

PART II**SUMMARY****OF THE REQUEST FOR AUTHORIZATION IN ACCORDANCE WITH ARTICLES 5 AND
17 OF REGULATION (EC) No. 1829/2003****GLUFOSINATE AMMONIUM-TOLERANT AND INSECT-PROTECTED GENETICALLY
MODIFIED COTTON
LLCOTTON25 X MON 15985****FOR DERIVED FOOD, FEED AND FOR INDUSTRIAL USES****A. GENERAL INFORMATION****1. Details of application**

a) Member State of application: [The Netherlands](#)

b) Application number: [Not available at the date of application](#)

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

[LLCotton25 X MON 15985: Cottonseed oil produced from genetically modified cotton \(*Gossypium hirsutum*\) with tolerance to glufosinate ammonium and protected from lepidopteran insects pests, derived by traditional breeding methods from crosses between GM cotton transformation event LLCotton25 \(OECD code ACS-GHØØ1-3\), marketed in association with the trademark LibertyLink®, and MON 15985 cotton transformation event, marketed in association with the trademark BollgardII®.](#)

[Other name: BG2xLL.](#)

d) Date of acknowledgement of valid application: [Not available at the date of application](#)

2. Applicant

a) Name of applicant: [Bayer CropScience GmbH](#)

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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)):

BG2xLL products will be imported and used in the EU in the same way as the equivalent products from commercial cotton and by the same groups who import and distribute commodity cotton today.

3. Scope of the application

- GM plants for food use
- Food containing or consisting of GM plants
- Food produced from GM plants or containing ingredients produced from GM plants
- GM plants for feed use
- Feed containing or consisting of GM plants
- Feed produced from GM plants
- Import and processing (Part C of Directive 2001/18/EC)
- Seeds and plant propagating material for cultivation in Europe (Part C of Directive 2001/18/EC)

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

Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>
If no, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC	

6. Has the GM plant or derived products been previously notified for marketing in the Community under Part C of Directive 2001/18/EC or Regulation (EC) 258/97?

Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
If yes, specify:	

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

Yes <input type="checkbox"/>	No <input type="checkbox"/>
<p>If yes, specify:</p> <p>- LLCotton 25 is grown commercially in US, and will be released soon in Australia. Applications for import or growing are approved or pending in various countries such as Brazil, Canada, China, Mexico, Japan, Korea.</p> <p>- Bollgard II: Outside the E.U., such as in U.S. and Australia, MON 15985 is authorized for all uses, corresponding to the full range of uses of traditional cotton. The scope of the 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 wherein countries require specific approvals are posted by these regulatory agencies on their official websites.</p> <p>- BG2xLL: Outside the EU, Japan and Korea are the only countries that require import approval for stacked events.</p>	

8. General description of the product**a) Name of the recipient or parental plant and the intended function of the genetic modification:**

The recipient plant belongs to the species, *Gossypium hirsutum* L. BG2xLL has been obtained by crossing LLCotton25 (LibertyLink)® and MON 15985 (Bollgard II®) events, and developed by breeding with non-GM cotton adapted for planting in the temperate cotton production regions of the Americas.

The genetic modifications intend to confer the tolerance to the herbicide glufosinate ammonium through the genetic locus defined as LLCotton25 and protection against lepidopteran insects pests through the genetic modification defined as MON 15985.

Herbicide tolerance is based upon the *bar* gene, a bialaphos resistance gene, isolated from the soil microorganism, *Streptomyces hygroscopicus*. The *bar* gene encodes the production of the enzyme, Phosphinothricin-Acetyl-Transferase (PAT). The specific enzymatic action of the PAT protein is tolerance to glufosinate ammonium herbicide.

The protection against lepidopteran pests is based on two *Bacillus thuringiensis* proteins, Cry1Ac and Cry2Ab2. The two proteins confer insect protection for the effective control of major bollworm, tobacco budworm and pink bollworm.

Agricultural production of cotton requires weed control and insect pest control, which depend also upon the combinations of management practices. Growing BG2xLL cotton allows:

1) more options to rotate herbicides for weed resistance management programs; 2) control of less sensitive weeds, *i.e.* amaranths, lambsquarters...; 3) control of currently identified biotypes of herbicide resistant weeds, thus more options for crop management, lesser impact on cotton growing areas and potential implications for soil conservation through minimum tillage practices; 4) control of the major lepidopteran insect pests, with lesser impact on cotton growing areas, through lower doses of target insecticides.

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

Cottonseed oil products derived from BG2xLL will be imported and distributed in the European Union for all uses as any other cottonseed oil products (food, feed and industrial uses).

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

In the EC, cottonseed oil is an important vegetable oil source. Cottonseed oil from BG2xLL seeds will be imported in the EU from the major cotton growing areas as commodity and could be used for downstream purposes as food, feed and industrial products identically to non-GM cottons.

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

No mandatory restrictions for use, storage and handling are proposed as a condition of the authorisation. All standard practices applicable to cottonseed oil products today remain adequate for the handling of oil derived from BG2xLL varieties.

When the oil derived from genetically modified cotton is placed on the EU market, the corresponding batch will be labelled and handled according to the legislation in application in the EU, in particular the Regulation No. 1830/2003 (EC).

e) Any proposed packaging requirements:

BG2xLL is substantially equivalent to traditional cotton varieties (except for the tolerance to glufosinate and for the protection from targeted lepidopteran insect pests). Therefore food and feed products produced from BG2xLL will be used in the same manner as other cotton and no specific packaging is foreseen.

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

BG2xLL does not harbour characteristics that require specific labelling. Hence, no additional labelling is proposed on top of the GM labelling requirements foreseen in regulations (EC) 1829/2003 and 1830/2003.

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

Not applicable as the scope of this application is food and feeds produced from BG2xLL.

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

No restrictions are necessary as BG2xLL is suitable for food, feed and industrial uses in all regions of the European Union.

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

The safety profile in terms of human and animal health and environmental impact of oil products of BG2xLL and conventional cottons are identical and do not constitute a hazard.

No specific conditions are warranted or required for the placing on the market of BG2xLL either for food and feed, or for industrial uses.

B. INFORMATION RELATING TO THE RECIPIENT OR (WHERE APPROPRIATE) PARENTAL PLANTS**1. Complete name**

a) Family name:	<i>Malvaceae</i>
b) Genus:	<i>Gossypium</i>
c) Species:	<i>hirsutum</i>
d) Subspecies:	Not applicable.
e) Cultivar/breeding line or strain:	FM989 and other FiberMax elite varieties
f) Common name:	cotton

2 a. Information concerning reproduction**(i) Mode(s) of reproduction**

Vegetative proliferation of cotton requires human intervention. Its mode of reproduction can be restricted to sexual reproduction only.

Cotton is mainly an **autogamous** species, however some degree of insect mediated **cross-pollination** may take place.

Gene flow can occur into adjacent cotton crops however, the rate is likely to be very low because of the existence of genetic, botanical, geographic and agricultural barriers to gene flow. Gene flow will not occur into wild *Gossypium* species, which are not present in Europe.

Further evidence for the limited amount of cross-pollination that occurs in cotton comes from the limited isolation distance required (30m) established for certification of hybrid plant materials by the AOSCA Handbook.

(ii) Specific factors affecting reproduction

The main abiotic environmental factors affecting cotton reproduction that also determine the areas of cotton production are of a temperature profile, such as a) active vegetative growth range: 15 - 38 °C, b) accumulated heat GD15.5°C need: 1,200 unit, c) number of frost free days: 200, d) rapid and consistent spring warming pattern, as well as high light intensity.

The frequency of cross-pollination varies with the insect pollinator population in particular with various wild bees, bumble bees (*Bombus* spp.) and honey bees (*Apis mellifera*). All the factors reducing the density of pollinators such as the use of insecticides, or increased air humidity as the result of irrigation will essentially limit the extent of cross-pollination.

(iii) Generation time

Cotton in nature is a perennial shrub, which has been domesticated and converted to an annual crop. The generation time of cultivated cotton varies between 100 and 200 days.

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

There are no reported non *G. hirsutum* plants that are sexually compatible with cultivated cotton in the EU.

Pre-zygotic, and **post-zygotic barriers** greatly limit the sexual compatibility of *G. hirsutum* with other plant species in the Gossypiae tribe. In addition, plants of the *Gossypium* genus are not native to Europe. Several members of the genus are cultivated as ornamental plants (e.g. *Hibiscus rosa-sinensis*) or vegetables (e.g. *Abelmoschus esculentus*—okra), but hybridisation experiments of these species with *Gossypium sp.* failed or resulted in sterile seeds.

G. hirsutum, an allotetraploid species that combines the AADD genomes, will hybridise only with other tetraploid members of the *Gossypium* genus including *G. tomentosum*, *G. darwinii*, *G. mustelinum*, *G. hirsutum*, *G. lanceolatum*, and *G. barbadense*, which species are not known to have a habitat in Europe.

3. Survivability

a) Ability to form structures for survival or dormancy

Cotton is cultivated annually. Seeds are the only vegetative structure for survival. Some wild forms may produce “hard seeds” that, upon drying, become impermeable to water and suffer delayed germination. However this trait is undesirable agronomically and has been largely eliminated from modern cultivars through breeding and selection.

Cultivated cotton does not produce seeds which can persist in the environment for long periods of time, furthermore cottonseed lacks the ability to develop dormancy.

b) Specific factors affecting survivability

The main factors affecting survivability of cotton are related to soil microclimate such as temperature and humidity. If planted in moist soil before the soil temperature reaches 15 °C, it is likely to undergo degradation.

4. Dissemination

a) Ways and extent of dissemination

The two reproductive structures with the capability to disperse cotton genes in the environment are the seed and pollen.

- Seed dispersal could occur during transport, at sowing and essentially before and during harvest.
- Pollen dispersal studies conclude that when out-crossing occurs, it is localised around the pollen source and decreases significantly with distance.

b) Specific factors affecting dissemination

Seed dispersal: Cotton seed has no structural modifications to facilitate transfer by animals. Dissemination is mainly the result of human activity.

Pollen dispersal in cotton shows a correlation with insect prevalence. Proximity of more attractive vegetation, climate and insect management will essentially limit the extent of cross-pollination.

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

Plants of the tribe Gossypiae originated in the tropics and subtropics. Wild species of the tribe are extremely sensitive to photoperiod conditions and do not flower in long day-light regime, therefore they are essentially excluded from temperate climates. In spite of their origin, more than 50 % of cultivated cottons are produced in temperate zone above 30° Latitude N, but they also tend to be plants of the southern hemisphere.

Gossypium hirsutum in its wild form is distributed over the most arid areas of Central America and in the South and North of America, with wild populations that are rare and sporadic. Cultivated *G. hirsutum* (Upland or Mexican cotton) represents over 90 % of world-wide production besides one only “New Word” tetraploid species, *G. barbadense* (Pima or South American cotton) and two “Old Word” diploid species: *G. arboreum* and *G. herbaceum*. Main cotton producers are China, USA, India, Pakistan, Uzbekistan, Brazil and Turkey.

In Europe, the cultivated cotton is *G. hirsutum*. No wild relatives have been reported.

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

Cotton is commercially grown in **Greece, Spain, Cyprus and Portugal**.

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 ecosystem including a range of beneficial and pestiferous arthropods, bacteria, fungi, surrounding weed species, animals and humans. The crop has been cultivated in Spain Greece Cyprus and Portugal for decades and has a history of safe use.

The cotton crop was produced for fibre for thousands of years; in the 20th century it turned to food/feed channels. Cotton is not considered harmful or pathogenic to animals or humans, however the plant does produce a small amount of natural antinutritional factors such as gossypol, cyclopropenoid fatty acids and phytic acid.

With the exception of phytic acid, all the anti-nutritional are subject to neutralisation during processing. Free gossypol binds to lysine and other products, and then becomes unavailable to animals. Cyclopropenoid fatty acids are deactivated or removed from the oil by hydrogenation or during deodorization at 230-235°C.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION**1. Description of the methods used for the genetic modification**

BG2xLL is the result of a conventional breeding cross between the GM events BG2xLL without the use of recombinant DNA technology.

For more information on LLCotton25, please refer to application EFSA/GMO/NL-2005-13.

For more information on MON 15985, please refer to application EFSA/GMO/UK-2005-10.

2. Nature and source of the vector used

Please refer to Section C.1.

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

Please refer to Section C.1.

D. INFORMATION RELATING TO THE GM PLANT**1. Description of the trait(s) and characteristics which have been introduced or modified**

BG2xLL expresses the tolerance to commercial herbicides containing glufosinate ammonium (active form L-glufosinate), trait inherited from LLCotton25, as well as the insect protection trait found in MON 15985.

For more information on LLCotton25, please refer to application EFSA/GMO/NL-2005-13.
For more information on MON 15985, please refer to application EFSA/GMO/UK-2005-10.

2. Information on the sequences actually inserted or deleted**a) The copy number of all detectable inserts, both complete and partial**

Southern blot analysis demonstrated that the DNA inserts in BG2xLL are the same as those that occur in LLCotton25 and MON 15985.

For more information on LLCotton25, please refer to application EFSA/GMO/NL-2005-13.
For more information on MON 15985, please refer to application EFSA/GMO/UK-2005-10.

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

Not relevant. No deletion occurred.

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 BG2xLL contains the DNA inserts from both LLCotton25 and MON 15985 in its nuclear genome, as demonstrated by Southern blot analysis.

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

BG2xLL is the result of traditional breeding of LLCotton25 and MON 15985. The presence of the inserts in BG2xLL has been demonstrated by Southern blot analysis. As traditional breeding methods were used in the production of the cotton BG2 X LL, no genetic modification was involved and therefore the molecular structures of the DNA inserts are expected to remain unchanged as indicated by the preservation of the observed agronomic performance and reproductive morphology. The molecular analysis by Southern blot of BG2xLL confirms the presence of both inserts.

For more information on LLCotton25, please refer to application EFSA/GMO/NL-2005-13.
For more information on MON 15985, please refer to application EFSA/GMO/UK-2005-10.

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

The CaMV 35S, a constitutive promoter with highest activity in the leaves, drives the expression of the *bar*, *CryIAC*, *Cry2Ab2*, *uidA* and *nptII* genes in the components of the LLCotton25 X MON 15985 breeding stack (please refer to applications EFSA/GMO/UK-2005-10 and /GMO/NL-2005-13).

Field phenotypic data demonstrate that the herbicide tolerance trait is expressed in a sufficient manner so as to protect the plants at the two stages of herbicide treatment, and the insect resistance trait is efficient until harvest.

However, the scope of the current application covers cottonseed oil and its constituents produced from BG2xLL only, and does not involve the environmental release of the GM plants.

b) Parts of the plant where the insert is expressed

The scope of the current application covers only cottonseed oil and its constituents, produced from BG2xLL, and does not involve the environmental release of the GM plants. Therefore, the following information related to the expression of the insert can be considered as mainly informative.

The promoter elements derived from CaMV 35S, have been shown to be active in the vascular tissue of cotton leaf, root and floral organs, and the cotton leaf receives the major exposure of glufosinate herbicide. We expect BG2xLL cotton plants to show similar levels of protein expression as the parents of the stack (please refer to applications EFSA/GMO/UK-2005-10 and EFSA/GMO/NL-2005-13). Indeed, all measured protein analytes present in the leaves of the parents (MON 15985 and LLCotton25) are present in the leaves of BG2xLL cotton at essentially the same levels, as confirmed by the statistical analysis of the data provided in the notification.

In support of application EFSA/GMO/NL-2005-13, it has been demonstrated that there is no detectable level of protein in refined cottonseed oil produced from cotton modified through biotechnology or traditional cottonseeds.

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

a) Reproduction

Comparative assessments of the phenotypic and agronomic characteristics of MON 15985 and LLCotton25 and traditional cotton cultivars have been conducted at multiple sites in the U.S. since development of these products began. Further, MON 15985 and LLCotton25 are currently registered and grown commercially in the U.S. and elsewhere. The extensive experience from commercial use of these products has demonstrated that, except for the insect protection and herbicide tolerance traits, there are no biologically significant differences in the reproductive capability

b) Dissemination

The introduced traits have no influence on cotton reproductive morphology thus on dissemination.

c) Survivability

For cultivated cotton, survival is largely determined by seed characteristics. There is no indication of changes in the seed characteristics as a result of the inserted DNA sequences in BG2xLL.

d) Other differences

The only biologically significant difference observed in field evaluations is that as BG2xLL is the result of conventional breeding between the transformation event LLCotton25 and MON 15985, cotton varieties based upon BG2xLL are tolerant to Liberty® herbicide, active ingredient glufosinate ammonium, and protected against the most important lepidopteron pests of cotton.

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

As traditional breeding methods were used in the production of the cotton BG2xLL, no genetic modification was involved and therefore the molecular structures of the DNA inserts are not expected to change as indicated by the preservation of the observed agronomic performance, reproductive morphology and compositional data.

The stable integration of the inserts in BG2xLL has been demonstrated by Southern blot analysis.

6. Any change to the ability of the GM plant to transfer genetic material to other organisms**a) Plant to bacteria gene transfer**

Not applicable. However no aspect of the nature of the genetic elements used gives any indication that a transfer from BG2xLL to bacteria could occur.

b) Plant to plant gene transfer

Not applicable. Neither the import of viable seed nor cultivation is within the scope of this application, nor would therefore plant to plant gene transfer have no opportunity to occur.

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**

BG2xLL was compared with its parent variety FM989.

7.2 Production of material for comparative assessment**a) Number of locations, growing seasons, geographical spread and replicates**

Plant variety descriptors and agronomic performance traits were studied in a total of 8 locations in season 2004.

Measurements were made in the 2004 season in side-by-side plantings in eight different sites representing the cotton regions of adaptation of FiberMax989 (Tift County, Georgia; Jackson County, Crittenden County and Drew County, Arkansas; two sites in Tate County, Mississippi; Wharton County and Hockley County, Texas) from 10 representative plants of the variety FM989 and the BG2xLL in a FM989 genetic background (F6). Plots sizes varied by type of test, and were 6 to 8 rows with 3 replications.

b) The baseline used for consideration of natural variations

Published literature was consulted to establish a range of values to be expected for each nutritional component and ranges built from values of the non-transgenic, reference variety, FM 989.

7.3 Selection of material and compounds for analysis

The analysis of the compounds was based on international accepted guidelines.

The results of the composition analysis of BG2xLL in comparison with the conventional cotton variety

demonstrate equivalence and do not indicate a need for further analysis of selected compounds of BG2xLL derived oil products.

For more information on LLCotton25, please refer to application EFSA/GMO/NL-2005-13.

For more information on MON 15985, please refer to application EFSA/GMO/UK-2005-10.

7.4 Agronomic traits

Throughout the field testing of BG2xLL there were no differences observed that could be attributed to pleiotropic effects of the inserted DNA. Neither did BG2xLL differ from the counterpart in agronomic or reproductive characteristics. The agronomic evaluations included a detailed phenotypic analysis based upon plant variety description, agronomic performance evaluations common to yield trials, pest resistance evaluations and agronomic practice evaluations. Field studies were conducted in 8 sites in the Southern States of Arkansas, Georgia, Mississippi and Texas in 2004. A summary of the comparisons between BG2xLL and the conventional variety counterpart is provided in Table 1.

Agronomic performance data further confirmed that BG2xLL is like cotton currently grown and consumed.

Table 1. Summary of parameters evaluated in the comparison of BG2xLL cotton and the conventional variety counterpart.

	Characteristics	Parameters	Findings
1. Plant variety descriptors	Plant morphology using PVP standards	Overall plant morphology, height to node ratio, internode length, sympodia length, leaf morphology	Same as counterpart variety
	Fiber quality using PVP standards	Micronaire Fiber elongation % Fiber strength (g/tex) Fiber length (inches) Fiber length uniformity %	Same as counterpart variety, with the exception of fiber elongation at 3 of the 4 sites reported
2. Agronomic performance traits	Field performance	Emergence and stand establishment Rate of growth (days to first bloom) Height Lodging	Same as counterpart variety
	Productivity	Lint percent Lint yield (lbs/acre)	Same as counterpart variety, with the exception of inconsistent lint percent values between sites
3. Plant reproductive characteristics	Reproduction	Pollen morphology Days to first bloom Days to first open boll Days to 50% open bolls	Same as counterpart variety
	Fecundity	Fertility / seed per plant Pollen germination and viability Number of seed per boll Seed index	Same as counterpart variety
	Disease susceptibility	Severity rating for naturally occurring pathogens	Same as counterpart variety
4. Key nutrients	Nutritional composition of seed	Proximates (moisture, total fat, total protein, ash, total carbohydrates, crude fiber, ADF, NDF), amino acids, minerals, fatty acids, vitamin E	Same as counterpart variety
	Anti-nutritional components	Gossypol, cyclopropenoid fatty acids and phytic acid	Same as counterpart variety

7.5 Product specification

The derived food is cottonseed oil.

Glufosinate ammonium-tolerant and insect-protected cotton transformation event BG2xLL has been conventionally bred into an array of varieties with adaptation to the various zones of cotton cultivation. BG2xLL varieties belong to the species, *Gossypium hirsutum* L. and are distinguished from other cotton only by tolerance to the herbicide, glufosinate ammonium, and the insect resistance traits inherited from the parents lines.

7.6 Effect of processing

As cotton BG2xLL is substantially equivalent to traditional cottons in commerce, the same production process applied to cotton will be used for the seed derived from BG2xLL cotton varieties. The genetic modifications were not aimed at changing the processing methods.

7.7 Anticipated intake/extent of use

The intake of cottonseed oil in the diet of the European Union (EU25) is not anticipated to change with the introduction of BG2xLL varieties. Cottonseed products derived from BG2xLL cotton varieties are not different in quality or nutritional composition from the cottonseed products now consumed. No change in the use patterns for cottonseed oil is anticipated. No potential dietary and nutritional impacts have been identified for cottonseed products derived from BG2xLL cotton varieties.

The total consumption of cottonseed oil for the European diet was 29,863 metric Tons (mT) in 2003. The extremes of cottonseed oil consumption in the member States include 20,667 mT in Spain and 6,370 mT in Greece down to 36 mT for the Belgian population. Luxembourg, Germany and Italy did not consume any. In Turkey during that same period, the total consumption was 192,981 mT, amounting to a *per capita* consumption of 2.7 kg/year (FAOStat, 2006).

7.8 Toxicology

7.8.1 Safety assessment of newly expressed proteins

BG2xLL was produced by the traditional breeding cross of LLCotton25 and MON 15985. The new traits in BG2xLL are inherited from LLCotton25 and MON 15985.

The safety of these events has been assessed. The proteins encoded by the introduced genes are not toxic to mammals and present no unacceptable risk to human safety, and no risk specific to the expression of the new proteins in the same plant can be anticipated.

For more information on LLCotton25, please refer to application EFSA/GMO/NL-2005-13.

For more information on MON 15985, please refer to application EFSA/GMO/UK-2005-10.

7.8.2 Testing of new constituents other than proteins

Not required for BG2xLL cotton, as no constituent other than the Cry1Ac, Cry2Ab2, GUS, NptII and PAT proteins is novel.

7.8.3 Information on natural food and feed constituents

Natural constituents of cotton have not been changed in BG2xLL. 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 cottons contain cyclopropenoid fatty acids (CPFA), gossypol and phytic acid, natural compounds that are considered to be undesirable and anti-nutritional. The steps taken during the processing of cottonseed, in order to produce cottonseed oil, detoxify gossypol and greatly reduce the CPFA content. Phytic acid is not present in the lipid fraction. 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

An animal feeding study was conducted to supplement the safety evaluation: this feeding study was performed with male broiler chickens. Poultry were selected to evaluate the effects of a feed component over an entire life span and under conditions of rapid growth, thus the assay is highly sensitive for nutritional deficiencies or toxic effects.

The broiler chicken is an economically significant and widely distributed food animal. The species used is based upon commercial practice and is very sensitive to detect differences in nutrient quality because of its rapid growth (30-fold increase in body weight over four weeks). This study showed no indications that neither the events LLCotton25 and MON 15985 nor breeding cross itself, has adverse effects on feeding, growth or general health. Moreover, no negative impacts of the nutritional quality of BG2xLL were observed on poultry.

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

The scope of the current application covers cottonseed oil and its constituents produced from BG2xLL.

For more information on the allergenicity of the PAT/*bar* protein introduced in cotton event LLCotton25, please refer to application EFSA/GMO/NL-2005-13.

For more information on the allergenicity of the proteins introduced in cotton event MON 15985, please refer to application EFSA/GMO/UK-2005-10, and AFSSA Opinion (2005).

7.9.2 Assessment of allergenicity of the whole GM plant or crop

Cotton (*Gossypium hirsutum* L.) is not considered an allergenic food.

The introduced proteins do not have any allergenic potential, the BG2xLL cotton does not lead to an increased risk for allergic reactions compared to the equivalent range of food and feed uses of traditional cotton.

7.10 Nutritional assessment of GM food/feed

7.10.1 Nutritional assessment of GM food

BG2xLL expresses the introduced traits of insect protection and glufosinate-ammonium tolerance, which are agronomic traits and are not expected to change any nutritional aspect in this cotton.

A multi-site trial design provided a robust data set to demonstrate that the key nutrients, fatty acids and vitamin E (tocopherol), which are the principal components of cottonseed oil, from BG2xLL, are not different from those of the non-transgenic counterpart, and values for nutritional components fall within the range of values reported for commodities in commerce. As a consequence, no further nutritional assessment of BG2xLL for use in food is considered necessary.

Finally the uses are anticipated to be the same as the uses of the conventional non-GM products. Therefore no specific concerns have been identified as a result of the use of BG2xLL.

7.10.2 Nutritional assessment of GM feed

Once compositional equivalence has been established in GM feed modified for agronomic input traits, nutritional equivalence can be assumed. The results of the compositional analyses have established the compositional equivalence of cottonseed from BG2xLL and traditional cottonseed and as a

consequence, no further nutritional assessment of BG2xLL for use in feed is considered necessary.

Considering the compositional equivalence of BG2xLL, it can be concluded that cottonseed oil and its constituents, produced from BG2xLL are equivalent to cottonseed oil produced from traditional cotton and have the same nutritional properties.

7.11 Post-market monitoring of GM food/feed

No post-market monitoring plan is required for GM food/feed produced from BG2xLL. A traditional comparator, the cotton variety, FM989, was used in the comparative analysis (D.7.1-3). The intent of the genetic modification was for agronomic benefit (D.7.4), no change in the nutritional composition or value was intended and no change was identified (D.7.6, D.10). No health claims are intended and BG2xLL will not be marketed as an alternative to or replacement for traditional cotton (D7.5). BG2xLL has no specific properties that might increase the dietary intake compared to traditional cotton (D.7.7). There is no evidence that the long term nutritional and health status of the European population could be impacted by the marketing of BG2xLL (D.7.8-10).

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

Not applicable. There are no target organisms.

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

Not applicable as this application under Regulation (EC) No 1829/2003 includes food and feed, specifically oil and its constituents, produced from BG2xLL for uses equivalent to any other cotton and does not include the import of whole seeds and environmental release of this cotton in the E.U.

9.1 Persistence and invasiveness

Please see question D.9

9.2 Selective advantage or disadvantage

Please see question D.9

9.3 Potential for gene transfer

Please see question D.9

9.4 Interactions between the GM plant and target organisms

Please see question D.9

9.5 Interactions of the GM plant with non-target organisms

Please see question D.9

9.6 Effects on human health

Please see question D.9

9.7 Effects on animal health

Please see question D.9

9.8 Effects on biogeochemical processes

Please see question D.9

9.9 Impacts of the specific cultivation, management and harvesting techniques

Please see question D.9.

10. Potential interactions with the abiotic environment

Not applicable as this application under Regulation (EC) No 1829/2003 includes food and feed, specifically oil and its constituents, produced from BG2xLL for uses equivalent to any other cotton and does not include the import of whole seeds and environmental release of this cotton 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 and if the applicant has clearly shown that environmental exposure is absent or will be at levels or in a form that does not present a risk to other living organisms or the abiotic environment)

Not applicable as the EFSA opinion document on the Post Market Environmental Monitoring (PMEM) of genetically modified plants¹ has excluded an environmental monitoring plan (including general surveillance) in the case of non-viable GM material (*e.g.* derived products not containing any living GMOs). There will be no environmental release or import of cottonseed of BG2xLL in the E.U. The scope of the current application only includes food and feed and its constituents produced from oil, derived from BG2xLL.

11.1 General (risk assessment, background information)

Please see question D.11

11.2 Interplay between environmental risk assessment and monitoring

Please see question D.11

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

Please see question D.11

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

Please see question D.11

11.5 Reporting the results of monitoring

Please see question D.11

¹ Opinion of the Scientific Panel on Genetically Modified Organisms on the Post Market Environmental Monitoring (PMEM) of genetically modified plants, The EFSA Journal (2006), 319, 1-27

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

A discriminating PCR (dPCR) method and control materials have been provided to the DG Joint Research Centre – Community Reference Laboratory – as defined by EU Regulation 1829/2003.

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**

No releases of BG2xLL have been made under Part B.

b) Conclusions of post-release monitoring

No release in Europe, however in the USA, no persistent volunteers that could not be managed by current agricultural practice were observed.

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

No release in Europe, however in the USA, no human health or environmental risks were observed.

2. History of previous releases of the GM plant carried out outside the Community by the same notifier**a) Release country**

Field tests of BG2xLL in the US and Australia have been conducted since 2002.

b) Authority overseeing the release

USA: There is no oversight specific to the combined trait product in US as the single traits are approved.

Australia: Office of Gene Technology Regulator.
Information on the releases at <http://www.ogtr.gov.au/>

c) Release site

See E.2.b

d) Aim of the release

See E.2.b. Field releases for breeding and variety development, technical developments for best agronomic practices and cotton integrated pest management systems have been conducted.

e) Duration of the release

The generation time for cotton from planting to harvest is 100 to 200 days.

f) Aim of post-releases monitoring

See E.2.b.

g) Duration of post-releases monitoring

See E.2.b.

h) Conclusions of post-release monitoring

See E.2.b.

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

No risk to human health or the environment has been indicated by the field release experience.

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 JRC websites http://gmoinfo.jrc.it/gmc_browse.asp and <http://gmocrl.jrc.it/statusofdoss.htm> provide publicly accessible links to up-to-date databases on the regulatory progress of notifications under Regulation (EC) No 1829/2003.

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

Not applicable.

c) EFSA opinion

Not yet available

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

Not yet available

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

Information on detection protocols will likely be posted at www.gmo-crl.jrc.it/

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

www.bch.biodiv.org/

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

Not applicable