# PART II

## SUMMARY OF THE APPLICATION FOR REQUEST FOR AUTHORIZATION

## GLYPHOSATE-TOLERANT COTTON GHB614
## FOR FOOD AND FEED USES, AND IMPORT AND PROCESSING,
## IN ACCORDANCE WITH ARTICLES 5 AND 17 OF REGULATION 1829/2003
## GM FOOD AND GM FEED, AND
## FOR INDUSTRIAL USES

## A. GENERAL INFORMATION

### 1. Details of application

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|---|
| 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):**<br>GlyTol™ Cotton, Event GHB614 (OECD code BCS-GHØØ2-5)<br>Seed of genetically modified cotton (*Gossypium* spp.) with tolerance to herbicide products containing the active ingredient glyphosate, derived by traditional breeding methods from crosses between GM cotton event GHB614 (OECD code BCS-GHØØ2-5) and non-GM cotton varieties. |
| d) **Date of acknowledgement of valid application:** Not available at the date of application |

### 2. Applicant

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|---|
| a) **Name of applicant:** Bayer CropScience AG, represented by Bayer BioScience NV |
| b) **Address of applicant:**<br>Bayer CropScience AG<br>Alfred-Nobel-Strasse 50<br>D - 40789 Monheim am Rhein<br>Bayer BioScience NV<br>Technologiepark 38<br>B-9052 Gent<br>**E-mail address:** info@bayercropscience.com |
| 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)):**<br>GHB614 cotton will be imported and processed in the EU by the same groups who currently import, process and distribute commodity cottonseed. |

**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 ☐ | No ☒ |
| If *yes*, specify | |

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

| | |
|---|---|
| Yes ☒ | No ☐ |
| 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 ☐ | No ☒ |
| If *yes*, specify: | |

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

| | |
|---|---|
| Yes ☒ | No ☐ |
| If *yes*, specify:<br>Authorisation requested for cultivation and commercial use in USA.<br>Authorisations requested for food, feed and industrial uses in Australia & New Zealand, Canada, Japan, Korea and Mexico. | |

## 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 is cotton, *Gossypium* spp. The genetic modification confers tolerance to the active ingredient glyphosate through the genetic locus defined as GHB614. GlyTol cotton varieties are developed by traditional breeding methods from crosses between GHB614 and conventional cotton adapted for planting in the temperate cotton production regions of the Americas. Glyphosate (N-phosphonomethyl-glycine) is a non-selective, foliar applied, broad-spectrum and post emergent herbicide.

The *epsps* gene was originally isolated from maize. The *2mepsps* gene encodes a modified 5-enolpyruvyl-shikimate-3-phosphate synthase (2mEPSPS), that is insensitive to the action of glyphosate, and thereby allows the plant to grow in the presence of the herbicide. The modified 2mEPSPS protein differs from the wild type maize EPSPS enzyme by two amino acid substitutions.

Agricultural production of commercial cotton requires weed control, and successful weed control depends upon a combination of management practices. For temperate cotton production, farmers use the planting of weed-free seed, crop rotations to break weed cycles, precision land levelling to aid irrigation, seed bed preparation, conservation tillage programs, the application of one or more herbicides and herbicide rotation.

Growing GlyTol cotton allows: 1) More options to rotate herbicides for weed resistance management programs, 2) Control of less sensitive weeds (*i.e.*, nutsedge, pigweed, grasses…), thus more options for crop management, lesser impact on cotton growing areas and potential implications for soil conservation through minimum tillage practices whilst maintaining excellent crop performance and yield, 3) New cotton varieties with enhanced cotton germplasm which provide robust, season-long tolerance to a number of commercial formulations of glyphosate herbicide.

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

Two different types of product are planned to be placed on the market: 1) grain from GHB614 and 2) cottonseed products derived from event GHB614.

1) GHB614 grain will be imported, processed and distributed in the European Union similar to current cottonseed usage (food, feed and industrial uses) excluding cultivation.

2) Cottonseed products derived from event GHB614 (cottonseed oil, meal and linters) will be imported in the EU, similar to current usage of products derived from cottonseed (food, feed and industrial uses).

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

In the EC, cotton grain and meal are used as high protein sources especially in the dairy industry. Cottonseed oil is an important vegetable oil source. GHB614 grain and cottonseed products derived from event GHB614 will be imported in the EU from the major cotton growing areas as a commodity and will be used for downstream purposes for food, feed and industrial products identical to current cottonseed and cottonseed products imports.

**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 cotton today remain adequate for the handling of glyphosate-tolerant, GHB614 cotton varieties.

When genetically modified cotton is placed on the EU market (including co-mingled with conventional cotton during use, storage and handling), the corresponding batch will be labelled and handled according to the relevant EU legislation, in particular Regulation (EC) 1830/2003.

**e) Any proposed packaging requirements:**

Cotton grain will be imported as a bulk and will not be packaged.

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:**

GHB614 does not harbour characteristics that require specific labelling. Hence, no additional labelling is proposed other than the GM labelling requirements under 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):**

BCS-GHØØ2-5.

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 GHB614 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 majority of imported cotton commodities will be processed products from different levels of downstream processing without the ability for natural reproduction. Viable cottonseed will be imported in small quantities only. The safety profile in terms of human and animal health and environmental impact of grains of GHB614 and conventional cottons are identical and do not constitute a hazard.

The case of accidental spillage of non-processed GHB614 grains, in transit or at the processing facility, has been assessed in the risk assessment and foreseen in the post market monitoring plan (see paragraph 11.4).

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

### 1. Complete name

| | |
|---|---|
| a) Family name: | *Malvaceae* |
| b) Genus: | *Gossypium* |
| c) Species: | *hirsutum* |
| d) Subspecies: | Not applicable |
| e) Cultivar/breeding line or strain: | GHB614 cotton |
| f) Common name: | cotton |

### 2 a. Information concerning reproduction

(i) Mode(s) of reproduction

Vegetative proliferation of cotton requires human intervention; therefore the mode of reproduction can be restricted to sexual reproduction only, through the production of seeds.

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

Gene flow can occur into an adjacent cotton crop however, the rate is likely to be very low because there exists a combination of genetic, botanical, geographic and agricultural barriers to gene flow. Gene flow will not occur into compatible wild *Gossypium* species, as these are not present in Europe.

(ii) Specific factors affecting reproduction

The main abiotic environmental factors affecting cotton reproduction which also determine the areas of cotton production are **high light intensity** and **optimal temperature profiles**, such as a) active vegetative growth range: 15 - 38 °C, b) accumulated heat GD 15.5°C need: 1,200 units, c) number of frost free days: 200, d) rapid and consistent spring warming pattern**.**

Although cotton is mainly autogamous, the **frequency of cross-pollination** varies with **the insect pollinator population,** in particular with various wild bees, bumble bees (*Bombus* ssp.) 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 when found 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 identified non-cotton plants that are sexually compatible with cultivated cotton varieties presently found in the EU.

***Pre-zygotic***, and ***post-zygotic*** **barriers** greatly limit the sexual compatibility of *G. hirsutum* and *G. barbadense* with other plant species in the Gossypiae tribe. In addition plants of the *Gossypium* genus are not native to Europe. Several members of the Malvaceae family 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* spp. failed or resulted in sterile seeds.

*G. hirsutum* and *G. barbadense*, allotetraploid species that combine the AADD genomes, will hybridise only with other tetraploid members of the *Gossypium* genus including *G. tomentosum, G. darwinii, G. mustelinum, G. hirsutum, G. barbadense* and *G. lanceolatum*, 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 and cannot survive without human assistance. 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 cotton seed 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, the cotton seed is likely to rot and die.

## 4. Dissemination

### a) Ways and extent of dissemination

The two differentiated reproductive structures suitable for dispersal of 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 principally located 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, while South America is considered to be the center of origin of the species *G. barbadense*. Cultivated *G. hirsutum* (Upland or Mexican cotton) represents over 90 % of world-wide production besides one only "New World" tetraploid species, *G. barbadense* (Pima, South American cotton or Egyptian cotton) and two "Old World" 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 mainly *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

Today, cotton is commercially grown in **Greece** and **Spain**, and very few hectares also in **Bulgaria** 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, nematodes, surrounding weed species, animals and humans**. The crop has been cultivated in Spain and Greece for centuries and has a history of safe use.

The cotton crop was produced for fibre for thousands of years, and was first utilized for food and feed in the 20$^{th}$ century. Cotton is not considered harmful or pathogenic to animals or humans, however the plant does produce a small amount of natural anti nutritional factors such as **gossypol and cyclopropenoid fatty acids.**

All of the anti-nutritional factors 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

The genetic modification was performed by *Agrobacterium*-mediated introduction of the chimeric gene.

## 2. Nature and source of the vector used

Plasmid pTEM2 is a derivative of pGSC1700 (itself a derivative of the vector pBR322), which was constructed in *Escherichia coli*, and thereafter transferred to a suitable *Agrobacterium tumefaciens* strain.

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

The genetic elements to be transferred into the plant are described in Table 1.

**Table 1. Size, source and intended function of each constituent fragment of the region intended for insertion**

| Source | Approximate Size (Kb) | Reference | Intended function |
|---|---|---|---|
| Left border repeat from *Agrobacterium tumefaciens* | 0.03 | Zambryski, 1988 | *Cis*-acting element for T-DNA transfer |
| **Ph4a748At**: promoter from *Arabidopsis thaliana* | 1.01 | Chaboute *et al*., 1987 | High level constitutive expression, especially in the rapidly growing plant tissues |
| **intron1 h3At**: intron from *Arabidopsis thaliana* | 0.52 | Chaubet *et al*., 1992 | |
| **TPotpC**: transit peptide from *Zea mays* and *Helianthus annuus* | 0.37 | Lebrun *et al*., 1997 | Targeting of the protein to the plastids |
| ***2mepsps***: glyphosate tolerance gene from *Zea mays* | 1.34 | Lebrun *et al*., 2003 | Herbicide tolerance and selectable marker |
| **3' histon At**: Terminating signal from *Arabidopsis thaliana* | 0.74 | Chaboute *et al*., 1987 | Stop signal |
| Right border repeat from *Agrobacterium tumefaciens* | 0.03 | Zambryski, 1988 | *Cis*-acting element for T-DNA transfer |

Chaboute M., Chaubet N., Philipps G., Ehling M., Gigot C. 1987. Genomic organization and nucleotide sequences of two histone H3 and two histone H4 genes of *Arabidopsis thaliana*. Plant Molecular Biology. 8: 179-191.

Chaubet N., Clement B., Gigot C. 1992. Genes encoding a histone H3.3-like variant in *Arabidopsis* contain intervening sequences. J. Mol. Biol. 225: 569-574.

Lebrun M., Leroux B., Sailland A. 1997. Chimeric gene for the transformation of plants. US Patent US5510471 (23-APRIL-1996). RHONE POULENC AGROCHIMIE (FR).

Lebrun M., Sailland A., Freyssinet G., Degryse E. 2003. Mutated 5- enolpyruvylshikimate-3-phosphate synthase, gene coding for said protein and transformed plants containing said gene. US patent US6566587B1 ( 20-MAY-2003). BAYER CROPSCIENCE SA (FR).

Zambryski P. 1988. Basic processes underlying *Agrobacterium*-mediated DNA transfer to plant cells. Ann. Rev. Genet. 22: 1-30.

## D. INFORMATION RELATING TO THE GM PLANT

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

GlyTol cotton is tolerant to commercial herbicide products containing the active ingredient glyphosate. The herbicide tolerance is based upon the *2mepsps* gene, which encodes a modified 5-enolpyruvyl-shikimate-3-phosphate synthase (2mEPSPS). The 2mEPSPS enzyme confers tolerance to herbicide products containing glyphosate. Glyphosate is a broad-spectrum herbicide that works by inhibiting the enzyme, EPSPS, involved in the shikimic acid pathway for aromatic amino acids in plants and micro organisms. The *epsps* gene was originally isolated from maize (*Zea mays* L.). The modified 2mEPSPS protein differs from the wild type maize EPSPS enzyme by two amino acid substitutions, which results in a protein with high tolerance to glyphosate. The 2mEPSPS enzyme is not inhibited by glyphosate and the expression is sufficiently high to provide a good level of specific activity and ensure glyphosate tolerance to cotton event GHB614.

Cotton varieties with the genetic insertion GHB614 express the 2mEPSPS protein mainly in their young and green leaf tissues. When sprayed with herbicide products containing glyphosate, the GHB614 plants can continue growing while the surrounding weeds rapidly die.

Several formulations of glyphosate are commercially used in many regions of the world.

### 2. Information on the sequences actually inserted or deleted

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

Southern blot, PCR and sequence analysis demonstrated that the glyphosate-tolerant cotton event GHB614 contains one copy of the *2mepsps* gene.

**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**

Based upon Southern blot and genetic segregation analysis, it was demonstrated that the DNA is integrated in a single genetic locus in the cotton nuclear genome (chromosome).

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

The characterization of the inserted sequences in event GHB614 confirmed the presence of one intact copy of the *2mepsps* gene cassette, and also the absence of vector backbone. There are no antibiotic resistance markers present in GHB614.

### 3. Information on the expression of the insert

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

The promoter used for the transformation of GHB614 drives a constitutive expression of the *2mepsps* gene. The amount of 2mEPSPS protein in the leaves of GHB614 during the vegetative life cycle of the plant has an upper limit of approximately 15 µg/g fresh weight (0.14% of the total crude protein). The mean amount of 2mEPSPS protein in fuzzy seed is 21.2 µg/g fresh weight (0.01% of the total crude protein).

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

Controlled by a promoter and an intron, both of plant origin, the expression of the *2mepsps* gene is mainly targeted to rapidly growing green tissues of the plant. Expression level was measured by 2mEPSPS protein specific ELISA. Tissue samples were harvested from greenhouse grown cotton, under conditions representative of cotton cultivation, at the 2-3 and 4-6 leaf stages of growth, pre-flowering and at flowering. It was found that 2mEPSPS protein ranged between 0.45 - 11.16 µg/g fresh weight of leaves, 0.99 - 4.04 µg/g fresh weight of roots, 1.58 - 1.94 µg/g fresh weight of stems, depending on the growth stage of the plant, and was 5.47 ± 0.22 µg/g fresh weight of apices, 5.35 ± 0.25 µg/g of squares and 0.16 ± 0.01 µg/g fresh weight of pollen. 2mEPSPS protein comprises a maximum of 0.39 %, 0.34 %, 0.18 %, 0.06 % and 0.001 % of the total crude protein in leaves, apices, roots and squares, stems and pollen respectively, of cotton event GHB614.

From published experience with the promoter and intron used, GHB614 plants were expected to show high levels of 2mEPSPS protein in rapidly growing plant parts, and lesser amounts in the other organs. Indeed, the following order of 2mEPSPS expression was found: leaf, apex >> roots, squares >> stems, seeds >> pollen.

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

**a) Reproduction**

The trait of herbicide tolerance had no effect on the mode and rate of seed reproduction which was found to be the same as for conventional cotton, as observed during two seasons of field trials.

**b) Dissemination**

Two developmental stages in cotton are susceptible to dispersal: pollen and seed. No differences in dissemination capacity have been observed between GHB614 and conventional cotton. Studies show that the genetic modification did not change any characteristics of the cotton that could impact dissemination:

- no difference in pollen characteristics including viability, fertility in crosses as either a male or female parent;
- no difference in pollen dispersal to cultivated cotton;
- no difference in seed morphology or fecundity measured as number of seed per boll and 100 seed weight;
- no difference in germination/stand count, seedling vigour or dormancy as measured by standard laboratory cotton seed physiology tests.

**c) Survivability**

For cultivated cotton, survival is primarily determined by seed characteristics. There is no indication of any changes in the seed characteristics as a result of the genetic modification.

**d) Other differences**

The only biologically significant difference observed in field evaluations is that cotton varieties based upon transformation event GHB614 are tolerant to herbicide products containing glyphosate.

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

The trait is inherited as a single dominant gene. To demonstrate the stability of the inserted DNA, Southern blot analysis was completed for plants of different generations, different environmental growth conditions and from crosses into different genetic backgrounds.

The isolated DNA was digested with the *Eco*RV restriction enzyme, which has one recognition site in the insert. Probing *Eco*RV restricted genomic DNA with the "promoter-intron-transit peptide" fragment of pTEM2 showed the two expected bands in all samples of cotton event GHB614. These bands represent the 5' and 3' integration fragments, and were identical in all 179 tested samples.

The resulting Southern blots demonstrate the molecular stability of the cotton GHB614 at the genetic level over multiple generations, different locations, and in 2 distinctive genetic backgrounds.

Phenotypic stability was demonstrated by Mendelian inheritance.

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

### a) Plant to bacteria gene transfer

No aspect of the nature of the genetic elements used gives any indication that a transfer from GHB614 to bacteria could occur.

### b) Plant to plant gene transfer

**Genetic transfer possible only to cotton.** There is no evidence of genetic transfer and exchange under natural conditions with organisms other than those with which cotton is able to produce fertile crosses through sexual reproduction. There are no indications that the potential for successful exchange of genetic material has changed due to the genetic modification.

## 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

GHB614 was compared to its parent variety, Coker 312.

### 7.2 Production of material for comparative assessment

#### a) Number of locations, growing seasons, geographical spread and replicates

The geographic range included the Southern United States cotton growing regions of Arkansas, Florida, Georgia, Mississippi and Texas. Seed samples were collected from two growing seasons (2005 and 2006), 17 locations, three treatments from every location, and a 3-fold replication per treatment, as well as 8 locations repeated over 2 years. The three treatments consisted of: a) conventional cotton grown using conventional herbicide weed control, b) GHB614 cotton grown using conventional herbicide weed control, and c) GHB614 cotton grown with glyphosate herbicide weed control.

#### b) The baseline used for consideration of natural variations

A range of values to be expected for each nutritional component was established from published literature, as well as from the values for the reference counterpart variety, Coker 312.

### 7.3 Selection of material and compounds for analysis

Bayer CropScience undertook a systematic review of the composition of the seed derived from GHB614. The scope of the evaluation included the seed and selected processed seed products. The components selected for compositional and nutritional analyses comprise the important nutrients of cotton, as defined by the OECD. These are proximates, amino acids and fatty acids, micronutrients such as vitamins and minerals, and anti-nutrients such as gossypol and cyclopropenoid fatty acids. The data demonstrate that grain from GHB614 has the same nutritional composition as its conventional counterpart, and values for nutritional components fall within the range of values reported for commodities in commerce.

Cottonseed oil is a high-quality cooking oil, due to its balance in unsaturated fatty acids, and high tocopherol (vitamin E) content. The lipid profile is preserved in GHB614: the fatty acid levels in the cottonseed oil samples are similar to those of the conventional counterpart and within the range reported by the literature, and the tocopherol determinations show an excellent correspondence for crude and refined-deodorised cottonseed oil samples.

Anti nutritional factors common to cotton were best measured in toasted cottonseed meal and are well below acceptable levels, and similar to levels in conventional cotton.

### 7.4 Agronomic traits

Throughout the field testing history of GHB614 there were no differences observed that could be attributed to pleiotropic effects of the *2mepsps* gene insertion. Neither did GHB614 differ from the parent variety in agronomic or reproductive characters. 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. The variety development program performed replicated agronomic evaluations in 2004-2005 in Georgia, Louisiana, Mississippi, Missouri, North Carolina, South Carolina and Texas. A summary of the comparisons between GHB614 and its parent cotton variety, Coker 312, is provided in Table 2.

There is no indication in the data of agronomic performance that GHB614 is unlike cotton that is currently grown and consumed.

### 7.5 Product specification

The derived food is cottonseed oil and cottonseed linters, and the derived feed the by-products of cottonseed processing (e.g. cottonseed meal).

Glyphosate-tolerant cotton event GHB614 has been conventionally bred into an array of varieties with adaptation to the various zones of cotton cultivation (GHB614 varieties). GHB614 varieties belong to the species, *Gossypium hirsutum* L. / *G. barbadense* L. and are distinguished from other cotton only by tolerance to herbicide products containing glyphosate, the genetic locus defined as GHB614 and the presence of the 2mEPSPS protein.

### 7.6 Effect of processing

The GHB614 varieties are grown using the agronomic practices of the region of production, and the seed is harvested, transported, stored and processed using the same processes as cotton currently in commerce. The genetic modification was not aimed at changing the processing method.

Upon chemical analysis, the nutritional composition of whole seed and processed seed (delinted seed, lint, untoasted and toasted cottonseed meal, crude and refined cottonseed oil) were found to be equivalent to any other conventional cotton variety.

Processing using heat, for example cooking, high pressure steam, plus solvents, alkali treatments, degrades the 2mEPSPS protein, which was not detected in toasted meal and crude or refined oil.

**Table 2. Summary of parameters evaluated in the comparison of varieties containing GHB614 and the parent cotton variety, Coker 312**

| Characteristic | Parameters | Finding |
|---|---|---|
| **Plant morphology using PVP standards** (Plant Variety Protection standard descriptors of the USDA) | Overall plant morphology<br>Height to node ratio<br>Leaf morphology<br>Strain uniformity | Same as recipient variety |
| **Fibre quality using PVP standards** | Micronaire<br>Fibre elongation<br>Fibre strength<br>Fibre length<br>Fibre length uniformity | Same as recipient variety or better |
| **Field performance** | Emergence and stand establishment<br>Rate of growth<br>Total boll load<br>Height | Same as recipient variety or better |
| **Productivity** | Yield seed cotton<br>Lint percent<br>Lint yield | Same as recipient variety or better |
| **Pest and disease resistance** | Severity rating for naturally occurring pathogens | Same as recipient variety |
| **Dormancy** | Germination rate | Same as recipient variety |
| **Persistence** | Census of volunteers in the subsequent season | Same as recipient variety |
| **Reproduction** | Days to first bloom<br>Flower morphology<br>Days to first open boll<br>Fertility | Same as recipient variety |
| **Fecundity** | Seed per boll<br>Seed index (100 seed weight) | Same as recipient variety |
| **Nutritional composition of seed** | Proximates, amino acids, minerals, vitamin E, fatty acids | Same as recipient variety |
| **Anti-nutritional components** | Gossypol, cyclopropenoid fatty acids | Same as recipient variety |

## 7.7 Anticipated intake/extent of use

The intake of cottonseed oil and linters in the diet of the European Union is not anticipated to change with the introduction of GHB614 varieties. Cottonseed and cottonseed products derived from GHB614 varieties are not different in quality or nutritional composition from the cottonseed products now consumed. No change in the use patterns for cotton is anticipated. No potential dietary and nutritional impacts have been identified for cottonseed and cottonseed products derived from GHB614 varieties.

The *per capita* consumption of cottonseed oil for the European diet is 0.04 kg/year. The extremes of cottonseed oil consumption in the Member States include 0.50 kg/person/year in Spain and 0.58 kg/person/year in Greece. Austria, Luxembourg, Germany and Italy do not consume any. The *per capita* consumption in Turkey is 2.71 kg/year.

## 7.8 Toxicology

### 7.8.1 Safety assessment of newly expressed proteins

The 2mEPSPS protein is not toxic to mammals and does not possess any of the characteristics associated with food allergens. Findings to support this conclusion include:

- The coding sequence of the *2mepsps* gene is derived from maize, a safe crop plant widely used for food and feed with little pathogenic, toxic or allergenic effects for humans and animals;
- The 2mEPSPS protein is quickly degraded and denatured in simulated gastric and intestinal fluids;
- The identity of the 2mEPSPS enzyme with the wild type maize EPSPS is greater than 99.5 %. The metabolic effects of the 2mEPSPS in plants are comparable to those of endogenous plant EPSPS enzymes except for the insensitivity to glyphosate;
- The 2mEPSPS is present at extremely low levels in GHB614;
- An acute oral toxicity study of 2mEPSPS in mice confirmed that the protein is not toxic to mice at the high dose tested of 2000 mg/kg body weight.

Supplemental information was also provided by a poultry feeding study showing no adverse effects on chickens.

### 7.8.2 Testing of new constituents other than proteins

No other constituent than the 2mEPSPS protein is novel and no changes in composition of cotton were discovered by chemical analysis.

### 7.8.3 Information on natural food and feed constituents

Plants are known to naturally produce toxins and allergens that often serve the plant as natural defence compounds against pests and pathogens. The inclusion of cottonseed products in human food or animal feed is limited due to the presence of some anti-nutrients in cottonseed that could act as toxic compounds. These anti-nutritional and toxic factors are gossypol and cyclopropenoid fatty acids (CPFA). Gossypol is present in the meal and the seed. Thus, the cottonseed is processed to reduce the content of gossypol and CPFA to acceptable levels as well as to minimise the toxicological properties of these two compounds.

Cottonseed oil intended for human consumption is highly purified: the purification process substantially reduces the content of CPFA and gossypol. Therefore, cottonseed oil and meal are currently considered not to contain common food toxins or anti-nutritional compounds of concern for human and animal health, because either the product only has minor amounts of these active compounds or their levels decrease (or they even disappear) during processing.

Natural constituents of cotton have not been changed in GHB614. Extensive compositional analysis was undertaken, taking into consideration the OECD consensus document on “compositional considerations for new varieties of cotton: key food and feed nutrients and anti-nutrients”. Equivalence in the fuzzy seed was demonstrated for all proximates, fiber compounds, and the total amino acids. Good agreement between the findings for GHB614, the comparator and the baseline support the conclusion of compositional equivalence to cotton currently in commerce.

### 7.8.4 Testing of the whole GM food/feed

Although not scientifically requested, a zootechnical study was conducted to supplement the safety evaluation: this 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 for the detection of differences in nutrient quality because of its rapid growth (45-fold increase in body weight over 40 days). This study showed no indications that neither the event GHB614 nor the transformation process itself, has adverse effects on feeding, growth or general health. Moreover, no negative impacts of the nutritional quality of the event GHB614 were observed on poultry.

## 7.9 Allergenicity

### 7.9.1 Assessment of allergenicity of the newly expressed protein

The 2mEPSPS protein does not possess any of the characteristics associated with food allergens.

The 2mEPSPS protein has no homology with any known allergens, toxins or anti nutrients.

The 2mEPSPS protein has no glycosylation sites present on certain food allergens.

The 2mEPSPS protein forms only an extremely minor part of the crude protein fraction in GHB614, making it unlikely to become a food allergen, as food allergens tend to be major proteins.

### 7.9.2 Assessment of allergenicity of the whole GM plant or crop

Cotton (*Gossypium* spp.) is not considered an allergenic food crop.

A consideration of specific food safety issues did not identify food allergenic potential as one outcome that would cause concern for human consumption. Edible oils that are refined, bleached and deodorised do not appear to pose a risk to allergic individuals, as they contain virtually no proteins. Literature to date on cottonseed oil validates this theory: the absence of water-soluble allergens in cottonseed oil is correlated with no clinical allergy observations after consumption of cottonseed oil. Therefore, no allergic reaction is expected from its current use pattern.

## 7.10 Nutritional assessment of GM food/feed

### 7.10.1 Nutritional assessment of GM food

The introduced trait in GHB614 is intended for agronomic benefits. Extensive compositional analysis was undertaken, taking into consideration the OECD consensus document on “compositional considerations for new varieties of cotton: key food and feed nutrients and anti-nutrients”. No change in the nutritional composition was intended and upon extensive analysis, none was found.

The primary use of cotton is for the textile industry. However the by-products of cotton ginning find many uses in human and animal diets. Compositional equivalence was demonstrated for the food proprieties of the cottonseed oil. The key nutrients, fatty acids and vitamin E (tocopherol), which are the principal components of cottonseed oil, were investigated. The lipid profile is preserved in GHB614, and the fatty acid levels in the cottonseed oil samples are similar to those of the conventional cottonseed oil samples and within the range reported in the literature.

Cottonseed oil from GHB614 has the same nutritional composition as its conventional counterpart, and values for nutritional components fall within the range of values reported for cotton commodities in commerce.

### 7.10.2 Nutritional assessment of GM feed

Extensive compositional analysis was undertaken, taking into consideration the OECD consensus document on “compositional considerations for new varieties of cotton: key food and feed nutrients and anti-nutrients”. The by-products of cottonseed processing (cottonseed meal and cottonseed hulls) can be used in animal feed. Cotton contains some anti-nutritional factors, most of which are concentrated in the meal fraction. The anti-nutritional compounds include gossypol and cyclopropenoid fatty acids, which are subject to heat denaturation. Cottonseed meal is typically subjected to a moist heat treatment to facilitate oil removal. This treatment denatures proteins and detoxifies the gossypol that otherwise would cause the cottonseed meal to be unsuitable as an animal feed. Anti-nutritional compounds common to cotton were best measured in toasted cottonseed meal and are well below acceptable levels, and similar to levels in conventional cotton.

In addition, the wholesomeness of GHB614 has been demonstrated in a zootechnical study with chicken.

## 7.11 Post-market monitoring of GM food/feed

No post-market monitoring plan is required for GM food/feed produced from GHB614. A traditional comparator, the cotton variety Coker 312, was used in the comparative analysis (D.7.1-3). The intent of the genetic modification was for agronomic benefits (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 GHB614 will not be marketed as an alternative to or replacement for traditional cotton (D7.5). GHB614 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 GHB614 (D.7.8-10).

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

Cotton derived from event GHB614 expresses the 2mEPSPS protein that confers tolerance to herbicide products containing glyphosate. Since the only modified trait expressed by the GHB614 cotton is that of herbicide tolerance, there are no target organisms. .

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

### 9.1 Persistence and invasiveness

A review of the reproductive and vegetative fitness finds that GHB614 compares to its parent variety Coker 312 in all aspects except for the tolerance to herbicide products containing glyphosate. Subsequent season monitoring for volunteers has found no indication of increased persistence or invasiveness of GHB614.

### 9.2 Selective advantage or disadvantage

None. Agronomic performance shows no disadvantage. The only circumstance in which a selective advantage could occur would be if some plants from escaped seed would be sprayed with herbicide products containing glyphosate. The likelihood that some escaped seed would germinate is very low because most of the imported seed is non-viable. In any case it could be controlled with any other herbicide active on cotton.

### 9.3 Potential for gene transfer

**Plant to bacteria gene flow**. In order for any horizontal gene transfer to lead to a new type of micro-organism and therefore to introduce a significant impact, some of the following conditions will have to be fulfilled:
- the uptake should result in the incorporation of complete undegraded DNA
- the plant targeted genes should result in significant expression in a prokaryotic background
- the expression should represent a significant increase over the background level
- the traits should convey a competitive advantage to the strain in which they are incorporated.

Sequence analysis of cotton event GHB614 confirmed the insertion of one copy of the *2mepsps* gene cassette only and also the absence of vector backbone sequences. GHB614 does not contain either an origin of replication from plasmid pTEM2, or any sequences responsible for an enhanced frequency of recombination. Furthermore the introduced *2mepsps* gene is under the control of a eukaryotic promoter, which is not functional in bacteria. Considered altogether, these facts make the possibility of gene transfer from plants of GHB614 to bacteria to be unlikely.

**Plant to plant gene flow**. Gene flow to other crop cotton is possible in cotton producing areas of Europe. Studies find the potential to be small. Measurement of natural pollen movement from GHB614 to cultivated cotton found the rate of out-crossing to be the same as for other cotton, an average of 0.14% between plants at distances between 1 and 12 meters. Thus small isolation distances would decrease the occurrence of out-crossing to other cultivated cotton.

**Likelihood of gene flow.** Gene flow can occur into an adjacent cotton crop, however, the rate is likely to be very low because there exists a combination of genetic, botanical, geographic and agricultural barriers to gene flow. Compatible wild *Gossypium* species are not present in Europe.

The only foreseeable chance for GHB614 to outcross to cotton in Europe would be the unlikely case of imported seed spilled in transit, if plants established within 12 meters of cultivated cotton.

**Consequence of gene flow.** In the unlikely event of the transfer of the *2mepsps* gene into cultivated cotton, it is not expected to exacerbate problems of weed control or adversely impact agriculture.

The scope of the present application is limited to "import and processing" in the EU of GHB614 and does not include cultivation.

### 9.4 Interactions between the GM plant and target organisms

The introduced trait is not a pesticidal trait. There are no target organisms.

### 9.5 Interactions of the GM plant with non-target organisms

Three possible interactions with other organisms were examined. The genetic modification, tolerance to herbicide products containing glyphosate, did not change the interaction of GM cotton varieties with other organisms in the absence of herbicide application. Under agricultural conditions in the USA, when the herbicide is applied: i.) some advantage may be gained in plant population dynamics; ii.) in habitats outside agriculture, the interaction with other plant communities is similar to that of any other cotton; iii.) no changes could be identified in interactions with non-target organisms in the environments under which glyphosate-tolerant cotton will be cultivated. Under agricultural conditions, with direct comparisons of herbicide application, insect population diversity and measures of sensitivity to natural pathogens of cotton found no advantage for the transgenic event GHB614.

a) Effects on biodiversity in the area of cultivation

Under selection pressure within the area treated with herbicide products containing glyphosate, GHB614 may establish in the environment and, thereby, modify the biodiversity. Furthermore it might transfer the trait via pollen flow to other cultivated cotton (wild relatives of cotton are not found in Europe) in the vicinity and contribute to their establishment and modification of the biodiversity too. However extensive environmental risk assessment has been carried out with GHB614 and approval is anticipated in the USA. Moreover the scope of the present application does not include cultivation in Europe and is limited to "import and processing" in EU of GHB614.

b) Effects on biodiversity in other habitats

GHB614 will be imported primarily as non-viable seed. Therefore the likelihood that some imported seed could escape from silos or lorries and germinate is very low. In the unlikely event that GHB614 plants would germinate, they would only have a selective advantage in those cases where herbicide products containing glyphosate are used. In all other cases, the likelihood to establish a feral population of GHB614 is no higher than for conventional cotton.

c) Effects on non-target organisms

There are no non-target organisms specific to GHB614. All non-target organisms would be the same as for conventional cotton. There are no observed effects of the herbicide-tolerant cotton on non-target organisms. Under agricultural conditions, with direct comparisons of herbicide application, insect population diversity and measures of sensitivity to natural pathogens of cotton found no advantage for event GHB614. Field observations found no differences in insect populations, or reactions to natural infestation of cotton pathogens.

### 9.6 Effects on human health

No effects on human health are indicated for people working with, coming into contact with or in the vicinity of an environmental release of GHB614. Cotton grain of GHB614 has the same nutritional quality as cotton in commerce. The plants of GHB614 have the same qualities as other cotton. No toxic or allergic effect from handling GHB614 has been observed on workers in the field since 2002, year of its first field release.

### 9.7 Effects on animal health

The primary use of cotton is for its lint; however cotton seed and the by-products of cotton processing are often included in animal diets. The nutritional composition of the seed was demonstrated to be equivalent to other cotton by chemical analysis.

To support the finding of nutritional equivalence and to demonstrate bioavailability, poultry were fed diets containing cotton under study conditions designed to evaluate growth and health parameters. Poultry were selected to evaluate the effects of a feed component over an entire life span and under conditions of very rapid growth, thus the assay is highly sensitive for nutritional deficiencies or toxic effects. No differences were identified for nutritive value of the seed and no indications of toxic or adverse effects were associated with any of the sources of cotton in the tested animal species. Cottonseed of GHB614 is not anti-nutritional or toxic for animals and no effects on animal health are expected.

### 9.8 Effects on biogeochemical processes

Potential effects on biogeochemistry were assessed indirectly in agronomic studies designed to identify best agronomic practices for growing glyphosate-tolerant cotton. For example, studies to evaluate the fitness of the event found cotton varieties containing the transformation event, GHB614 are not different in seed or lint yield in response to soil composition than comparable cotton varieties.

Chemical analysis of the components seed and lint found no differences in the mineral composition and thus no reason to consider mineral utilisation from the soil to be different than for conventional cotton.

Moreover the scope of the present application does not include cultivation in Europe and is limited to "import and processing" in the EU of GHB614.

### 9.9 Impacts of the specific cultivation, management and harvesting techniques

GHB614 cotton varieties will be grown in principally the United States of America (USA), Brazil, Australia and Mexico and will enter the European Union (EU) by import as commodity cotton seed, cottonseed meal or cottonseed oil. Crushing, processing and consumer packaging are accomplished in the EU. No new crushing or processing activities are required for GHB614.

Cotton in agricultural production requires weed control, and successful weed control depends upon a combination of management practices. For cotton production, farmers use the planting of weed-free seed, crop rotation to break weed cycles, precision land levelling to aid irrigation, seed bed preparation, conservation tillage programs, irrigation, the application of one or more herbicides and herbicide rotations.

Advantages for farmers provided by the GlyTol cotton system include: 1) more options to rotate herbicides for resistance management programs; 2) control of less sensitive weeds (*i.e.* nutsedge, pigweed, grasses…); thus more options for crop management, lesser impact on cotton growing areas and potential implications for soil conservation through minimum tillage practices.

Moreover the scope of the present application does not include cultivation in Europe and is limited to "import and processing" in the EU of GHB614.

## 10. Potential interactions with the abiotic environment

No interaction with the abiotic environment is foreseen that would differ from cotton now in cultivation and in commerce. Soil enrichment and lesser soil erosion may be a benefit of the cultivation of GHB614 as farmers growing it will be able to practice minimum tillage and conservation tillage systems.

Moreover the scope of the present application does not include cultivation in Europe and is limited to "import and processing" in the EU of GHB614.

## 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)

### 11.1 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 GHB614 cotton 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 the Annex VII.

### 11.2 Interplay between environmental risk assessment and monitoring

The scope of this application is the authorisation of GHB614 cotton varieties for import, processing, food and feed use in the European Union (EU) under Regulation (EC) No. 1829/2003. The scope of the application does not include authorisation for the cultivation of GHB614 cotton seed products in the EU.

An environmental risk assessment (e.r.a.) was carried out for GHB614 cotton according to the principles laid down in Annex II to Directive 2001/18/EC and Decision 2002/623/EC. The scientific evaluation of the characteristics of GHB614 cotton in the e.r.a. 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 GHB614 cotton.

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

The scientific evaluation of the characteristics of GHB614 cotton in the e.r.a. 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 GHB614 cotton. It is therefore considered that there is no need for case-specific monitoring.

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

The objective of general surveillance is to identify the occurrence of unanticipated adverse effects of the viable GMO or its use on human or animal health or the environment that were not predicted in the e.r.a.

The baseline and controls for general surveillance will rely on the historical knowledge and experience with non-GM cotton as comparable reference where necessary as the intended uses are the same as that of any other commercial cotton.

The people and their networks participating in the surveillance plan, such as operators involved in the import, handling and processing of viable GHB614 cotton, would tend, although not exclusively, to be best suited to observe and report any unanticipated adverse effect in the framework of their routine surveillance of the commodities they handle and use. They will report immediately any adverse effect to Bayer CropScience, who will directly investigate and inform the European Commission in accordance with Regulation (EC) No 1829/2003, or at least annually whether or not a potential adverse effect was observed.

The operators will be provided with guidance to facilitate reporting of any unanticipated adverse effect from handling and use of viable GHB614 cotton. Bayer CropScience will provide appropriate technical information on GHB614 and further information on the product and relevant legislation will be available from a number of sources, including industry and government websites, official registers and government publications.

The general surveillance information reported to and collected by Bayer CropScience from the European trade associations or other sources will be analysed for its relevance. Where information indicates the possibility of an unanticipated adverse effect, Bayer CropScience will immediately investigate to determine and confirm whether a significant correlation between the effect and GHB614 cotton can be established.

### 11.5 Reporting the results of monitoring

If information that confirms an adverse effect of GHB614 cotton and that alters the existing risk assessment becomes available, Bayer CropScience will immediately investigate and inform the European Commission. Bayer CropScience, 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.

Bayer CropScience will submit an annual monitoring report including results of the general surveillance in accordance with the conditions of the authorisation. The report will contain information on any unanticipated adverse effects that have arisen from handling and use of viable GHB614 cotton.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of GHB614 cotton and, as appropriate, the measures that were taken to ensure the safety of human and animal health or the environment.

## 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

Releases of GHB614 have been notified under Part B of the Directive 2001/18/EC in Spain in 2006 (B/ES/06/10-CON) and 2007 (B/ES/07/28-CON; B/ES/07/40-CON).

b) Conclusions of post-release monitoring

No results from the 2007 trials, however in 2006, 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 results from the 2007 trials, however in 2006, 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 :

GHB614 has been field tested in the USA since 2002 under permit numbers 02-072-04n; 02-296-01n; 03-064-14n; 03-255-03n; 04-064-10n; 04-247-01n; 05-060-03n; 05-091-07n; 05-217-05-n; 05-257-04n; 06-031-01n; 06-054-02n; 06-054-03n; 06-089-03n; 06-223-106n; 07-044-101n; 07-065-110n; 07-065-111n; 07-082-101n; 07-122-102n; 07-137-101n; 07-243-106n.

GHB614 has been also field tested in Argentina in 2007 under permit number N° 281.585/06.

b) Authority overseeing the release

USA: United States Department of Agriculture (USDA)

Argentina: National Advisory Committee on Agricultural Biosafety (CONABIA).

c) Release site

USA: Information on the releases at www.aphis.usda.gov/

Argentina: information on the releases at http://www.sagpya.mecon.gov.ar/new/0-0/programas/conabia/bioseguridad_agropecuaria2.php

d) Aim of the release

See E.2.a., 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

Volunteer GHB614 plants in subsequent season.

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| g) **Duration of post-releases monitoring**<br>One or two seasons, until no volunteers observed. |
| h) **Conclusions of post-release monitoring**<br>Occurrence of volunteers is very infrequent and dependent upon mild conditions in the winter season. |
| i) **Results of the release in respect to any risk to human health and the environment**<br>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):

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| a) **Status/process of approval**<br>The JRC websites http://gmoinfo.jrc.it/gmp_browse.aspx and http://gmo-crl.jrc.it/statusofdoss.htm provide publicly accessible links to up-to-date databases on the regulatory progress of notifications under Directive 2001/18/EC and Regulation (EC) No 1829/2003. |
| b) **Assessment Report of the Competent Authority (Directive 2001/18/EC)**<br>A notification for GHB614 cotton according to Directive 2001/18/EC has not been submitted by Bayer CropScience. |
| c) **EFSA opinion**<br>Not available at the time of submission of this application. |
| d) **Commission Register (Commission Decision 2004/204/EC)**<br>Not yet available |
| e) **Molecular Register of the Community Reference Laboratory/Joint Research Centre**<br>Information on detection protocols will likely be posted at http://gmo-crl.jrc.it/statusofdoss.htm |
| f) **Biosafety Clearing-House (Council Decision 2002/628/EC**<br>http://bch.biodiv.org/ |
| g) **Summary Notification Information Format (SNIF) (Council Decision 2002/812/EC)**<br>http://gmoinfo.jrc.it/<br>Reference notifications B/ES/06/10-CON; B/ES/07/28-CON; B/ES/07/40-CON. |