intake of cotton-derived foods is not expected to be altered upon the renewal of MON 15985 and MON 15985 × MON 1445 authorisations, and no nutritional imbalances are expected as a result of the use of MON 15985 and MON 15985 × MON 1445-derived food products.

7.10.2 Nutritional assessment of GM feed

Confirmatory feeding studies in channel catfish were performed to compare the nutritional value of MON 15985 and MON 1445 and conventional control grain, as well as commercial reference hybrids, and to provide additional confirmation of the safety of these cottons. The results of these studies show that there were no biologically relevant differences in the parameters tested between catfish fed the MON 15985 or MON 1445 cottonseeds meal-containing diets and the conventional control diets. This conclusion was consistent with the evaluation of the composition of MON 15985 and MON 15985 × MON 1445, which showed that there were no biologically relevant differences in nutritional and compositional properties relative to control and reference cottonseeds. These data confirm the conclusion that MON 15985 and MON 15985 × MON 1445-derived feed products are as safe and nutritious as their counterpart products produced from current commercial conventional cotton.

7.11 Post-market monitoring of GM food/feed

The assessment of the human and animal safety of MON 15985 and MON 15985 × MON 1445 was conducted on the basis of these products' substantial equivalence to conventional cotton (except for the introduced traits) and by extensive characterization of the introduced traits, which are of agronomic interest, resulting in the expression of the Cry1Ac, Cry2Ab2 and CP4 EPSPS.

Based on compositional comparisons of cottonseeds, it can be concluded that food additives, feed materials and feed additives produced from MON 15985 and MON 15985 × MON 1445 are not different from the counterpart products produced from conventional cottonseed.

There are no intrinsic hazards related to MON 15985 and MON 15985 × MON 1445 as no signs of adverse or unanticipated effects have been observed in a number of safety studies. The pre-market risk characterization for food and feed from MON 15985 and MON 15985 × MON 1445 is based on the pre-market risk characterizations of both MON 15985 and MON 1445. These pre-market risk assessments have demonstrated that the risks of consumption of food additives, feed materials and feed additives produced from both MON 15985 and MON 15985 × MON 1445 are negligible and no different than the risks associated with the consumption of conventional cotton and cotton-derived products. As a consequence, and as previously stipulated in the Community Register of GM food and feed, no specific risk management measures are

indicated for MON 15985 and MON 15985 × MON 1445, and post-market monitoring of the use of food additives, feed materials and feed additives is not considered appropriate.

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

Not applicable as the scope of this renewal application under Regulation (EC) No 1829/2003 does not cover the deliberate release of cottonseeds into the environment but only the food additives, feed materials and feed additives produced from MON 15985 and MON 15985 × MON 1445 cottonseeds..

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

Not applicable as neither the GMO, nor the food and feed containing or consisting of the GMO, are within the scope this renewal application under Regulation (EC) No 1829/2003. This renewal application includes only food additives, feed materials and feed additives produced from MON 15985 and MON 15985 × MON 1445 cottonseeds.

10. Potential interactions with the abiotic environment

Not applicable as neither the GMO, nor the food and feed containing or consisting of the GMO, are within the scope this renewal application under Regulation (EC) No 1829/2003. This renewal application includes only food additives, feed materials and feed additives produced from MON 15985 and MON 15985 × MON 1445 cottonseeds.

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

Not applicable as neither the GMO, nor the food and feed containing or consisting of the GMO, are within the scope this renewal application under Regulation (EC) No 1829/2003. This renewal application includes only food additives, feed materials and feed additives produced from MON 15985 and MON 15985 × MON 1445 cottonseeds..

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

MON 15985 contains the MON 15947 insert and therefore is detectable using the event-specific PCR method for detecting the introduced DNA present from MON 15947.

As MON 15985 × MON 1445 is the result of a traditional cross of MON 15985 and MON 1445, it contains both inserts. Therefore, MON 15985 × MON 1445 is detectable using either the event-specific PCR method for detecting the introduced DNA present in MON 15985 or the equivalent method for MON 1445. However, as for all plants in which one or more events are combined by traditional breeding, the unambiguous detection of MON 15985 × MON 1445 in mixed consignments will require single seeds to be subjected to detection methods for both MON 15985 and MON 1445, and to test positive for both.

These methods are presently on step 5 (Reporting) of their validation process, being done by the Community Reference Laboratory (CRL). Once completed, they will be posted; together with the validation report for MON 15985 × MON 1445 in the CRL website http://gmo-crl.jrc.it/.

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

Not applicable.

b) Conclusions of post-release monitoring

Not applicable.

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

Not applicable.

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

a) Release country

MON 15985 and MON 15985 × MON 1445 have been grown commercially in the U.S.A. and Australia.

Field tests of MON 15985 and MON 15985 × MON 1445 in countries such as the U.S.A. and Australia have been conducted since 1999.

b) Authority overseeing the release

In the U.SA.: Environmental Protection Agency (EPA), Food and Drug Administration (FDA), and the United States Department of Agriculture (USDA).

In Australia: Office of the Gene Technology Regulator (OGTR) and Food Standards Australia and New Zealand (FSANZ).

It should be noted that only in a few countries around the world, stacked products require separate approvals by regulatory agencies. In most countries, including the U.S.A., stacked products are not regulated provided that each of the parental lines is already approved.

c) Release site

Across major cotton growing regions

d) Aim of the release

Commercial release for all uses as conventional cotton.

e) Duration of the release

Please see question E.2.(a).

f) Aim of post-releases monitoring

Extensive risk assessment did not provide evidence of adverse effects potentially associated with the cultivation, handling or use of MON 15985 and MON 15985 × MON 1445, indicating that a requirement for post-release monitoring would not be appropriate.

In addition, MON 15985 and MON 15985 × MON 1445 are commercialized alongside stewardship programmes such as insect resistance management programmes, involving downstream stakeholders in the use of this cotton, in order to ensure the implementation of good agricultural practice in its cultivation and to ensure a channel of communication in the unlikely event that unanticipated adverse effects might occur.

However, no such unanticipated effects have been observed since the large-scale commercialization of MON 15985 and MON 15985 × MON 1445 in North America, nor during the field-testing programmes outside the E.U.

g) Duration of post-releases monitoring

Please *see* Section E.2.(f)

h) Conclusions of post-release monitoring

Please *see* Section E.2.(f)

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

Field-testing and post-marketing experience provided no evidence of any adverse effect 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 http://www.efsa.europa.eu/en/science/gmo/gm_ff_applications.html 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)

Not applicable

c) EFSA opinion

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

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

http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

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

The CRL is currently on step 5 (Reporting) of the validation process for the event specific detection methods for MON 15985 and MON 1445. Once completed, they will post them; together with the validation report for MON 15985 × MON 1445 in their website http://gmo-crl.jrc.it/.

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)

This public summary for the renewal application of MON 15985 and MON 15985 × MON 1445 under Regulation (EC) No 1829/2003 will be posted at http://www.efsa.europa.eu/en/science/gmo/gm_ff_applications.html.