Application for authorization to place on the market MON 88701 cotton in the European Union, according to Regulation (EC) No 1829/2003 on genetically modified food and feed

Part VII

Summary

1. GENERAL INFORMATION

1.1. Details of application

(a) Member State of application

The Netherlands

(b) Application number

Not available at the time of submission.

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

The Monsanto development code for this genetically modified cotton is MON 88701. Currently, no commercial name has been attributed to this product.

(d) Date of acknowledgement of valid application

Not available at the time of submission.

1.2. Applicant

(a) Name of applicant

Monsanto Company, represented by Monsanto Europe S.A.

(b) Address of applicant

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

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

See above.

1.3. Scope of the application

(a) GM food

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

(b) GM feed

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

(c) GM plants for food or feed use

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

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

No ☑

Yes ☐ (in that case, specify)

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

Yes ☐

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

The protein expression, composition, safety, agronomic and phenotypic characteristics of MON 88701 have been studied at multiple locations in North America that cover a range of environmental conditions. The risk assessment presented in the MON 88701 application includes data collected from these field trials. A summary of the conclusions of the risk analysis that demonstrate the safety of MON 88701 to humans, animals and the environment has been presented in the respective sections throughout this summary.

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

No ☑

Yes ☐ (in that case, specify)

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

No ☐

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

Regulatory submissions have been made to the United States Department of Agriculture Animal and Plant Health Inspection Service (USDA-APHIS), the United States Food and Drug Administration (FDA), the Canadian Food Inspection Agency (CFIA) and Health Canada. Additionally, submissions have been made in Japan to the Ministry of Agriculture, Forestry, and Fisheries (MAFF) and the Ministry of Health, Labour, and Welfare (MHLW), and in Korea to the Food and Drug Administration (KFDA) and the Rural Development Administration (RDA).

Regulatory submissions will also be made to countries that import significant quantities of cotton or food and feed products derived from cotton and have functional regulatory review processes in place. These will include submissions to countries such as Mexico. Also, as appropriate, notifications will be made to countries that import significant quantities of cotton and cotton products and do not have a formal regulatory review process for biotechnology derived crops.

No approval from these agencies have been obtain yet.

1.8. General description of the product

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

Monsanto Company has developed dicamba and glufosinate-tolerant cotton, MON 88701 that will allow in-crop applications of dicamba herbicide for the control of broadleaf weeds from pre-emergence to seven days pre-harvest and glufosinate herbicide for broad spectrum weed control from emergence through early bloom growth stage.

MON 88701 contains a demethylase gene from *S. maltophilia* that expresses a dicamba mono-oxygenase (DMO) protein to confer tolerance to dicamba herbicide and a bialaphos resistance (*bar*) gene from *S. hygroscopicus* that expresses the phosphinothricin N-acetyltransferase (PAT) protein to confer tolerance to glufosinate herbicide.

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

This application is for authorization of MON 88701 for import, processing and all uses as any other cotton in the EU, according to Articles 5 and 17 of Regulation (EC) No. 1829/2003 on genetically modified food and feed. The range of uses of this cotton will be identical to the full range of equivalent uses of conventional cotton. The scope of this application does not include the cultivation of MON 88701 varieties in the EU.

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

MON 88701 cotton will be used and traded in the EU in the same manner as current commercial cotton and by the same operators currently involved in the trade and use of cotton.

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

MON 88701 is not different from conventional cotton, except for its tolerances to dicamba and glufosinate, which are traits of agronomic interest and was shown to be as safe and nutritious as conventional cotton. Therefore, MON 88701 and its derived products will be used, stored, packaged, transported and handled in the same manner as current commercial cotton. No specific instructions and/or recommendations are considered necessary for placing on the market MON 88701 for import, processing and all uses in the EU, as specified in Section 1.8(b) of this document.

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

MON 88701 is suitable for use throughout the EU as any other cotton. The scope of this application covers the import, processing and all uses of MON 88701, excluding cultivation.

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

MON 88701 is suitable for use throughout the EU as any other cotton.

(g) Any proposed packaging requirements

MON 88701 is not different from conventional cotton, except for its tolerances to dicamba and glufosinate. Therefore, MON 88701 and derived products will be used in the same manner as other cotton and no specific packaging is required.For labelling, *see* Section 1.8(h) of this document.

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

In accordance with Regulations (EC) No. 1829/2003 and 1830/2003, the current labelling threshold of 0.9% will continue to be applied for the marketing of MON 88701 and derived products.

Operators shall be required to label products containing or consisting of MON 88701 with the words “genetically modified cotton” or “contains genetically modified cotton” and shall continue to declare the unique identifier MON‑887Ø1‑3 in the list of GMOs that have been used to constitute a mixture that contains or consists of this GMO.

Operators shall be required to label foods and feeds derived from MON 88701 with the words “produced from genetically modified cotton”. In the case of products for which no list of ingredients exists, operators shall continue to ensure that an indication that the food or feed product is produced from GMOs is transmitted in writing to the operator receiving the product.

Operators handling or using MON 88701 and derived foods and feeds in the EU shall be required to be aware of the legal obligations regarding traceability and labelling of these products. Given that explicit requirements for the traceability and labelling of GMOs and derived foods and feeds are laid down in Regulations (EC) No. 1829/2003 and 1830/2003, and that authorized foods and feeds shall be entered in the Community Register, operators in the food/feed chain will be fully aware of the traceability and labelling requirements for MON 88701. Therefore, no further specific measures are to be taken by the applicant.

(i) Estimated potential demand

(i) In the Union

In the EU, cotton is commercially grown in Greece, Spain and Bulgaria but represents less than 10% of global cotton production.

(ii) In export markets for EU supplies

In 2010, cottonseed imports into the EU mainly come from Ivory Coast and US.

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

The unique identifier for this genetically modified cotton is MON‑887Ø1‑3.

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

Because this application is for consent to import, process and all uses of MON 88701 as any other cotton, not including the cultivation of varieties of MON 88701 in the EU, the only potential means of environmental release would be more likely to occur during import, storage and processing of MON 88701. However, modern methods of cotton handling minimize losses of seed, so there is little chance of germination of spilt cotton resulting in the development of mature MON 88701 plants in the EU. Moreover, in the event of incidental spillage, the establishment of volunteer plants would be unlikely, since MON 88701, like any other cotton, is unlikely to effectively compete with perennial vegetation outside agricultural fields. The likelihood for spilt seed to survive and establish is negligible. Cotton plants outside agricultural fields can produce seed but this is often prevented because most plants do not survive to reach maturity. This is due to competition from other vegetation, management operations such as roadside mowing, the use of broadleaf herbicides, animal predation, diseases and environmental conditions.

MON 88701 is shown to be not different from conventional cotton, except for the dicamba and glufosinate-tolerance traits, therefore, is unlikely to pose any threat to the EU environment or to require special measures for its containment. Furthermore, cotton volunteers can be easily controlled using currently available selective herbicides (other than dicamba or glufosinate) or by mechanical means. Therefore, no special measures are considered to be required in case of misuse or unintended release.

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

2.1. Complete name

(a) Family name

Malvaceae

(b) Genus

Gossypium L.

(c) Species

spp.

(d) Subspecies

NA

(e) Cultivar/breeding line or strain

Coker *130*

(f) Common name

cotton

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

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. The majority of cotton is grown in areas that receive between 50 and 150 cm of rainfall per year.

In Europe, cotton is commercially grown in Greece, Spain and Bulgaria but represents less than 10% of global cotton production. Besides Europe, it is mainly grown in the People's Republic of China, India, US and Pakistan[1], representing 71 % of global cotton production.

[1]USDA/Foreign Agriculture Service, Grain: World Markets and Trade. http://www.fas.usda.gov/psdonline/psdreport.aspx?hidReportRetrievalName=BVS&hidReportRetrievalID=850&hidReportRetrievalTemplateID=8 - Accessed on 24 January 2013.

2.3. Information concerning reproduction (for environmental safety aspects)

(a) Mode(s) of reproduction

Cotton reproduction is generally carried out via seeds. Cotton is a perennial plant that is cultivated as an annual crop. Cross-pollination can occur, but cotton is normally considered to be a self-pollinating crop.

(b) 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*).

(c) 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.

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

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 88701 varieties in the EU, 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, Bulgaria or other countries of the EU.

2.5. Survivability (for environmental safety aspects)

(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 EU, 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 other than dicamba and glufosinate. Volunteer cotton is not found growing in fencerows, ditches or roadsides as a weed. Regardless, it should be noted that cultivation of MON 88701 is not in the scope of this application.

2.6. Dissemination (for environmental safety aspects)

(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 88701 in the EU.

(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.

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

There are no close wild relatives of cotton in the EU

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

In the EU, cotton is commercially grown in Greece, Spain and Bulgaria.

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

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 Greece, Spain and Bulgaria 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.

3. MOLECULAR CHARACTERISATION

3.1. Information relating to the genetic modification

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

MON 88701 was developed through *Agrobacterium*-mediated transformation of cotton hypocotyls using plasmid vector PV-GHHT6997.

(b) Nature and source of the vector used

PV-GHHT6997 is approximately 9.4 kb and contains one T-DNA that is delineated by Left Border and Right Border regions. The T-DNA contains the *dmo* and *bar* expression cassettes. The *dmo* expression cassette is regulated by the peanut chlorotic streak

caulimovirus (*PC1SV*) promoter, the tobacco etch virus (*TEV*) 5′ leader sequence, and the 3' non-translated sequence of the *E6* gene from *G. barbadense*. The chloroplast transit peptide CTP2 directs transport of the DMO protein to the chloroplast in MON 88701 and is derived from the *CTP2* target sequence of the *Arabidopsis thaliana shkG* gene. The *bar* expression cassette is regulated by the *e35S* promoter from the 35S RNA of cauliflower mosaic virus (CaMV), the heat shock protein 70 (*Hsp70)* leader, and the nopaline synthase (*nos)* 3′ non-translated region.

The backbone region of PV–GHHT6997, located outside of the T-DNA, contains two origins of replication for maintenance of plasmid vector in bacteria (*oriV* and *ori-pBR322*), a bacterial selectable marker gene (*aadA*), and a coding sequence for repressor of primer (*rop*) protein for maintenance of plasmid vector copy number in *E. coli*.

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

The genetic elements of PV–GHHT6997 intended for insertion into MON 88701 comprised between the T-DNA borders are from the right border region, the the *PC1SV* promoter (P-*PC1SV)*, the *TEV* leader (L-*TEV)*, the chloroplast transit peptide (TS-*CTP2*), the *dmo* coding sequence (CS-*dmo*) and the *E6* 3′ non-translated region (T-*E6*), the *e35S* promoter from the 35S RNA (P-*e35S)* of cauliflower mosaic virus (CaMV), the heat shock protein 70 leader (L-*Hsp70*), the *bar* coding sequence (CS-*bar*) and the nopaline synthase (nos) 3′ non-translated region.

The individual components and the function of the DNA sequences intended for insertion into MON 88701 are given in Table 1.

Table 1. Summary of genetic elements intended for insertion in MON 88701

Genetic element[1]	Size (kb)	Function and Source
B-Right Border Region	0.33	DNA region from *A. tumefaciens* containing the Right Border sequence used for transfer of the T-DNA
P-*PC1SV*	0.432	Promoter from the Full-Length Transcript (FLt) of peanut chlorotic streak caulimovirus (P*C1SV*) that directs transcription in plant cells
L-*TEV*	0.131	5' UTR leader sequence from the RNA of tobacco etch virus (TEV) that is involved in regulating gene expression
TS-*CTP2*	0.227	Targeting sequence of the ShkG gene from *Arabidopsis thaliana* encoding the EPSPS transit peptide region that directs transport of the protein to the chloroplast
CS-*dmo*	-1.02	Codon optimized coding sequence for the dicamba mono-oxygenase (DMO) protein of *S. maltophilia* that confers dicamba tolerance
T-*E6*	0.314	3' UTR sequence of the E6 gene from *G. barbadense* (cotton) encoding a fiber protein involved in early fiber development that directs polyadenylation of mRNA
P-*e35S*	0.611	Promoter from the 35S RNA of cauliflower mosaic virus (CaMV) containing the duplicated enhancer region that directs transcription in plant cells
L-*Hsp70*	0.095	5' UTR leader sequence of the DnaK gene from *Petunia hybrida* that encodes heat shock protein 70 (HSP70) that is involved in regulating gene expression
CS-*bar*	0.551	Coding sequence for the phosphinothricin N-acetyltransferase (PAT) protein of *S. hygroscopicus* that confers glufosinate tolerance
T-*nos*	0.252	3' UTR sequence of the nopaline synthase (*nos*) gene from *A. tumefaciens* pTi encoding NOS that directs polyadenylation
B-Left Border Region r1	0.261	DNA region from *A. tumefaciens* containing the Left Border sequence used for transfer of the T-DNA

[1]P, Promoter; L, Leader; TS, Targeting Sequence; CS, Coding Sequence; T, Transcription Termination Sequence; B, Border.

3.2. Information relating to the GM plant

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

Monsanto Company has developed dicamba and glufosinate-tolerant cotton, MON 88701. It contains a demethylase gene from *S. maltophilia* that expresses a dicamba mono-oxygenase (DMO) protein to confer tolerance to dicamba herbicide and a bialaphos resistance (*bar*) gene from *S. hygroscopicus* that expresses the phosphinothricin N-acetyltransferase (PAT) protein to confer tolerance to glufosinate herbicide.

The use of MON 88701 will enable growers to utilize both dicamba and glufosinate for effective control of weeds.

3.2.2. *Information on the sequences actually inserted or deleted*

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

Molecular characterization of MON 88701 by Southern blot analyses confirmed that the T-DNA was inserted into the cotton genome at a single locus containing one copy of the *dmo* and *bar* expression cassettes. No additional elements were detected other than those associated with the insert. Moreover, no plasmid backbone sequences were detected in the genome of MON 88701.

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

There was an unintended deletion of 123 bp of DNA sequence at the site of insertion in MON 88701.

Minor deletions and/or insertions of DNA due to double-strand, break-repair mechanisms in the plant during the *Agrobacterium*-mediated transformation process are not uncommon. Furthermore, the bioinformatic analyses of the DNA sequences flanking the insertion site of MON 88701 revealed that there is no known function associated with this deleted region.

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

The presence of MON 88701 insert in the nuclear genome is best shown by the *Chi* square analysis of the segregation results (Part II Section A.2.2.4).The *Chi* square analysis of the segregation pattern, according to Mendelian genetics, was consistent with a single site of insertion into cotton nuclear DNA.

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

Molecular analysis was conducted to characterize the insert in MON 88701. Genomic DNA was analyzed using Southern blot to determine the insert number (number of insertions of the integrated DNA within the cotton genome), the copy number (the number of copies of the integrated DNA within one locus), the integrity and organization of the inserted *dmo* and *bar* expression cassettes and the presence or absence of plasmid backbone sequences. DNA sequence analyses confirmed the sequence identity between the MON 88701 insert and the corresponding insert from the plasmid PV–GHHT6997. The results of PCR and sequence analyses further confirmed the organisation of the genetic elements within the *dmo* and *bar* expression cassettes of MON 88701, which were identical to that in plasmid PV–GHHT6997.

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

Not applicable

3.2.3. *Information on the expression of the insert*

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

As described in Section 3.2.2 of this document, the *dmo* and *bar* are the only expression cassettes inserted in MON 88701. Therefore, MON 88701 DMO and PAT (*bar*) are the only newly expressed proteins in MON 88701.

MON 88701 DMO and PAT (*bar*) protein levels in various tissues of MON 88701 were determined by a validated enzyme-linked immunosorbent assay (ELISA).

The expression levels of the MON 88701 DMO and PAT (*bar*) proteins were analysed in tissues of MON 88701 obtained from four replicate plots planted in a randomized complete block field design during the 2010 growing season in US.

The mean MON 88701 DMO and PAT (*bar*) protein levels in dicamba and glufosinate-treated MON 88701 were 21 µg/g dwt and 6.6 µg/g dwt in seed respectively.

The mean MON 88701 DMO and PAT (*bar*) protein levels in dicamba and glufosinate-not treated MON 88701 were 18 µg/g dwt and 6.3 µg/g dwt in seed respectively.

The MON 88701 DMO and PAT (*bar*) protein levels (µg/g dwt) determined from MON 88701 dicamba and glufosinate-treated seeds were comparable to those determined from MON 88701 glufosionate and dicamba -not treated seeds, showing that dicamba and glufosinate applications in MON 88701 do not alter nor have any negative effects on the expression of MON 88701 DMO and PAT (*bar*) proteins in the plant.

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

The expression of the DMO and PAT (*bar*) proteins occurs throughout the plant. In terms of food and feed safety assessment of MON 88701, seed is the relevant tissue.

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

MON 88701 contains a single copy of the T-DNA sequence that was integrated into a single locus of the cotton genome. The inserted DNA is inherited in a Mendelian fashion and is stably maintained through multiple generations of breeding. This has been confirmed by Southern blot analyses.

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

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

Phenotypic and agronomic characterization as well as environmental interaction data were collected from eight sites at field trials in major cotton-growing areas of US during the 2010 field season. Randomized complete block design with four replicates at each field site was used. In each of the assessments MON 88701, either treated or not with dicamba and glufosinate, was compared to an appropriate cotton conventional counterpart (control) which has a genetic background similar to MON 88701 but does not possess the *dmo* and *bar* expression cassettes. In addition, multiple conventional varieties (references) were employed to provide a range of baseline values that are common to the existing commercial cotton for each measured phenotypic, agronomic, and ecological interaction characteristic.

Results of this field study demonstrate that the assessed characteristics of MON 88701 were within the range expected for cotton. The statistical analyses of the field evaluations support a conclusion of no unexpected changes in the phenotype indicative of increased plant weed/pest potential of MON 88701 compared to conventional cotton. Furthermore, the results demonstrate that in-crop applications of dicamba and glufosinate herbicide do not alter the phenotypic and agronomic characteristics of MON 88701 compared to conventional cotton.

Based on the study described above, it is possible to conclude that no differences in the mode or rate of reproduction, dissemination, survivability or other agronomic, phenotypic or ecological characteristics are expected in MON 88701 and that MON 88701 is similar to conventional cotton in its phenotypic and agronomic behaviour, except for the dicamba and glufosinate-tolerance traits.

(b) Dissemination

See Section 3.2.5(a) above.

(c) Survivability

See Section 3.2.5(a) above.

(d) Other differences

See Section 3.2.5(a) above.

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

(a) Plant to bacteria gene transfer

None of the genetic elements inserted in MON 88701 has 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

Not applicable. The scope of the current application does not include the cultivation of MON 88701 varieties in the EU.

4. COMPARATIVE ANALYSIS

4.1. Choice of the conventional counterpart and additional comparators

MON 88701 was compared to a conventional cotton counterpart with a genetic background similar to MON 88701, as well as with other commercially available cotton varieties.

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

MON 88701 and the conventional counterpart were grown in 2010 in eight US field sites. Additionally, several conventional commercial reference varieties were used to provide reference substances representative for their respective growing regions. At each field site, the test, the conventional counterpart and reference seed were planted in a randomized complete block design with four replicates per block. Field locations were acceptable environments for cotton growth and are distributed across a wide geographical area to provide a variety of agronomic practices, soils and climatic factors. All the plants were grown under normal agronomic field conditions for their respective geographic regions. The test MON 88701 was either treated or untreated with dicamba and glufosinate herbicides.

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

4.3. Selection of material and compounds for analysis

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

4.4. Comparative analysis of agronomic and phenotypic characteristics

An assessment of the phenotypic, agronomic and environmental interactions of MON 88701 compared to conventional cotton has been performed in the field. It was guided by the OECD concept of familiarity by scientists who are familiar with the production and evaluation of cotton.

Results of this field study showed that there are no unexpected changes in the phenotype or ecological interactions indicative of increased pest or weed potential of MON 88701 compared to the cotton conventional counterpart. *See* also Section 3.2.5 of this document.

4.5. Effect of processing

With the exception of the dicamba and glufosinate-tolerance traits, MON 88701 is not different from the conventional counterpart. Therefore, the processing of MON 88701 is not expected to be any different from that of conventional cotton.

5. TOXICOLOGY

(a) Toxicological testing of newly expressed proteins

The *dmo* and *bar* genes are the only genes expressing novel proteins in MON 88701. Therefore, the safety assessment of the newly expressed proteins is focused on the MON 88701 DMO and PAT (*bar*) proteins expressed in MON 88701.

The assessment of the potential toxicity of an introduced protein is based on comparing the biochemical characteristics of the introduced protein to characteristics of known toxins, based on the premise that a protein is not likely to have toxic effect if:

- 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;
- The protein is rapidly digested in mammalian gastrointestinal systems;

MON 88701 DMO and PAT (*bar*) proteins have a history of safe use. The *dmo* gene, which encodes the DMO protein, was derived from *S. maltophilia*. *S. maltophilia* is ubiquitous in the environment and is commonly found on the rhizosphere of plants. *S. maltophilia* can be found in a variety of foods and feeds, and is widespread in the home environment. Exposure to *S. maltophilia* is incidental to its presence in food. It has been found in "ready to eat" salads, vegetables, frozen fish, milk, and poultry. The *bar* gene is derived from the bacterium *S. hygroscopicus*. *S. hygroscopicus* is a saprophytic, soil-borne bacterium with no known safety issues. *Streptomyces* species are widespread in the environment and present no known allergenic or toxicity issues, though human exposure is quite common. *S. hygroscopicus* is not considered pathogenic to plants, humans or other animals. *S. hygroscopicus* is shown to have a history of safe use. Furthermore, the ubiquitous presence of *S. maltophilia* and *S. hygroscopicus* in the environment, the presence in healthy individuals without causing infections, the incidental presence in foods without any adverse safety reports, and the lack of reported allergenicity establishes the safety of the donor organism.

The MON 88701 DMO and PAT (*bar*) proteins lack structural similarity to known toxins, allergens or biologically active or anti-nutritional proteins known to have adverse effects on mammals. Furthermore no indications of toxicity were reported in mice administrated the MON 88701 DMO or PAT (*bar*) proteins by oral gavage. Finally, the low concentration of these proteins in tissues that are consumed and its rapid digestibility in simulated digestive fluids provide additional assurance for their safety. It is therefore possible to conclude that the MON 88701 DMO and PAT (*bar*) proteins are safe and pose no concerns for humans, animals and the environment. It should also be noted that cotton

products consumed by humans are not expected to contain proteins due to the excessive processing involved in cottonseed oil and linters prior to consumption.

(b) Testing of new constituents other than proteins

Since cotton is known as a common source of food and feed with a centuries-long history of safe use and consumption around the world and as MON 88701 was shown to be compositionally not different to conventional cotton, no testing of any constituent other than the introduced proteins is indicated.

(c) 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. These anti-nutrients were evaluated in MON 88701 compositional analyses and their levels were demonstrated to be not different to those in the conventional counterpart and similar to those of the conventional commercial reference varieties.

(d) Testing of the whole GM food/feed

The data presented in this application establish that seed composition of MON 88701 is not different from the seed composition of the conventional counterpart. Overall results of the comparison indicate that observed differences fell within the range of natural variability for cotton with a history of safe use.

In addition, the safety for humans and animals of the newly expressed MON 88701 DMO and PAT (*bar*) proteins has been demonstrated on the basis of extensive characterization, history of safe use, lack of structural similarities with known protein toxins and allergens, absence of acute toxicity in oral gavage studies in rodents and rapid digestion in simulated digestive fluids. Taken together there are no evidences of any adverse effects of the DMO and PAT (*bar*) proteins in MON 88701 on human or animal health.

Based on this weight of evidence, no more data is required to demonstrate that MON 88701 is as safe as conventional cotton from a food and feed perspective.

6. ALLERGENICITY

(a) Assessment of allergenicity of the newly expressed protein

The *dmo* and *bar* genes are the only expression cassettes inserted in MON 88701. Therefore, the safety assessment of the newly expressed proteins is focused on the MON 88701 DMO and PAT (*bar*) proteins expressed in MON 88701.

Following the guidelines adopted by the Codex Alimentarius Commission an assessment of potential allergenicity of introduced proteins has been conducted, by comparing the characteristics of the introduced protein to characteristics of known allergens. A protein is not likely to be associated with allergenicity if:

- the protein is from a non-allergenic source;
- the protein does not share structural similarities to known allergens based on the amino acid sequence;
- the protein represents only a very small portion of the total plant protein;
- the protein is rapidly digested in mammalian gastrointestinal systems;
- the protein is not stable to heat treatment.

The MON 88701 DMO and PAT (*bar*) proteins in MON 88701 have been assessed for their potential allergenicity according to these safety assessment guidelines and have been demonstrated not to be allergenic. Additionally, the DMO and PAT (*bar*) proteins and their respective donor organisms have a long history of safe use. Based on the weight of evidence, it can be concluded that the allergenic potential of the DMO and PAT (*bar*) proteins is negligible and therefore, these proteins do not pose a significant allergenic risk.

(b) Assessment of allergenicity of the whole GM plant

Cotton is not considered a common source of allergenic food. There is no reason to expect that the use of MON 88701 will significantly increase the intake and exposure to cotton. Therefore a possible overexpression of any endogenous protein, which is not known to be allergenic, would be unlikely to alter the overall allergenicity of the whole plant or the allergy risk for consumers.

7. NUTRITIONAL ASSESSMENT

(a) Nutritional assessment of GM food

The introduced traits in MON 88701 are of agronomic interest and are not intended to change any nutritional aspects of this cotton. The presence of the dicamba and glufosinate tolerance proteins in MON 88701 is not expected to alter patterns or volumes of cotton food product consumption. Also, cotton products consumed by humans are not expected to contain proteins due to the excessive processing involved in cottonseed oil and linters prior to consumption.

Results of the extensive compositional analyses indicate that observed differences fell within the range of natural variability for cotton with a history of safe use, and the seed composition of MON 88701 is not different to the seed composition of the conventional counterpart.

Overall, MON 88701 cottonseed is nutritionally comparable to conventional cottonseed as well as to cotton varieties in commerce. Hence this cottonseed is not expected to be more or less attractive for use as food (or feed), for processing or as a food (or feed) ingredient. Therefore, anticipated dietary intake of cottonseed-derived foods (and feeds) is not expected to be altered upon EU authorization of MON 88701, and no nutritional imbalances are expected as a result of the presence of MON 88701 in the suppy.

(b) Nutritional assessment of GM feed

Results of the extensive compositional analyses establish that seed composition of MON 88701 is not different to the seed composition of the conventional counterpart and that it is equivalent to seed composition of the set of conventional reference varieties, except for the expression of the MON 88701 DMO and PAT (*bar*) proteins.

8. EXPOSURE ASSESSMENT – ANTICIPATED INTAKE/EXTENT OF USE

The exposure assessment in humans and animals indicates that here is minimal, if any, dietary exposure to MON 88701 DMO and PAT (*bar*) proteins from consumption of foods and feed derived from MON 88701. There are no anticipated changes in the intake and/or extent of use of cotton or derived products for use as or in food or feed as a result of the addition of MON 88701 to the cotton supply. MON 88701 is expected to replace a portion of current cotton such that its intake or use will represent some fraction of the total products derived from cotton.

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

Based on the information provided in this application, it can be concluded that MON 88701 is as safe as conventional cotton. The molecular characterization of MON 88701 did not raise any safety concern and did not show any evidence of unintended changes in MON 88701. Detailed compositional comparisons of MON 88701, its conventional counterpart and conventional commercial cotton reference varieties demonstrated that MON 88701 is compositionally similar to the conventional cotton counterpart and that MON 88701 is not a contributor to compositional variability in cotton. The assessed phenotypic and agronomic characteristics of MON 88701 were within the range expected for cotton and did not show any phenotypic changes indicative of increased plant weed/pest potential of MON 88701 compared to conventional cotton. An extensive characterisation of the DMO and PAT (*bar*) proteins expressed in MON 88701 confirmed that these proteins are safe for human and animal consumption. Additionally, the exposure assessment in humans and animals indicates that there is minimal, if any, dietary exposure to MON 88701 DMO and PAT (*bar*) proteins from consumption of food and feed derived from MON 88701.

In summary, there are no signs of adverse or unanticipated effects observed in a number of safety studies and the pre-market risk characterisation for food and feed use of MON 88701. The consumption of food and feed derived from MON 88701 is as safe as the consumption of that of the conventional comparators. It can be concluded that the food derived from a GM plant is not nutritionally disadvantageous for the consumer compared to the food which is intended to replace. Finally, it can also be concluded that the feed derived from a GM plant does not harm or mislead the consumer by impairing distinctive features of the animal products compared to conventionally produced feed.

10. POST-MARKET MONITORING ON GM FOOD/FEED

Based on the information provided in this application, it is reasonable to conclude that MON 88701 is as safe as conventional cotton. There are no intrinsic hazards related to MON 88701 indicating that MON 88701 is less safe than its conventional counterpart. The pre-market risk characterisation for food and feed use of MON 88701 demonstrates that the risks of consumption of MON 88701 or its derived products are no different from the risks associated with the consumption of conventional cotton or its derived products. As a consequence, specific risk management measures are not indicated and post-market monitoring of the use of this cotton for food and feed is not considered necessary.

11. ENVIRONMENTAL ASSESSMENT

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

According to the EFSA ERA Guidance, the primary focus for the assessment on target organisms is the development of resistance to the insect or pathogen tolerance traits expressed by the GM plant. The scope of this application covers the import, processing and all uses as any other cotton, but excludes the cultivation of MON 88701 varieties in the EU. Hence, no deliberate release of viable plant material in the EU environment is expected and no target organisms are associated with this event. Therefore an assessment of the potential resistance development in target organisms resulting from import, processing and all uses as any other cotton, but excluding the cultivation of MON 88701 in the EU is not relevant for this submission.

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

(a) Persistence and invasiveness

Results from the assessment support a conclusion that the abilities of MON 88701 that receive the trait to persist in agricultural fields or invade non-agricultural habitats are comparable to those of conventional cotton in the EU. Thus, MON 88701 is not more likely to represent an agronomic problem in agricultural fields or become more invasive in natural habitats and no adverse effects on ecological functions within agricultural production fields or on biodiversity are expected as a result of the import, processing and all uses as any other cotton. Given the negligible hazard and the low levels of environmental exposure that could arise from the import, processing and all uses as any other cotton of this product and the fact that any exposure would be limited spatially and temporally, the uncertainties associated with this risk characterization and the probability of long-term adverse environmental effects are negligible.

(b) Selective advantage or disadvantage

Compared with conventional cotton, the presence of the dicamba and glufosinate-tolerance traits confer a selective advantage only under specific conditions (*i.e.* following treatment with dicamba and/or glufosinate), 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 dicamba and glufosinate-tolerance traits in MON 88701 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.

(c) Potential for gene transfer

The scope of this application covers the import, processing, and all uses of MON 88701 as any other cotton in the EU. Therefore, no deliberate release of viable plant material in the EU environment is expected, and interactions of MON 88701 with the biotic environment will be limited. Given the low likelihood of occurrence of horizontal gene transfer and lack of adverse consequences if it were to occur, the import, processing, and all uses of MON 88701 in the EU is not likely to adversely impact human, animal, or environmental health, and poses negligible risk. Considering the low exposure and lack of hazard from horizontal gene transfer of the *dmo* and *bar* genes from MON 88701 to micro-organisms, the uncertainties associated with this risk characterization and the probability of long-term adverse environmental effects are negligible.

(d) Interactions between the GM plant and target organisms

The scope of this application covers the import, processing and all uses as any other cotton, but excluding the cultivation of MON 88701 in the EU, no deliberate release of viable plant material in the EU environment is expected and no target organisms are associated with this event. Therefore an assessment of the potential resistance development in target organisms resulting from the import, processing and all uses as any other cotton, but excluding the cultivation of MON 88701 in the EU is not relevant for this submission.

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

The scope of this application covers the import, processing and all uses as any other cotton, but excluding the cultivation of MON 88701 in the EU. Therefore, no deliberate release of viable plant material in the EU environment is expected and interactions of MON 88701 with the biotic environment will be very limited.

Importantly, the MON 88701 DMO and PAT (*bar*) proteins are heat inactivated during processing for feed and can also be inactivated in the digestive tract of animals. Additionally, bioinformatics analyses confirmed that MON 88701 DMO and PAT (*bar*) homologues do not exist in insects and the suppression of these genes in MON 88701 will not have any pesticidal and/or biological activity on insects directly or indirectly exposed to MON 88701.

Given the low levels of environmental exposure combined with low hazard from exposure to MON 88701 to NTOs, the likelihood of adverse effects to NTO communities that perform in-field ecological functions and NTO communities outside of the field from import of MON 88701 is negligible. Considering low exposure and hazard from MON 88701 to NTOs, there is a low level of uncertainties associated with the conclusion of this NTO risk assessment and therefore the probability of long-term adverse environmental effects on NTOs is negligible.

(f) Effects on human and animal health

This application is for the import, processing and all uses as any other cotton, but excluding the cultivation of MON 88701 in the EU. MON 88701 will be imported into the EU as cottonseed, and therefore the most relevant tissue pertinent to the routes of exposure related to occupational hazard is seed. Cottonseed are normally held, transported and handled in a confined manner that restricts the potential for workers exposure. Under such conditions, cottonseed is significantly limited in its entry into the environment, and therefore environmental exposure is low.

(g) Effects on biogeochemical processes

The scope of this application covers the import, processing, and all uses of MON 88701 as any other cotton in the EU. Therefore, no deliberate release of viable plant material in the EU environment is expected, and interactions of MON 88701 with the biotic environment will be very limited. Importantly, the MON 88701 DMO and PAT (*bar*) proteins are subject to degradation during processing for feed, and also in the digestive tract of animals thereby limiting any exposure via faeces of animals fed processed or unprocessed seed of MON 88701. Given the low level of environmental exposure combined with a lack of hazard, the import, processing, and all uses of MON 88701 as any other cotton in the EU is not likely to adversely impact soil micro-organisms that perform ecological functions in-field or in non-agricultural habitats, and therefore poses negligible environmental risk. Considering the low exposure and hazard from MON 88701 to soil micro-organisms, the uncertainties associated with this risk characterization and the probability of long-term adverse environmental effects are negligible.

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

Cultivation of MON 88701 in the EU is not included in the scope of this application. An assessment of the impacts of specific cultivation, management and harvesting techniques of MON 88701 is therefore not relevant for this application.

11.3. Potential interactions with the abiotic environment

Although the DMO and PAT (*bar*) proteins are introduced in cotton, it already have a safe history of use and it have no known negative interactions with the abiotic environment.

Overall results of the comparative analysis of MON 88701 with respect to its conventional counterpart indicate that observed differences in composition and agronomic and phenotypic characteristics, fell within the range of natural variability for coton with a history of safe usage. Therefore, there is no evidence that this cotton would be any different from conventional cotton with regard to its baseline interactions with the abiotic environment.

In addition, because this application is for import, processing and all uses as any other cotton in the EU, interactions of MON 88701 with the environment will be limited. Moreover no negative impact of MON 88701 on the abiotic environment is expected to result from the import, processing and all uses as any other cotton in the EU.

11.4. Risk characterisation for the environmental risk assessment

Results from the environmental risk assessment which takes into consideration the risk characterization and includes results described above addressing risk hypotheses for the specific areas of assessment lied down in 2010 EFSA guidance, support a conclusion that the import, processing and all uses (excluding cultivation) of MON 88701, as any other cotton, in the EU represents negligible risk to human and animal health and the environment, and poses no greater risk than the import, processing and uses of conventional cotton. Because no immediate adverse effects are expected, the probability of long-term adverse effects is also negligible.

12. ENVIRONMENTAL MONITORING PLAN

(a) General (risk assessment, background information)

As required by Article 5(5)(b) and 17(5)(b) of Regulation (EC) No. 1829/2003 the proposed monitoring plan for MON 88701 has been developed according to the principles and objectives outlined in Annex VII of Directive 2001/18/EC and Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC. The monitoring plan also takes into account the Scientific Opinion on guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants[2].

(b) Interplay between environmental risk assessment and monitoring

The scope of this application is the authorization of MON 88701 for import, processing, and all uses of MON 88701 as any other cotton in the European Union (EU) under Regulation (EC) No. 1829/2003. The scope of the application does not include authorization for the cultivation of MON 88701 seed products in the EU.

An environmental risk assessment (ERA) was carried out for MON 88701 according to the principles laid down in Annex II to Directive 2001/18/EC, the Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC and the Guidance Document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed[3]. The scientific evaluation of the characteristics of MON 88701 in the ERA has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses of MON 88701 relative to:

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

[2] www.efsa.europa.eu/en/efsajournal/doc/2316.pdf -Accessed on 24 January 2013.
[3] www.efsa.europa.eu/en/scdocs/doc/1879.pdf -Accessed on 24 January 2013.

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

As discussed in Section E.4.2 of Part II of this application, the scientific evaluation of the characteristics of MON 88701 in the ERA has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses of MON 88701. It is therefore considered that there is no need for case-specific monitoring.

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

Any potential adverse effects of MON 88701 on human health and the environment, which were not anticipated in the ERA, can be addressed under the general surveillance. General surveillance is largely based on routine observation and implies the collection, scientific evaluation and reporting of reliable scientific evidence, in order to be able to identify whether unanticipated, direct or indirect, immediate or delayed adverse effects have been caused by the placing on the market of a genetically modified (GM) crop in its receiving environment.

In order to allow detection of the broadest possible scope of unanticipated adverse effects, general surveillance is performed by either selected, existing networks, or by specific company stewardship programmes, or by a combination of both. The consent holder will ensure that appropriate technical information on MON 88701 and relevant legislation will be available for the relevant networks, in addition to further relevant information from a number of sources, including industry and government websites, official registers and government publications.

Following the approval of this cotton in the EU, the consent holder will approach key stakeholders and key networks of stakeholders of the product (including international grain traders, cotton processors and users of cotton seed for animal feed) and inform them that the product has been authorised. The consent holder will request key stakeholders and networks for their participation in the general surveillance of the placing on the market of this cotton, in accordance with the provisions of Directive 2001/18/EC and the consent. Key stakeholders and networks will be requested to be aware of their use of this cotton and to inform the consent holder in case of potential occurrence of any unanticipated adverse effects to health or the environment, which they might attribute to the import or use of this product. Appropriate technical information on MON 88701 will be provided to them.

Where there is scientifically valid evidence of a potential adverse effect (whether direct or indirect), linked to the genetic modification, then further evaluation of the consequence of that effect should be science-based and compared with available baseline information. Relevant baseline information will reflect prevalent use practices and the associated impact of these practices on the environment. Where scientific evaluation of the observation confirms the possibility of an unanticipated adverse effect, this would be investigated further to establish a correlation, if present, between the use of MON 88701 and the observed effect. The evaluation should consider the consequence of the observed effect and remedial action, if necessary, should be proportionate to the significance of the observed effect.

(e) Reporting the results of monitoring

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

If information that confirms an adverse effect of MON 88701 and that alters the existing risk assessment becomes available, the authorization holder will immediately investigate

and inform the European Commission. The authorization holder, in collaboration with the European Commission and based on a scientific evaluation of the potential consequences of the observed adverse effect, will define and implement management measures to protect human and animal health or the environment, as necessary. It is important that the remedial action is proportionate to the significance of the observed effect.

The authorization holder will submit an annual monitoring report including results of the general surveillance in accordance with the conditions of the authorization. The report will contain information on any unanticipated adverse effects that have arisen from handling and use of viable MON 88701.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of MON 88701 and, as appropriate, measures that were taken to ensure the safety of human and animal health or the environment.

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

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

The presence of the *dmo* and *bar* genes and the DMO and PAT (*bar*) proteins in cotton or in cotton derived products can be identified by employing different techniques. Southern blot or PCR techniques can identify the inserted nucleotide sequence, while the DMO and PAT (*bar*) proteins can be detected, by optimised tissue extraction, standardised electrophoretic blotting and immunodetection methodologies.

A MON 88701-specific PCR-based assay allowing the identification and quantification of MON 88701 has been provided to the Joint Research Centre (JRC)[4], acting as the European Union Reference Laboratory for GM Food and Feed (EURL-GMFF).

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

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

(a) Notification number

There is no history of field realease of MON 88701 in EU.

(b) Conclusions of post-release monitoring

Not applicable

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

Not applicable

[4] http://gmo-crl.jrc.ec.europa.eu/ Accessed on 24 January 2013.

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

(a) Release country

MON 88701 has been field tested in the US (2007-2012), Japan (2011) and Costa Rica (2012).

(b) Authority overseeing the release

US: United States Department of Agriculture (USDA)

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

Costa Rica: Ministry of Agriculture and Livestock Department of Health Protection Services

(c) Release site

US: in major cotton growing states (Alabama, Arkansas, Arizona, California, Florida, Georgia, Kansas, Louisiana, Mississippi, Missouri, New Mexico, North Carolina, Oklahoma, Puerto Rico, South Carolina, Tennessee, and Texas.)

Japan: Ibaraki

Costa Rica: Puntarenas

(d) Aim of the release

U.S/Japan/Costa Rica: regulatory trials, efficacy, yield, product development, and demonstration.

(e) Duration of the release

US/Japan/Costa Rica: One growing season.

(f) Aim of post-releases monitoring

US/Japan/Costa Rica: Assessment of volunteers.

(g) Duration of post-releases monitoring

US/Japan/Costa Rica: 12 months.

(h) Conclusions of post-release monitoring

US/Japan/Costa Rica: In general, no volunteers have been observed in cotton. If volunteers occur, practice is to eliminate them manually or chemically to prevent occurrence in subsequent crops.

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

Field-testing provided no evidence that MON 88701 would be the cause of any adverse effects to human health or to the environment.