Application for authorization of MON 88913 × MON 15985 cotton in the European Union, according to Regulation (EC) No 1829/2003 on genetically modified food and feed

Part II

Summary

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

A. GENERAL INFORMATION

1. Details of application

a) Member State of application

UK

b) Notification number

Not available at the time of application.

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

The Monsanto development code for this genetically modified cotton is: MON 88913 × MON 15985. In countries where MON 88913 × MON 15985 is being cultivated, packages of this cotton are marketed under the name of the variety, in association with the trademark Roundup Ready®[1] Flex with Bollgard II® cotton.

d) Date of acknowledgement of notification

Not available at the time of application.

2. Applicant

a) Name of applicant

Monsanto Company, represented by Monsanto Europe S.A.

b) Address of applicant

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

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

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

MON 88913 × MON 15985 will be traded and used in the European Union (E.U.) in the same manner as the equivalent products from current commercial cotton varieties and by the same operators currently involved in the trade and use of conventional cotton.

[1] Roundup Ready and Bollgard II are registered trademarks of Monsanto Technology LLC.

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 or containing ingredients produced from GM plants (x) Import and processing (Part C of Directive 2001/18/EC) ( ) Seeds and plant propagating material for cultivation in Europe (Part C of Directive 2001/18/EC)

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

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

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

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

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

Yes (x)	No ( )

If *yes*, specify

MON 88913 × MON 15985 has been authorized in the U.S.A. and Australia for the full range of uses. The scope of other approvals already granted for this genetically modified cotton product and the status of pending regulatory reviews, which are currently in progress in numerous countries around the world, depend on the country and its local regulatory framework. Final approvals are posted by these regulatory agencies on their official websites.

8. General description of the product

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

MON 88913 × MON 15985 was obtained by traditional breeding of two genetically modified parental inbred lines derived from MON 88913 and MON 15985. MON 88913 × MON 15985, as well as its parental lines, have been developed by Monsanto Company.

MON 88913 has been developed to produce the CP4 EPSPS protein that confers tolerance to glyphosate[2]. MON 88913 was produced by *Agrobacterium*-mediated transformation of cotton cells with plasmid vector PV-GHGT35.

MON 15985 has been developed to produce the Cry1Ac and Cry2Ab2 proteins that confer protection against feeding damage caused by major lepidopteran insect pests of cotton, including the cotton cotton bollworm (CBW, *Helicoverpa armigera*), tobacco budworm (TBW, *Heliothis virescens*) and pink bollworm (PBW, *Pectinophora gossypiella*). It was produced by stable insertion of the coding sequence for Cry2Ab2 protein from *Bacillus thuringiensis* subsp. *kurstaki* into the genome of an existing genetically modified cotton, MON 531 (Bollgard®[3] cotton), which expresses the Cry1Ac protein.

As MON 88913 × MON 15985 inherits the introduced traits from its parental inbreds, it is tolerant to glyphosate and it is protected against targeted lepidopteran insect pests.

The use of MON 88913 × MON 15985 enables the farmer to effectively control the targeted lepidopteran 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. In addition, growers will have the ability to apply glyphosate over the top of cotton crop at later stages of development than is possible with the first-generation glyphosate-tolerant cotton product from Monsanto, MON 1445

[2] N-phosphonomethyl-glycine, the active ingredient in the non-selective, foliar-applied, broad-spectrum, post-emergent Roundup® herbicides. Roundup is a registered trademark of Monsanto Technology LLC

[3] Bollgard is a registered trademark of Monsanto Technology LLC.

(Roundup Ready® cotton).

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

The scope of the current application covers the import of MON 88913 × MON 15985 for processing and the use of food and feed produced from MON 88913 × MON 15985 in the E.U. Neither the use of the whole cottonseed as such nor the cultivation of MON 88913 × MON 15985 varieties in the E.U. are included in this application.

c) Intended use of the product and types of users

MON 88913 × MON 15985 will be traded and used in the E.U. in the same manner as the equivalent products from current commercial cotton varieties 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 authorization applied for

No specific conditions are considered necessary for the placing on the market of MON 88913 × MON 15985 for processing and use of foods and feeds produced from this cotton. MON 88913 × MON 15985 is substantially equivalent to conventional cotton except for its tolerance to glyphosate and its protection against target lepidopteran pests, which are traits of agronomic interest. This cotton is as safe and nutritious as conventional cotton. Therefore, MON 88913 × MON 15985 and the food and feed products produced from MON 88913 × MON 15985 will be stored, packaged, transported, used and handled in the same manner as current commercial cotton, and the measures for waste disposal and treatment of MON 88913 × MON 15985 products are the same as those of conventional cotton.

e) Any proposed packaging requirements

MON 88913 × MON 15985 is substantially equivalent to conventional cotton varieties (except for its tolerance to glyphosate and protection against certain lepidopteran insect pests). Therefore, MON 88913 × MON 15985 and the food and feed products produced from MON 88913 × MON 15985 will be used in the same manner as other cotton and no specific packaging is foreseen (for the labelling, *see* question A.8.(f)).

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

In accordance with Regulations (EC) No 1829/2003 and 1830/2003, a labelling threshold of 0.9 % is applied for the placing on the market of MON 88913 × MON 15985 and derived products.

Operators shall be required to label foods and feeds derived from

MON 88913 × MON 15985 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 GMOs is transmitted in writing to the operator receiving the product.

Operators handling or using MON 88913 × MON 15985 cottonseed and derived foods and feeds in the E.U. are required to be aware of the legal obligations regarding traceability and labelling of these products. Given that explicit requirements for the traceability and labelling of GMOs and derived foods and feeds are laid down in Regulations (EC) No 1829/2003 and 1830/2003, and that authorized foods and feeds shall be entered in the Community Register, operators in the food/feed chain will be fully aware of the traceability and labelling requirements for MON 88913 × MON 15985. Therefore, no further specific measures are to be taken by the applicant.

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

MON-88913-8 × MON-15985-7

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

The use in foods and feeds produced from MON 88913 × MON 15985 is suitable throughout the E.U.

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

Because this application is for consent to import MON 88913 × MON 15985 for processing and to use food and feed produced from MON 88913 × MON 15985 as any other cotton product, not including the cultivation of varieties of MON 88913 × MON 15985 in the E.U., environmental release would more likely occur through incidental release during import, handling, storage and processing. However, modern methods of transporting and handling minimize such losses of cottonseed, so there is little chance of germination, growth and reproduction of cotton destined for processing in the E.U. In practice, the cottonseed will mostly be confined to fixed locations (seaports, seed elevators and processing facilities) and enclosed to minimize or prevent spillage (transport vehicles including trucks and railroad cars). Such conditions significantly limit entry into the environment. Moreover, in the event of incidental spillage, the establishment of volunteer plants would be unlikely, since cotton cannot survive without human assistance and is not capable of surviving as a weed. Although cottonseed could over-winter in mild conditions and germinate the following year, cotton does not persist as a weed. The appearance of cotton volunteers in rotational fields is highly unlikely under European conditions and, if they

occur, they can be easily controlled by current agronomic practices, including cultivation or the use of appropriate herbicides such as glufosinate and paraquat.

In addition, the information presented in this application established that MON 88913 × MON 15985 is unlikely to be different from other cotton, and therefore, is unlikely to pose any threat to the environment or to require special measures for its containment.

No specific conditions are warranted or required for the import of MON 88913 × MON 15985 for processing and for the use of foods and feeds produced from MON 88913 × MON 15985.

B. INFORMATION RELATING TO (A) THE RECIPIENT OR (B) (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** MON 88913 × MON 15985.
f)	**Common name** Cotton

2. a) Information concerning reproduction

(i)	***Mode(s) of reproduction*** Cotton (*Gossypium* spp.) reproduction 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*** Cotton is normally considered to be a self-pollinating crop. However, since there are no morphological barriers to cross-pollination based on flower structure, cross-pollination can also occur. In practice, though, cotton pollen is heavy and sticky and transfer by wind is unlikely. Pollen is transferred instead 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

Out-crossing with cultivated *Gossypium* varieties

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 outcrossing in a production field is strongly dependent upon the geographic location of the field, which means upon the crop ecology. Regardless, since the scope of the current application does not include cultivation of MON 88913 × MON 15985 varieties in the E.U., outcrossing with cultivated *Gossypium* varieties is not expected.

Out-crossing with wild *Gossypium* species

Closely related feral or wild relatives of cotton do not exist in Spain, Greece or other countries of the E.U.

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. Seeds are the only survival structures. Cotton is not considered to have seed that can persist in the environment for long periods of time. Natural regeneration from vegetative tissue is not known to occur.

b) Specific factors affecting survivability

Cotton cannot survive without human assistance and is not capable of surviving as a weed. 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, 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. Even in cotton growing regions with mild and dry winters, such as in Spain and Greece, it is highly unlikely that cottonseed would over-winter and germinate the following spring. Nevertheless, in the case it would, cotton volunteers can be easily controlled by current agronomic practices including cultivation and the use of appropriate herbicides such as glufosinate and paraquat. Volunteer cotton is not found growing in fencerows, ditches or roadsides as a weed. Regardless, it should be noted that cultivation of MON 88913 × MON 15985 is not in the scope of this application.

4. Dissemination

a) Ways and extent of dissemination

As cotton does not generally reproduce vegetatively, dissemination of cotton may occur by means of seed dispersal and pollen dispersal. However, the current application does not include the environmental release of MON 88913 × MON 15985 in the E.U.

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. However, most recent cotton pollen dispersal studies consistently demonstrate that the frequency of cross-pollination decreases significantly (from five to less than one per cent from one to seven meters, respectively) with distance from the pollen source.

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 Peoples Republic of China, U.S.A., India, Pakistan and the Republic of Uzbekistan. Turkey, Brazil 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 neither considered harmful nor 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 cottonseed oil or cottonseed meal.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification

MON 88913 × MON 15985 was produced by crossing inbred plants of MON 88913 and MON 15985, using traditional breeding methods.

MON 88913 was produced by *Agrobacterium*-mediated transformation of cotton hypocotyl tissues.

MON 15985 was produced by stable insertion of the coding sequence for Cry2Ab2 protein from *Bacillus thuringiensis* subsp. *kurstaki* into the genome of an existing genetically modified cotton, MON 531, using particle acceleration technology.

2. Nature and source of the vector used

MON 88913 × MON 15985 has been obtained by traditional breeding of MON 88913 and MON 15985.

The binary vector PV-GHGT35 was used for the transformation of cotton hypocotyl tissue to produce MON 88913. This vector contains left and right border T-DNA sequences. This T-DNA region contains two tandem *cp4 epsps* expression cassettes.

The plasmid vector PV-GHBK11 was used to generate MON 15985, by the transformation of MON 531. It contains the *cry2Ab2* and the *uidA* expression cassettes.

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

MON 88913 × MON 15985 results from a traditional cross of the inbred parental lines MON 88913 and MON 15985, which are made homozygous for their respective inserted sequences.

By crossing MON 88913 and MON 15985, MON 88913 × MON 15985 inherits the inserted DNA fragments from both its parental cotton lines. The

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

Table 1. Size and intended function of each constituent fragment of the inserted DNA fragment inherited from MON 88913

Sequence	Size (kb)	Source	Function
B-Right Border	0.02	*Agrobacterium*	Border
First *cp4 epsps* gene cassette			
P-*FMV/Tsf1*	1.04	Figwort mosaic virus/ *Arabidopsis thaliana*	Promoter
L-*Tsf1*	0.05	*Arabidopsis thaliana*	Leader
I-*Tsf1*	0.62	*Arabidopsis thaliana*	Intron
TS-*ctp2*	0.23	*Arabidopsis thaliana*	Targeting sequence
CS-*cp4 epsps*	1.37	*A. tumefaciens*	Coding sequence
T-*E9*	0.64	*Pisum sativum*	Transcript termination sequence
Second *cp4 epsps* gene cassette			
P-*35S/act8*	1.17	*Cauliflower mosaic virus* /*Arabidopsis thaliana*	Promoter
L-*act8*	0.14	*Arabidopsis thaliana*	Leader
I-*act8*	0.47	*Arabidopsis thaliana*	Intron
TS-*ctp2*	0.23	*Arabidopsis thaliana*	Targeting sequence
CS-*cp4 epsps*	1.37	*A. tumefaciens*	Coding sequence
T-*E9*	0.64	*Pisum sativum*	Transcript termination sequence
B-Left Border	0.28	*Agrobacterium*	Border

Table 2. Size and intended function of each constituent fragment of the inserted DNA fragment inherited from MON 15985

Sequence	Size (kb)	Source	Function
Genetic elements associated to the functional copy of the *cry1Ac* insert (MON 531)			
***cry1Ac* cassette**			
T-*7S*	0.44	*Glycine max*	Transcript termination sequence
CS-*cry1Ac*	3.54	*Bacillus thuringiensis*	Coding sequence
P-*e35S*	0.6	Cauliflower mosaic virus	Promoter
Non functional element			
aad	0.79	Bacteria	None
***nptII* cassette**			
T-nos	0.24	*A. tumefaciens*	Transcript termination sequence

CS-nptII	0.97	*E. coli*	Coding sequence
P-35S	0.32	Cauliflower mosaic virus	Promoter
Non functional element			
OR-*ori-V*	0.39	*Agrobacterium*	None
Genetic elements associated to the non functional copy of the *cry1Ac* insert (MON 531)			
T-7S	0.44	*Glycine max*	None
CS-cry1Ac	0.89	*Bacillus thuringiensis*	None
Genetic elements associated to the cry2Ab2 insert (MON 15947)			
uidA cassette			
P-e35S	0.3	Cauliflower mosaic virus	Promoter
CS-uidA	1.8	*E. coli*	Coding sequence
T-nos	0.26	*A. tumefaciens*	Transcript termination sequence
cry2Ab2 cassette			
P-e35S	0.6	Cauliflower mosaic virus	Promoter
L-Hsp70	0.1	Petunia heat shock protein	Leader
TS-ctp2	0.23	*Arabidopsis thaliana*	Targeting sequence
CS-cry2Ab2	1.9	*Bacillus thuringiensis*	Coding sequence
T-nos	0.26	*A. tumefaciens*	Transcript termination sequence

D. INFORMATION RELATING TO THE GM PLANT

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

MON 88913 × MON 15985, which was developed using traditional methods of cotton breeding, expresses:

1. the CP4 EPSPS protein, derived from *Agrobacterium* sp. strain CP4, which provides tolerance to glyphosate.
2. the Cry1Ac and the Cry2Ab2 insecticidal proteins, which provide protection against feeding damage caused by certain lepidopteran insect pests, such as the cotton bollworm, the tobacco budworm and the pink bollworm.

Use of MON 88913 × MON 15985 would provide substantial benefits to growers by improving the control of agricultural pests and limiting yield losses from lepidopteran feeding damage, reducing the risk from insecticide use to humans and the environment while at the same time limiting weed pressure. In general, it would improve the economic outlook for the cotton industry.

2. Information on the sequences actually inserted or deleted

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

MON 88913 and MON 15985 each contain one functional insert with one functional copy of the DNA fragments intended for insertion and this at different loci in the cotton genome. Each fragment is inherited in a Mendelian fashion in MON 88913 × MON 15985.

As the parental cotton lines used in the traditional cross to produce MON 88913 × MON 15985 are inbred lines that are homozygous for their respective inserts, all the inserted fragments are inherited by the MON 88913 × MON 15985. The presence of these inserts in MON 88913 ×MON 15985 was confirmed through Southern blot analysis.

Therefore, MON 88913 ×MON 15985 contains the three parental inserts, as they were present in MON 88913 and MON 15985.

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

Not applicable.

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

The traditionally bred MON 88913 × MON 15985 contains the parental inserts on separate chromosomes in the nuclear genome, as they were present in the parental lines MON 88913 and MON 15985,

respectively. The presence of the inserts from MON 88913 and MON 15985 in MON 88913 × MON 15985 was confirmed by Southern blot analyses.

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

The molecular comparison of MON 88913 × MON 15985 to the parental lines, MON 88913 and MON 15985, indicates that the inserts are preserved in MON 88913 × MON 15985. There is no scientific basis to support the fact that those inserts would be intrinsically more unstable when combined together by traditional breeding.

The molecular characteristics of the respective introduced DNA sequences, present in MON 88913 and MON 15985, also apply to MON 88913 × MON 15985, including the structural organisation and integrity of the inserts, as well as the characteristics of the sites of insertion and the flanking sequences, immediately adjacent to the introduced sequences.

A schematic representation of the MON 88913 and MON 15985 inserts is given in Figures 1 and 2.

Figure 1. Schematic representation of the MON 88913 insert

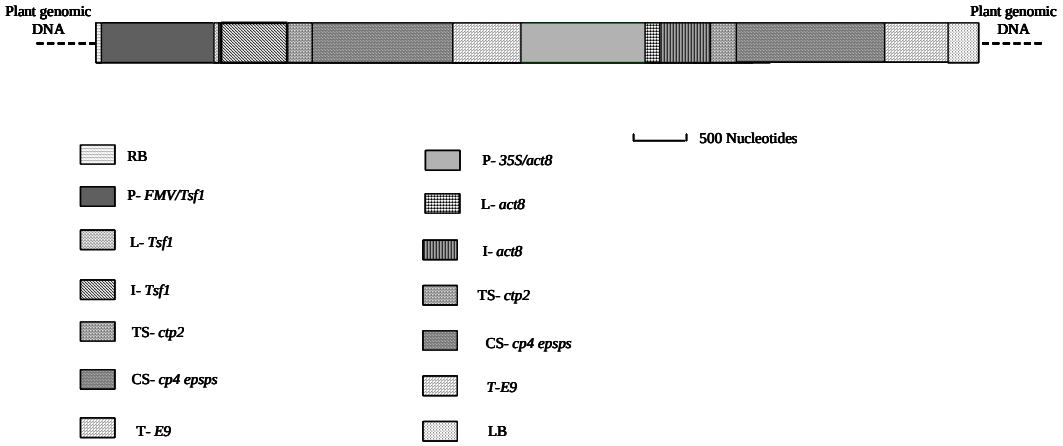
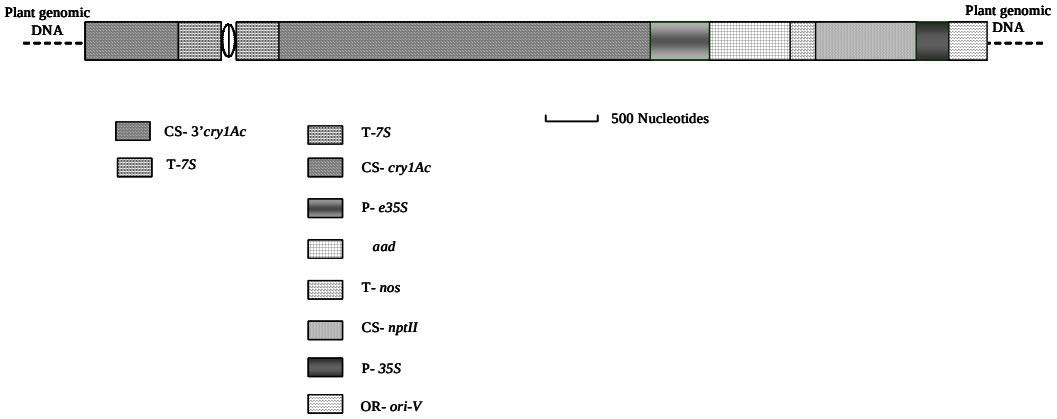
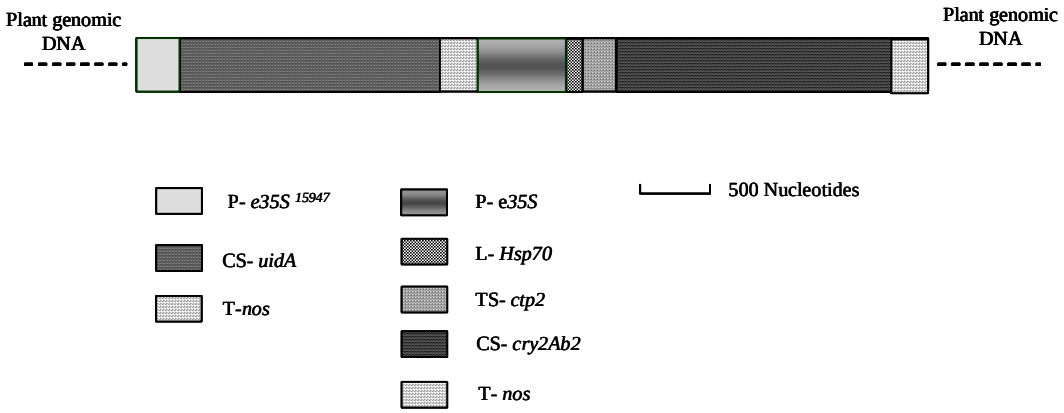


Figure 2. Schematic representation of the MON 15985 inserts

a) MON 531 insert



b) MON 15947 insert



3. Information on the expression of the insert

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

The levels of CP4 EPSPS, Cry1Ac, Cry2Ab2, NPTII and GUS proteins were assessed in leaf and seed tissues of MON 88913 × MON 15985 plants by validated Enzyme-Linked Immunosorbent Assay (ELISA). Tissue samples for analysis were collected from four field trials conducted in the U.S.A. in 2004. The field trials were planted in Georgia, Mississippi, New Mexico and Texas. These field sites provided a variety of environmental conditions representative of regions where cotton is grown for commercial use. At each site, three replicated plots of MON 88913 × MON 15985 and its were planted in a non-systematic manner using a randomized complete block field design.

The CP4 EPSPS protein levels in MON 88913 × MON 15985 was compared to that in MON 88913, whereas, the Cry1Ac, Cry2Ab2, NPTII and GUS protein levels in MON 88913 × MON 15985 were compared to those of MON 15985. Mean CP4 EPSPS, Cry1Ac, Cry2Ab2, NPTII and GUS protein levels across all sites for seed tissues of the test plant were 310, 1.8, 270, 3.4 and 130 µg/g dw, respectively.

Overall, the ranges across all sites for the CP4 EPSPS, Cry1Ac, Cry2Ab2, NPTII and GUS protein levels in MON 89034 × MON 88017 were comparable to the corresponding ranges in either MON 88913 or MON 15985.

b) Parts of the plant where the insert is expressed

Expression levels of the introduced proteins were measured in leaf and seed tissues of MON 88913 × MON 15985. Since food and feed are produced from cottonseed, the measurement of protein expression in seed should be considered the most relevant in terms of food and feed safety.

The results of the protein expression analysis is reported in Section D.3.a) of this document.

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

a) Reproduction

Agronomic data collected from trials performed with MON 88913 × MON 15985 have demonstrated that MON 88913 × MON 15985 has not been altered in survival, multiplication or dissemination characteristics when compared to the control and commercial conventional cotton varieties. The introduced glyphosate-tolerance and lepidopteran-protection traits have no influence on cotton reproductive morphology and hence no changes in seed dissemination would be expected.

b) Dissemination

The inherited 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 88913 × MON 15985 has 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 88913 × MON 15985 and conventional cotton varieties, except for the introduced glyphosate-tolerance and lepidopteran-protection traits, which are of agronomic interest.

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

MON 88913 × MON 15985 is produced by crossing MON 88913 and MON 15985 parental inbred lines (made homozygous) by traditional breeding. Thereby, each parental line passes on its inserted DNA sequence to the resulting MON 88913 × MON 15985 progeny.

The parental lines MON 88913 and MON 15985 contain one and two inserts, respectively, which are stably integrated into the nuclear cotton genome. Each trait is inherited in a Mendelian fashion. This has been confirmed by Southern blot analyses.

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

a) Plant to bacteria gene transfer

None of the genetic elements inserted in MON 88913 × MON 15985 has a genetic transfer function. Therefore, no changes are expected in the ability of these cotton lines 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 88913 × MON 15985 varieties in the E.U.

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

7.1 Comparative assessment

Choice of the comparator

MON 88913 × MON 15985 was compared to a near-isogenic control, which has background genetics representative of the test (MON 88913 × MON 15985) but does not produce the CP4 EPSPS, Cry1Ac, Cry2Ab2, GUS and NPTII proteins. MON 88913 × MON 15985 was also compared to other commercial conventional cotton varieties.

7.2 Production of material for comparative assessment

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

MON 88913 × MON 15985, the control and eleven commercially available cotton varieties were grown during 2004 growing season at four sites, representing the major cotton-growing areas of the U.S.A.: Georgia, Mississippi, New Mexico and Texas.

b) the baseline used for consideration of natural variations

The compositional study compared the test with a near-isogenic 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.

The results of the compositional analyses for MON 88913 × MON 15985 in comparison with control cotton, demonstrate equivalence and do not indicate a need for further analysis of selected compounds.

7.3 Selection of material and compounds for analysis

The numerous compounds that were selected for analysis in the compositional study were chosen on the basis of internationally accepted guidance provided by the OECD.

Based on the results of these extensive compositional analyses, there is no indication to further analyze other selected compounds in this cotton.

7.4 Agronomic traits

Field trials with MON 88913 × MON 15985 were performed and the set of agronomic observations supports a conclusion that from an agronomic and phenotypic (morphological) point of view, MON 88913 × MON 15985 is equivalent to conventional cotton, except for the inherited glyphosate-tolerance and lepidopteran protection traits.

7.5 Product specification

Upon approval of the import of MON 88913 × MON 15985 for processing and of the use of MON 88913 × MON 15985 derived products in food and feed, these products will be imported and used, likely by operators traditionally involved in the processing and commerce of cottonseed in the E.U.

7.6 Effect of processing

As MON 88913 × MON 15985 is substantially equivalent and as safe and nutritious as conventional cotton, the use of MON 88913 × MON 15985 cottonseed for the production of foods and feeds is not different from that of conventional cotton. Consequently, any effects of the processing of MON 88913 × MON 15985 are not expected to be different from the processing of the equivalent foods and feeds, originating from conventional cottonseed.

7.7 Anticipated intake/extent of use

MON 88913 × MON 15985 is not expected to alter current usage patterns or volumes of cottonseed. Therefore, anticipated dietary intake of cottonseed-derived foods and feeds is not expected to be altered upon E.U. authorization of MON 88913 × MON 15985 derived products for food and feed use. MON 88913 × MON 15985 is expected to replace a portion of the current cotton in the market such that its intake or use will represent some fraction of the total cotton-derived products.

7.8 Toxicology

7.8.1 Safety evaluation of newly expressed proteins

MON 88913 × MON 15985 is produced by traditional breeding of MON 88913 with MON 15985. All the introduced traits from the parental lines are inherited by the MON 88913 × MON 15985

progeny. This resulted in the combined expression of the CP4 EPSPS, Cry1Ac, Cry2Ab2, NPTII and GUS proteins in the same plant.

The conclusion of safety to humans of those proteins was based upon the following considerations:

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

In addition, the low concentration of introduced proteins in tissues that are consumed and the rapid digestibility in simulated digestive fluids provide additional assurance for their safety.

It is therefore highly unlikely that CP4 EPSPS, Cry1Ac, Cry2Ab2, NPTII and GUS proteins would cause any toxic effects on human or animal health.

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 88913 × MON 15985 was shown to be substantially equivalent to conventional cotton except for the introduced glyphosate-tolerance and lepidopteran-protection traits, no testing of any constituent other than the introduced proteins is 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

The compositional and nutritional equivalence of MON 88913 × MON 15985 and conventional cotton have been established by compositional analysis. Additionally, the wholesomeness of MON 88913 × MON 15985 has been confirmed by a feeding study in catfish, using MON 88913 × MON 15985 cottonseed meal-containing diets, which demonstrate the absence of any toxic or pleiotropic effects linked to the genetic modification.

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

The CP4 EPSPS, Cry1Ac, Cry2Ab2, NPTII and GUS proteins were assessed for its potential allergenicity according to the recommendations of Codex Alimentarius Commission. The proteins are from non-allergenic sources, lack structural similarity to known allergens, are rapidly digested in simulated gastric fluid, and constitute a very small portion of the total protein present in the grain of MON 88913 × MON 15985. Taken together these data lead to the conclusion that the mentioned proteins are unlikely to have any allergenic potential, and MON 88913 × MON 15985 is as safe as conventional cotton regarding the risk for allergenicity.

7.9.2 Assessment of allergenicity of the whole GM plant or crop

As the introduced proteins do not have any allergenic potential, it was concluded that the use of food or feed derived from MON 88913 × MON 15985 does not lead to an increased risk for allergenic reactions compared to the equivalent range of food and feed uses derived from conventional cotton.

7.10 Nutritional assessment of GM food/feed

7.10.1 Nutritional assessment of GM food

The inherited traits in MON 88913 × MON 15985 are of agronomic interest, and are not intended to change any nutritional aspects of this cotton. In addition to the extensive compositional analyses which demonstrated the substantial equivalence of MON 88913 × MON 15985 to conventional cotton (except for the glyphosate-tolerance and lepidopteran-protection traits), a confirmatory feed performance study was conducted in channel catfish, confirming the nutritional equivalence of food and feed products produced from MON 88913 × MON 15985 cottonseed, and demonstrating the absence of any pleiotropic or unanticipated effects from the introduced trait.

In conclusion, MON 88913 × MON 15985 is nutritionally equivalent to its control, as well as to conventional cotton varieties in commerce.

7.10.2 Nutritional assessment of GM feed

The inherited traits in MON 88913 × MON 15985 are of agronomic interest, and are not intended to change any nutritional aspects of this cotton. In addition to the extensive compositional analyses which demonstrated the substantial equivalence of MON 88913 × MON 15985 to conventional cotton (except for the glyphosate-tolerance and lepidopteran-protection traits), a confirmatory feed performance study was conducted in channel catfish. Catfish were fed diets containing cottonseed

meal from MON 88913 × MON 15985, and their performance was compared to control groups fed diets containing a non-transgenic control variety or commercially available reference varieties. This study confirms the nutritional equivalence of food and feed products produced from MON 88913 × MON 15985 cottonseed, and demonstrates the absence of any pleiotropic or unanticipated effects from the introduced trait.

In conclusion, MON 88913 × MON 15985 is nutritionally equivalent to its control, as well as to conventional cotton varieties in commerce.

7.11 Post-market monitoring of GM food/feed

The assessment of the human and animal safety of MON 88913 × MON 15985 was conducted on the basis of its substantial equivalence to conventional cotton, (except for the introduced traits) and by extensive characterization of the newly expressed proteins, which are of agronomic interest.

There are no intrinsic hazards related to MON 88913 × MON 15985 as no signs of adverse or unanticipated effects have been observed in a number of safety studies, including animal feeding studies using doses of administration that are orders of magnitude above expected consumption levels. The pre-market risk characterization for food and feed use of MON 88913 × MON 15985 demonstrates that the risks of consumption of food and feed products produced from MON 88913 × MON 15985 are consistently negligible and no different from the risks associated with the consumption of their counterparts derived from conventional cotton.

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

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

MON 88913 × MON 15985 carries three traits, which confer tolerance to glyphosate and protection against certain lepidopteran insect pests. As there are no target organisms for the CP4 EPSPS protein, target organisms for the combined trait product will be the same as those for the Cry1Ac and Cry2Ab2 proteins together.

The Cry1Ac and Cry2Ab2 proteins produced in MON 88913 × MON 15985 provide protection from feeding damage caused by a wide spectrum of lepidopteran insect pests. Those lepidopteran insects may be considered the target organisms which interact with MON 88913 × MON 15985.

A generalized mode of action of Cry1Ac and Cry2Ab2 proteins includes the following steps: ingestion of the protoxin crystal by the insect, solubilization of the crystal in the insect midgut, proteolytic processing of the released Cry protein by digestive enzymes to produce an active toxin termed delta-endotoxin, binding of the endotoxin to receptors on

the surface of midgut epithelial cells of target organisms, formation of membrane ion channels or pores, and consequent disruption of cellular homeostasis. Electrolyte imbalance and pH changes render the gut paralyzed, which causes the insect to stop eating and die.

Any significant interactions of MON 88913 × MON 15985 with its target pest organisms are limited to those countries where the cultivation of this cotton has been authorized. The cultivation of MON 88913 × MON 15985 varieties in the E.U. is not within the scope of this application. In the context of the current application, the likelihood is negligible that the import of MON 88913 × MON 15985 will result in plants of this cotton being present in the environment, and the potential for interactions between MON 88913 × MON 15985 and its target organisms is, therefore, considered to be minimal

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

This application is limited to the import of MON 88913 × MON 15985 for processing and use of food and feed produced from MON 88913 × MON 15985, but it does not cover the cultivation of MON 88913 × MON 15985 varieties in the E.U. As such, exposure to the environment will be rare, occurring only through incidental release during shipment and handling. The conditions where incidental release could occur are not conducive to establishment of cotton.

9.1 Persistence and invasiveness

Like for conventional cotton, the likelihood of MON 88913 × MON 15985 spreading in the environment is negligible, as cotton is neither persistent nor invasive and these parameters are unaltered in MON 88913 × MON 15985 when compared to conventional cotton. In the event MON 88913 × MON 15985 cottonseed is spilt in the environment, its introduced traits would have negligible consequences for the environment. Hence the risk of establishment and spreading of MON 88913 × MON 15985 in the environment is negligible.

9.2 Selective advantage or disadvantage

Compared with conventional cotton, the presence of the glyphosate-tolerance and lepidopteran-protection traits confers a selective advantage only under specific conditions (*i.e.* following treatment with glyphosate, or upon attack by the target insects), which are short in duration. The advantage is of purely agronomic interest and presents negligible risk to the non-agricultural environments because of the poor survival characteristics of cotton under most European conditions. The potential for the glyphosate-tolerance and lepidopteran-protection traits in MON 88913 × MON 15985 to cause a selective advantage of cotton outside an agro-ecosystem is exceedingly low. Therefore, the risk of adversely impacting the receiving environment is negligible under the intended use for processing.

9.3 Potential for gene transfer

MON 88913 × MON 15985 is unchanged in its potential for gene transfer compared to conventional cotton. There is no potential for gene

transfer from MON 88913 × MON 15985 to wild plant species and negligible likelihood for gene transfer to other cotton crops, as this application is not for consent to cultivate MON 88913 × MON 15985 varieties in the E.U.

In the highly unlikely event that the introduced genes outcross to another cotton plant, their transfer would, in any event, have negligible consequences for the environment. The environmental risk posed by this transfer, and hence by the intended import of MON 88913 × MON 15985 for processing, is negligible.

9.4 Interactions between the GM plant and target organisms

The (intended) insecticidal action of the Cry proteins for the control of pest species is not considered adverse to the environment in an agro-ecosystem. In any case, since the likelihood is negligible that the import of MON 88913 × MON 15985 for processing will result in plants of this cotton being present in the environment at meaningful levels, it is not expected that the target organisms will be exposed to Cry1Ac and/or Cry2Ab2 proteins. Therefore, it is highly unlikely that the target organisms could develop resistance to the Cry1Ac and/or Cry2Ab2 proteins. As a consequence, there is negligible risk for harmful effects on the environmen posed by the import of MON 88913 × MON 15985 for processing.

9.5 Interactions of the GM plant with non-target organisms

Given the scope of the current application, which does not include the cultivation of MON 88913 × MON 15985 varieties in the E.U., the likelihood for direct or indirect interactions of this cotton with non-target organisms is considered to be negligible. In addition, the newly expressed proteins present a negligible hazard to non-target organisms, even if incidental spillage of MON 88913 × MON 15985 cottonseed during import, storage, transport or processing leads to the short survival of MON 88913 × MON 15985 plants in the environment. As a consequence, there is negligible risk for harmful effects of MON 88913 × MON 15985 on non-target organisms, either through direct or indirect interactions with this cotton or through contact with the newly expressed proteins. Furthermore, no adverse effects were brought forward by the people handling these products during the extensive field trials conducted in the U.S.A.

9.6 Effects on human health

The likelihood for any adverse effects occurring in humans as a result of their contact with this cotton is no different from conventional cotton, as MON 88913 × MON 15985 contains the CP4 EPSPS, Cry1Ac, Cry2Ab2, NPTII and GUS proteins, which have negligible potential to cause any toxic or allergenic effects in humans. Therefore, the risk of changes in the occupational health aspects of this cotton is negligible.

9.7 Effects on animal health

The likelihood of potential adverse effects in animals fed on MON 88913 × MON 15985 and in humans consuming those animals, is

negligible (*see* Sections D.7.8, D.7.9 and D.7.10 of this document). Therefore, the risk of MON 88913 × MON 15985 for the feed/food chain is also negligible.

9.8 Effects on biogeochemical processes

In the event of an incidental release of MON 88913 × MON 15985 in the environment, the risk for direct or indirect, immediate or delayed adverse effects on biogeochemical processes can be considered as negligible. There is no evidence that MON 88913 × MON 15985 plants would be any different from conventional cotton regarding their direct influence on biogeochemical processes or nutrient levels in the soil, as MON 88913 × MON 15985 is compositionally equivalent to conventional cotton and presents no biologically meaningful differences in its growth and development, morphology, yield, plant health and survival characteristics (*see* Sections D.4, D.7.1 and D.7.4 of this document). Furthermore, any indirect interactions of the GMHP and non-target organisms in the vicinity of an incidental release of the cottonseed are not likely to cause hazardous effects on the biogeochemical processes in the soil.

9.9 Impacts of the specific cultivation, management and harvesting techniques

Not applicable. This application is for consent to import MON 88913 × MON 15985 in the E.U. for processing and for the use of food and feed produced from this cotton as any other cotton, excluding the use for cultivation of varieties in the E.U. The above data requirement is meant to evaluate the cultivation of a GMHP in the E.U.

10. Potential interactions with the abiotic environment

As MON 88913 × MON 15985 was shown to be substantially equivalent to conventional cotton, except for the introduced glyphosate-tolerance and lepidopteran-protection traits, imparted by the expression of the CP4 EPSPS, Cry1Ac and Cry2Ab2 proteins, there is no evidence that this cotton would be any different from conventional cotton with regard to its baseline interactions with the abiotic environment. Although CP4 EPSPS, Cry1Ac and Cry2Ab2 are introduced proteins in cotton, they have a safe history of use and no known negative effects on biochemical processes (*see* Sections D.7.8.1 and D.9.8 in this document). Therefore, no adverse impact on the abiotic environment is expected to result from the import of MON 88913 × MON 15985 for processing and for use of food and feed products derived from MON 88913 × MON 15985 in the E.U.

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

11.1 General (risk assessment, background information)

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

11.2 Interplay between environmental risk assessment and monitoring

An environmental risk assessment (ERA) of MON 88913 × MON 15985 was undertaken in the context of the scope of the application, that is for MON 88913 × MON 15985 import and processing, and food and feed use of MON 88913 × MON 15985 derived products in the E.U., but excluding the cultivation of MON 88913 × MON 15985 varieties in the E.U.

Analysis of the characteristics of MON 88913 × MON 15985 has shown that the risk for potential adverse effects on human health and the receiving environment, resulting from the import of MON 88913 × MON 15985 and food and feed use of MON 88913 × MON 15985 derived products in the E.U. is consistently negligible. Therefore, the overall environmental risk posed by this genetically modified higher plant is negligible, and no specific strategies for risk management and no case-specific post-marketing monitoring actions are considered required.

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

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

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

Any potential adverse effects of MON 88913 × MON 15985 on human health and the environment, which were not anticipated in the ERA, can be addressed under general surveillance, in accordance with Directive 2001/18/EC. 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 applicant will ensure that appropriate technical information on MON 88913 × MON 15985 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.

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 88913 × MON 15985 and the observed effect. The evaluation should consider the consequence of the observed effect and remedial action, if necessary, should be proportionate to the significance of the observed effect.

11.5 Reporting the results of monitoring

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

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

As MON 88913 × MON 15985 is the result of a traditional cross of MON 88913 and MON 15985, it contains all inserts in combination. Therefore, MON 88913 × MON 15985 is detectable using either the event-specific PCR method for detecting the introduced DNA present in MON 88913 or the equivalent method for MON 15985. However, as for all plants in which one or more events are combined by traditional breeding, the unambiguous detection of MON 88913 × MON 15985 in mixed consignments of seed will require single seeds to be subjected to detection methods for both MON 88913 and MON 15985, and to test positive for both.

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

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

a) Notification number

There is no history of release of MON 88913 × MON 15985 in the E.U.

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 88913 × MON 15985 has been grown commercially on approximately one million hectares in 2006 in the U.S.A. In 2006 it was also grown commercially in Australia on limited hectares.

Prior to its commercialization, MON 88913 × MON 15985 has been field tested extensively in the U.S.A., Australia and South Africa since 2002.

b) Authority overseeing the release

U.S.A.: United States Department of Agriculture and Food and Drug Administration.

Australia: Food Standards Australia New Zealand and Office of the Gene Technology Regulator.

South Africa: Regulated in terms of the GMO Act (No. 15 of 1997) which has the oversight of six Government Ministries in the decision making process.

c) Release site

U.S.A.: Releases across major cotton growing regions (Alabama, California, Georgia, Mississippi, New Mexico, Texas, Arizona, Arkansas, Oklahoma, Kansas, Missouri, Kentucky, Tennessee, Virginia, North Carolina, South Carolina, Louisiana, and Florida).

Australia: Release sites centered in the major cotton production area.

South Africa: Releases sites centered in the major cotton production province, Mpumalanga.

d) Aim of the release

Commercial release in U.S.A. and Australia: All uses as conventional cotton

Field release in U.S.A., South Africa, Australia: Agronomic performance, efficacy, phytotoxicity, yield, breeding, residue.

e) Duration of the release

Commercial release in U.S.A. and in Australia: 2006 growing season.

Field release in U.S.A., Australia and South Africa: one or two field seasons.

f) Aim of post-releases monitoring

Extensive pre-market risk assessment did not provide evidence of adverse effects potentially associated with the cultivation, handling or use of MON 88913 × MON 15985, indicating that a requirement for post-release monitoring would not be appropriate.

In addition, MON 88913 × MON 15985 is commercialized alongside stewardship 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 commercialization of MON 88913 × MON 15985 in the U.S.A., nor during the extensive field-testing programmes.

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 or commercial release provide no evidence that MON 88913 × MON 15985 is likely to cause any adverse effects to human or animal health and the environment.

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

a) Status/process of approval

The EFSA website (http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.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)

A notification for MON 88913 × MON 15985 according to Directive

2001/18/EC has not been submitted by Monsanto.

c) EFSA opinion

An EFSA opinion, specifically for MON 88913 × MON 15985, was not available at the time of submission of this application.

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

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

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

Information on detection protocols can be found on the JRC website (http://gmo-crl.jrc.it/statusofdoss.htm).

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

The publicly accessible portal site of the Biosafety Clearing-House (BCH) can be found at http://bch.biodiv.org/

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

A notification and SNIF according to Directives 2001/18/EC and 2002/812/EC, respectively, have not been submitted for MON 88913 × MON 15985. EFSA provides a link to the summary of this application at http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html.