PART II

Request for Authorization

in accordance with articles 5 and 17 of Regulation (EC) 1829/2003 GM Food and GM Feed

Glyphosate and glufosinate ammonium-tolerant GM cotton GHB614xLLCotton25, for food and feed uses, and for import and processing

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): GHB614xLLCotton25 also referred in the application as GTxLL or GlytolxLL, cotton has been obtained by conventional crossing between two genetically modified cotton events: GHB614 and LLCotton25. No new genetic modification was used for the development of GTxLL cotton. The unique identifier assigned to GTxLL cotton is: BCS-GHØØ2-5 x ACS-GHØØ1-3.
d) Date of acknowledgement of valid application: Not available at the date of application.

2. Applicant

a) Name of applicant: Bayer CropScience AG.		
b) Address of applicant:		
Bayer CropScience AG Alfred-Nobel-Strasse 50 D - 40789 Monheim am Rhein Germany	represented by	Bayer BioScience N.V. Technologiepark 38 B-9052 Gent Belgium
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)): GTxLL 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 An environmental risk assessment for GTxLL cotton has been carried out in accordance with Annex II to Directive 2001/18/EC and Commission Decision 2002/623/EC and is described in Point D.9 below.	

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: GTxLL has been authorized for import in Canada, Australia and Mexico. Authorisation was requested for import in Japan.	

8. General description of the product

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

GTxLL cotton has been obtained by conventional crossing between two genetically modified cotton parental lines: GHB614 and LLCotton25. The parental lines GHB614 and LLCotton25 were obtained by genetic modification of *Gossypium hirsutum*. GHB614 and LLCotton25 were conventionally breed by introgression into an array of varieties belonging to the species *G. hirsutum*.

No new genetic modification was used for the development of GTxLL cotton.

The combined event GTxLL inherited the following traits from the parental lines: tolerance to glyphosate and glufosinate ammonium herbicides, respectively from GHB614 and LLCotton25.

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

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

1) GTxLL 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 GTxLL 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:

GTxLL grain and cottonseed products derived from event GTxLL 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 by users identical to current conventional cottonseed and cottonseed products importers.

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 GTxLL cotton.

When GTxLL cotton is placed on the EU market, the labelling and traceability requirements according to Regulation (EC) N° 1829/2003 and Regulation (EC) N° 1830/2003 will apply.

e) Any proposed packaging requirements:

No specific packaging requirements are necessary.

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:

GTxLL cotton 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 x ACS-GHØØ1-3

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:

Not applicable because restrictions are not necessary.

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 GTxLL seeds is identical to that of conventional cottons and do not constitute a hazard.

The case of accidental spillage of non-processed GTxLL cotton, in transit or at the processing facility, has been considered 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:	spp. (*G. hirsutum)*
d) Subspecies:	N.A.
e) Cultivar/breeding line or strain:	GHB614, LLCotton25
f) Common name:	cotton

2 a. Information concerning reproduction

(i) Mode(s) of reproduction

Cultivated cotton is propagated by seeds. In the absence of insect pollinators, cotton is a self-pollinator, but when pollinators are present, cross-pollination can be significant.

(ii) Specific factors affecting reproduction

Although natural crossing can occur, cotton is normally considered to be a self-pollinating crop. Cotton pollen is very large, heavy and sticky, and thus not wind-borne. The pollen can be transferred by various insects. 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.

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.

(iii) Generation time

The cultural cycle for cotton ranges from less than 100 days for newer varieties, to 200 growing days from seedling emergence to maturity. Rainfall, temperature, sunshine and spring warming, all have an impact on optimal growth. Cotton is susceptible to frost.

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 possible ways for dissemination in cotton are pollen movement and seeds dispersal due to human or animal intervention.

- Pollen dispersal studies conclude that when out-crossing occurs, it is located around the pollen source and decreases significantly with distance.

- Seed dispersal by humans could occur during transport, at sowing and essentially before and during harvest.

b) Specific factors affecting dissemination

Seeds dispersal: Cotton seed has no structural modifications to facilitate transfer by animals. Dissemination is mainly due to human activity.

Pollen dispersal in cotton shows 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 centre 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.*

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

In the E.U., cotton is commercially grown in Spain and Greece; and limited surface 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 20th 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

GTxLL cotton was obtained by conventional crossing between two genetically modified cotton events: GHB614 and LLCotton25. No new genetic modification was used for the development of GTxLL cotton

GHB614, LLCotton25 cotton events were produced by *Agrobacterium tumefaciens* -mediated transformation..

2. Nature and source of the vector used

The following vectors were used for the genetic transformation procedure of the single events:

- **GHB614:**

The plasmid vector used for the transformation of GHB614 is pTEM2 which is derived from pGSC1700 (itself a derivative of the vector pBR322). Plasmid pTEM2 is a part of a binary *A. tumefaciens* system and was specifically designed for the cloning of desirable expression cassettes in cotton.

- **LLCotton25:**

The plasmid vector used for the transformation of LLCotton25 is pGSV71, which is derived from pGSC1700 (itself a derivative of the vector pBR322). Plasmid pGSV71 is a part of a binary *A. tumefaciens* system and was specifically designed for the cloning of desirable expression cassettes in cotton.

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

Sources, sizes and intended functions of the inserted sequences in GTxLL combined cotton events, inherited from the respective parental lines are described in tables 1, 2 and 3

GHB614

Table 1. Size, source and intended function of each constituent component of the inserted DNA fragment inherited from GHB614

Genetic Element	Description	Source	Size (bp[1])	Intended function
LB	T-DNA left border sequence	*Agrobacterium tumefaciens*	4	T-DNA integration
Ph4a748At	Promoter region of the histone H4 gene	*Arabidopsis thaliana*	1010	High level constitutive expression, especially in the rapidly growing plant tissues
intron1 h3At	Sequence of the first intron of the histone H3.III	*Arabidopsis thaliana*	516	
TPotpC	Transit peptide	*Zea mays* and *Helianthus annuus*	372	Targeting of the protein to the plastids
2mepsps	Coding sequence of the modified 5-enol-pyruvylshikimate-3-phosphate synthase gene	*Zea mays*	1337	Glyphosate herbicide tolerance and selectable marker
3'histon At	3´ untranslated region of the histone H4 gene	*Arabidopsis thaliana*	742	Transcription termination signal
RB	T-DNA right border sequence	*Agrobacterium tumefaciens*	4	T-DNA integration

[1] bp: base pair

LLCotton25

Table 2. Size, source and intended function of each constituent component of the inserted DNA fragment inherited from LLCotton25

Genetic element	Description	Source	Size (bp[1])	Intended function
RB	T-DNA right border sequence	*Agrobacterium tumefaciens*	2	T-DNA integration
	Polylinker sequence	Synthetic	28	Plasmid cloning site
P35S3	Promoter	Cauliflower Mosaic Virus	1385	High level constitutive expression
bar	Coding sequence of the phosphinotricin acetyltransferase gene	*Streptomyces hygroscopicus*	552	Glufosinate-ammonium herbicide tolerance and selectable marker
	Polylinker sequence	Synthetic	19	Plasmid cloning site
3'nos	3´ untranslated region of the nopaline synthase gene	*Agrobacterium tumefaciens*	261	Transcription termination signal
	Polylinker sequence	Synthetic	51	Plasmid cloning site
LB	T-DNA left border sequence	*Agrobacterium tumefaciens*	21	T-DNA integration

[1] bp: bass

D. INFORMATION RELATING TO THE GM PLANT

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

The following **traits** were inherited in the GTxLL cotton from the single events GHB614 and LLCotton25:

- ***Tolerance to glyphosate herbicides***

The glyphosate herbicide tolerance trait in GTxLL cotton is inherited from the parental line GHB614 .

GHB614 cotton contains the *2mepsps* gene, which encodes a modified 5-enolpyruvylshikimate 3-phosphate synthase (2mEPSPS). The 2mEPSPS protein confers tolerance to the herbicide glyphosate. Glyphosate is a wide-spectrum herbicide that inhibits the enzyme, 5-enolpyruvylshikimate 3-phosphate synthase (EPSPS), which is involved in the shikimic acid pathway for aromatic amino acid biosynthesis in plants and microorganisms. The 2mEPSPS enzyme however is not inhibited by glyphosate and the expression is sufficiently high to provide a good level of specific activity and ensure glyphosate tolerance to event GHB614.

- ***Tolerance to glufosinate ammonium herbicides***

The glufosinate ammonium herbicide tolerance trait in GTxLL cotton is inherited from the parental line LLCotton25.

LLCotton 25 contains the *bar* gene, a bialaphos resistance gene, isolated from the soil microorganism, *Streptomyces hygroscopicus*. The *bar* gene, when expressed, enables the production of the enzyme, Phosphinothricin-Acetyl-Transferase (PAT) that acetylates L-glufosinate ammonium and thereby confers tolerance to glufosinate ammonium herbicides

2. Information on the sequences actually inserted or deleted

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

GTxLL cotton has been obtained by conventional crossing between two genetically modified cotton events: GHB614 and LLCotton25. The analyses of the single events showed that:

- GHB614 parental cotton event contains a single copy of the T-DNA region of the pTEM2 plasmid inserted at a single genomic locus. No vector backbone sequences were detected in GHB614 cotton.
- LLCotton25 parental cotton event contains a single copy of the pGSV71 plasmid T-DNA, inserted at a single genomic locus. No vector backbone sequences were detected in LLCotton25.

The intactness and stability of the inserts and their flanking regions inherited by GTxLL cotton from the individual parental events GHB614 and LLCotton25 was demonstrated by a complete and detailed Southern blot analysis.

Identical Southern hybridization patterns were observed for GTxLL cotton compared to GHB614 and LLCotton25 parents, thereby confirming the intactness and stability of the parents' inserted sequences and their flanking regions in GTxLL cotton.

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

Not relevant

c) Chromosomal location(s) of insert(s) (nucleus, chloroplasts, mitochondria, or maintained in a non-

integrated form), and methods for its determination

Since conventional crossing methods were used in the production of the GTxLL cotton, and no genetic modification was involved, the localization of all inserted sequences in GTxLL cotton is expected to be in the nuclear genome, as they are present in the parental lines GHB614 and LLCotton25, respectively. The stability of the inserted sequences in the GTxLL combined events cotton was also confirmed by Southern blot analyses.

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

As discussed in Point D.2 a), Southern blot analysis confirmed the intactness and stability of the GHB614 and LLCotton25 inserted sequences, including their flanking regions, in GTxLL cotton. Therefore, the organization of the inserted genetic material in GTxLL cotton is the same as in the single parental events GHB614 and LLCotton25, respectively.

3. Information on the expression of the insert

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

The 2mEPSPS and PAT protein expression levels have been determined in leaf, square and seed (kernel) tissue of GTxLL cotton and single parental events GHB614 and LLCotton25 by ELISA (Enzyme Linked Immuno Sorbent Assay).

Seeds of GHB614, LLCotton25 and GTxLL were produced in the field. Leaf and square material for these tests was collected from plants grown in greenhouse conditions. 2mEPSPS protein expression was detected in leaves, squares and seeds of GTxLL and GHB614. PAT protein expression was detected in leaf, squares and seeds of GTxLL and LLCotton25.

In addition, protein expression analysis demonstrated that the protein expression levels of 2mEPSPS and PAT proteins measured in leaves, squares and seed tissues of GTxLL are comparable to the levels observed in the GHB614 and LLCotton25 parental lines, thereby confirming that the combination of GHB614 and LLCotton25 events by conventional crossing did not have an impact on the 2mEPSPS and PAT protein expression levels.

b) Parts of the plant where the insert is expressed

As described in Section C.3., two constitutive promoters, CaMV 35S and *Arabidopsis* histon H4, regulate expression of the *bar* and *2mepsps* genes, respectively, with high activity in green tissues and seeds.

As described in detail in Section D.3.a., 2mEPSPS and PAT are expressed in leaves, squares and seed of GTxLL cotton at levels similar to those observed in the respective GHB614 and LLCotton25 parental lines, thereby confirming that the combination of GHB614 and LLCotton25 events by conventional crossing did not have an impact on the 2mEPSPS and PAT protein expression levels.

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

a) Reproduction

The traits of glyphosate and glufosinate ammonium herbicides tolerance of GTxLL cotton had no effect on the mode and rate of seed reproduction which was found to be the same as for conventional cotton, as observed in field trials in USA during the 2008 growing season.

b) Dissemination

Two developmental stages in cotton are susceptible to dispersal: pollen and seed. No differences in dissemination capacity have been observed between GTxLL 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 of GTxLL cotton as a result of the conventional crossing of GHB614 and LLCotton25 parental cotton events.

d) Other differences

The only biologically significant difference observed in field evaluations is that cotton varieties based upon transformation event GTxLL are tolerant to herbicides products containing glyphosate and herbicides based on glufosinate ammonium.

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

The molecular, genetic and phenotypic stability GTxLL cotton has been demonstrated by Southern blot analyses, protein expression studies and by assessment of agronomic performance of plants in multiple field trials.

Southern blot analysis confirmed (Section D.2.a) the intactness and stability in the GTxLL cotton event of inherited sequences from GHB614 and LLCotton25, including their flanking regions.

The protein expression analysis (Section D.3.a), demonstrated that 2mEPSPS PAT proteins present in the leaves, squares and seed of the parents GHB614 and LLCotton25, are present in the leaves, squares and seed tissues of the GTxLL cotton at essentially the same levels, thereby confirming the absence of interactions between transgene loci on a protein level.

Comparative assessment of phenotypic and agronomic characteristics of GTxLL and the GHB614 and LLCotton25 parental lines, in field trials conducted at different locations in the USA in the 2008 growing season (Section D.7.5.), demonstrated that GTxLL cotton is equivalent to its parents with regard to phenotypic characteristics and agronomic performance except for the intended traits.

In conclusion, the combination of the GHB614 and LLCotton25 inserts via conventional breeding cross leads to the stable inheritance of the desired traits over multiple generations.

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

a) Plant to bacteria gene transfer

Since GTxLL combined event cotton was produced by conventional crossing of two events, no change in ability to transfer genetic material to other organisms is expected in the combined product.

In addition, as cultivation is not within the scope of this application, transfer of genetic material to other organisms is a very remote possibility.

b) Plant to plant gene transfer

Analysis of the basic parameters relating to reproductive fitness of GTxLL cotton was performed in field trial studies in the USA during the 2008 growing season. For all parameters evaluated, GTxLL cotton was found to be unchanged compared to the conventional cotton, thereby confirming that the potential for gene transfer from GTxLL to cultivated cotton and/or wild relatives is the same as with any commercially available cotton.

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

7.1 Comparative assessment

A comparative assessment for compositional and nutritional equivalence was performed on GTxLL cotton grain collected from a field trial carried out at seven locations in the USA during the 2008 growing season. The comparative assessment was conducted to determine whether GTxLL cotton grain is compositionally and nutritionally equivalent to grain from the commercial comparator FiberMax 958 with the comparable genetic background and to grain from GHB614 and LLCotton25 parental lines, and whether GTxLL cotton is equivalent to the chosen comparators with regard to phenotypic and agronomic plant performance.

The results of this comparative analysis of GTxLL cotton grain from field trials in USA demonstrates that grain from GTxLL cotton is compositionally and nutritionally equivalent to grain from the commercial comparator and GHB614 and LLCotton25 parental lines, and spraying with glufosinate ammonium and glyphosate herbicides, does not have an effect on the nutrient composition of GTxLL cotton grain. The GTxLL phenotypic appearance and its agronomic performance did not differ in comparison with the commercial varieties and parental lines.

7.2 Production of material for comparative assessment

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

The comparative assessment of cotton event GTxLL was performed during field trials carried out in seven different locations, representing typical cotton growing regions of the south-eastern United States, over 2008 growing season. The field trial design was a Randomized Complete Block Design with three repetitions and five different treatment regimens.

b) The baseline used for consideration of natural variations

A range of values to be expected for each component was established from published literature, a well as from the values for the reference counterpart variety, a conventional variety FiberMax958, and the two parental lines GHB614 and LLCotton25.

7.3 Selection of material and compounds for analysis

The compounds which were selected for compositional and nutritional analyses of GTxLL cotton grain comprise the important basic nutrients of cotton as defined by the OECD. These are proximates (protein, fat, ash, carbohydrates, and moisture), amino acids, fatty acids, micronutrients, such as vitamins and minerals (alpha-tocopherol, calcium, phosphorus, magnesium, potassium, iron, zinc) and anti-nutrients, such as gossypol and cyclopropenoid fatty acids.

7.4 Agronomic traits

Agronomic performance evaluation of GTxLL cotton was carried out at 7 locations in the USA during the 2008 growing season. The agronomic evaluations included a detailed phenotypic analysis based upon plant variety description, agronomic performance evaluations common to yield trials, including disease resistance evaluations and agronomic practice evaluations.
Overall this study demonstrates that the agronomic characteristics of GTxLL cotton are comparable to commercially available cotton and its parents.

7.5 Product specification

GTxLL cotton has been obtained by conventional crossing between two genetically modified cotton events GHB614 and LLCotton25 and introgressed in the commercial variety FiberMax958. Commercial varieties derived from GTxLL belong to *Gossypium hirsutum* L. and are distinguished from other cotton only by tolerance to the glyphosate and glufosinate ammonium herbicides.

No new genetic modification was used for the development of GTxLL cotton. The derived food is cottonseed oil and cottonseed linters, and the derived feed, the by-products of cotton seed processing (e.g. cottonseed meal).

As discussed in detail in this application, GTxLL cotton is as safe as and as nutritious as commercially available cotton and therefore, the specification of food and animal feed from GTxLL cotton is equivalent to that of food and animal feed from commercially available cotton.

7.6 Effect of processing

The same production processes applied to traditional cottonseed will be used for GTxLL cottonseed. GTxLL cotton will be grown using the agronomic practices of the region of production and the grain will harvested, transported, stored and processed using the same processes as used for any other cotton in commerce.

7.7 Anticipated intake/extent of use

The intake of cottonseed products in the diet of the European Union (EU 27) is not anticipated to change with the introduction of GTxLL varieties. Cottonseed and cottonseed products derived from GTxLL 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 GTxLL varieties.

7.8 Toxicology

7.8.1 Safety assessment of newly expressed proteins

GTxLL cotton has been obtained by conventional crossing between two genetically modified cotton events: GHB614 and LLCotton25. No new genetic modification was used for the development of GTxLL cotton and therefore, there are no newly expressed proteins in GTxLL cotton other than the ones already assessed as safe in the case of GHB614 and LLCotton25.

7.8.2 Testing of new constituents other than proteins

Not applicable since no new constituents other than proteins are present in GTxLL cotton.

7.8.3 Information on natural food and feed constituents

As described in detail in Section D.7.1., natural constituents of cotton have not been changed in GTxLL cotton.

7.8.4 Testing of the whole GM food/feed

GTxLL cotton has been obtained by conventional crossing between two genetically modified cotton events: GHB614 and LLCotton25. No new genetic modification was used for the development of GTxLL cotton.

The single parental events GHB614 and LLCotton25 cotton have been previously assessed as safe and this was confirmed by the EFSA GMO Panel (EFSA Opinion, 2008; EFSA Opinion, 2006).

In addition and as described in Section D.3., the expression levels of the 2mEPSPS and PAT proteins are expressed in leaf, square and seeds (kernel) of GTxLL are comparable with the protein levels in respective GHB614 and LLCotton25 parental lines, thereby confirming that the combination of the GHB614 and LLCotton25 did not have an impact on the 2mEPSPS and PAT protein expression levels.

Furthermore and as described in Section D.7.1, compositional analysis has confirmed that grain from GTxLL cotton is compositionally and nutritionally equivalent to grain from commercially available cotton grain.

In conclusion, GTxLL cotton is as safe as and as nutritious as any other commercially available cotton for human food and animal feed use and no further testing of the whole GM food/feed is considered necessary.

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

GTxLL cotton has been obtained by means of conventional crossing between two genetically modified cotton events: GHB614 and LLCotton25. No new genetic modification was used for the development of GTxLL cotton. Therefore, there are no newly expressed proteins in GTxLL cotton other than the ones already assessed as safe in the case of GHB614 and LLCotton25 parental lines.

The absence of any allergenic potential of the proteins associated with the inherited genes *2mepsps* and *bar*, expressed in the parents, has previously been demonstrated.

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 in the case of GTxLL**.**

7.10 Nutritional assessment of GM food/feed

7.10.1 Nutritional assessment of GM food

The introduced traits in GTxLL are 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 GTxLL, 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 GTxLL 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.

In conclusion, vegetable oil derived from GTxLL cotton grain will be nutritionally equivalent to vegetable oil derived from commercially available cotton grain and there is no nutritional impact expected from the human food use of GTxLL cotton and derived food products.

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 conclusion, cotton meal and hulls derived from GTxLL cotton grain will be nutritionally equivalent to cotton meal and hulls derived from commercially available cotton grain and there is no nutritional impact expected from the animal feed use of GTxLL cotton and derived products.

7.11 Post-market monitoring of GM food/feed

No post-market monitoring plan is required for GM food/feed produced from GTxLL cotton.

The commercial counterpart cotton variety FiberMax 958 was used as a comparator 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 GTxLL cotton will not be marketed as an alternative to or replacement for traditional cotton (D7.5). GTxLL cotton 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 GTxLL cotton (D.7.8-10).

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

Not applicable since there no target organisms in the case of GTxLL cotton.

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 GTxLL compares to commercially available cotton in all aspects except for the tolerance to herbicide products containing glufosinate-ammonium and glyphosate.

In addition, the scope of this application is for authorization of GTxLL cotton for food and feed uses, and import and processing and does not include authorization for cultivation of GTxLL cotton seeds in the EU

In conclusion, there is negligible likelihood for GTxLL cotton to become environmentally persistent or invasive giving rise to any weediness within the context of this application

9.2 Selective advantage or disadvantage

None. Agronomic performance shows no disadvantage in GTxLL cotton.. The only circumstance in which a selective advantage could occur would be if some GTxLL plants from escaped seed would be sprayed with herbicide products containing glyphosate and glufosinate ammonium. The likelihood that some GTxLL 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

GTxLL cotton was developed by the conventional breeding cross of GHB614 and LLCotton25 lines. No new genetic modification was introduced in GTxLL cotton and therefore, there are no newly expressed proteins in GTxLL cotton other than the ones already assessed as safe in the case of GHB614 and LLCotton25.

The scope of this application is for authorization of GTxLL cotton for food and feed uses, as well as import and processing, and does not include authorization for cultivation of GTxLL cotton seeds in the EU. The only chance for GTxLL plants to exchange pollen with cotton grown in Europe would be the unintended release through a seed spill as a result of import

Plant to bacteria gene flow. In order for any horizontal gene transfer to lead to a new type of microorganism 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 non-degraded 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 GTxLL cotton parental events GHB614 and LLCotton25 confirmed the insertion of one copy of the *2mepsps* gene cassette and one copy of the *bar* gene cassette in the genomes of the respective parents.
Additionally, genomes GHB614 and LLCotton25 lines do not contain either an origin of replication from plasmid pTEM2, or plasmid pGSV71, respectively; or any sequences responsible for an enhanced frequency of recombination. Considered altogether, these facts make the possibility of gene transfer from plants of GTxLL to bacteria to be unlikely.

Plant to plant gene flow. The only foreseeable chance for GTxLL to outcross to cotton in Europe would be the unlikely case of imported seed spilled in transit, growing and flowering if plants established within 12 meters of cultivated cotton. However seeds of *G. hirsutum* and *G. barbadense* typically require some form of treatment to ensure adequate germination: heat treatment and a sulphuric acid delinting treatment to remove fuzz or linters from the seed coat.

9.4 Interactions between the GM plant and target organisms

Not applicable as since there are no target organisms in the case of GTxLL cotton.

9.5 Interactions of the GM plant with non-target organisms

GTxLL cotton was developed by the conventional crossing of GHB614 and LLCotton25 lines. No new genetic modification was introduced in GTxLL cotton and therefore, no newly expressed proteins or interaction between the inherited proteins has been observed in GTxLL cotton other than that already assessed as safe in the case of GHB614 and LLCotton25. Three possible interactions with other organisms were examined on the parental lines GHB614 and LLCotton25.

The genetic modification, tolerance to herbicide products containing glyphosate and glufosinate ammonium, did not change the interaction of GM cotton varieties with other organisms in the absence of herbicides application. Under agricultural conditions in the USA, when the herbicides are 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 and glufosinate ammonium tolerant cotton will be cultivated. Under agricultural conditions, with direct comparisons of herbicides application, insect population diversity and measures of sensitivity to natural pathogens of cotton found no advantage for the transgenic events GHB614 and LLCotton25.

a) Effects on biodiversity in the area of cultivation

Under selection pressure within the area treated with herbicide products, containing glyphosate or glufosinate ammonium, GHB614 and LLCotton25 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.

b) Effects on biodiversity in other habitats

GTxLL 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 GTxLL 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 GTxLL is no higher than for conventional cotton.

c) Effects on non-target organisms

There are no non-target organisms specific to GHB614 and LLCotton25. 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 glyphosate/glufosinate herbicide application, insect population diversity and measures of sensitivity to natural pathogens of cotton found no advantage for events GHB614 and LLCotton25. Field observations found no differences in insect populations, or reactions to natural infestation of cotton pathogens.

Based on the above mentioned features of the single parental lines, GHB614 and LLCotton25, no interaction of the GTxLL event with non-target organisms different than those of conventional cotton is expected.

The scope of the present application does not include cultivation in Europe and is limited to “import and processing” in EU of GTxLL.

9.6 Effects on human health

GTxLL cotton has been obtained by conventional crossing between two genetically modified cotton events: GHB614 and LLCotton25. No new genetic modification was used for the development of GTxLL cotton.

The single parental events GHB614 and LLCotton25 have been previously assessed as safe as and as nutritious as commercial cotton and this was confirmed by the EFSA GMO Panel. In the current application, it has been demonstrated that there are no interactions between GHB614and LLCotton25 events when combined by conventional crossing in GTxLL cotton. In conclusion, this confirms that GTxLL cotton is as safe as and as nutritious as any commercial cotton.

9.7 Effects on animal health

GTxLL cotton was developed by conventional crossing of the single parental lines GHB614 and LLCotton25. No new genetic modification was introduced in GTxLL. GTxLL cotton combines the tolerances to glufosinate ammonium and glyphosate herbicides.

The two parental lines have already been notified and submitted to a risk assessment. The EFSA GMO Panel concluded that LLCotton25 and GHB614 events are as safe and as nutritious as conventional cotton for humans and animals.

In the current application, it has been demonstrated that there are no interactions between GHB614and LLCotton25 events when combined by conventional crossing in GTxLL cotton. In conclusion, this confirms that GTxLL cotton is as safe as and as nutritious as any commercial cotton.

9.8 Effects on biogeochemical processes

As discussed in detail in Section D.7.4., the agronomic performance of GTxLL cotton has been demonstrated to be unchanged compared to other cotton in commerce. Furthermore, the scope of this application is for authorization of GTxLL cotton for food and feed uses, and import and processing and does not include authorization for cultivation of GTxLL seeds in the EU.

In conclusion, negligible effects are expected on the biogeochemical processes occurring in the soil within the context of the current application.

9.9 Impacts of the specific cultivation, management and harvesting techniques

Not applicable since the scope of this application is authorization of GTxLL cotton for food and feed uses, and import and processing and does not include authorization for cultivation of GTxLL cottonseed in the EU.

10. Potential interactions with the abiotic environment

GTxLL cotton was developed by conventional breeding cross of the GHB614 and LLCotton25 lines. No new genetic modification was introduced in GTxLL. GTxLL cotton combines the tolerances to glufosinate ammonium and glyphosate herbicides. The traits in GTxLL cotton are not aimed at modifying the interactions of the plant with the abiotic environment.

As presented in Section D.7.3, chemical analysis of the nutritional components in GTxLL cottonseed found no differences in the mineral composition and thus no reason to consider mineral utilization from the soil to be different than for commercially available cotton (Section D.7.3).

Furthermore, the scope of this application is for authorization of GTxLL cotton for food and feed uses, and import and processing, and does not include authorization for cultivation of GTxLL seeds in the EU.

11. Environmental monitoring plan

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 GTxLL 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 Annex VII to Directive 2001/18/EC. The structure of the monitoring plan also takes into account the guidance on presentation of applications provided in the Guidance Document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed (The EFSA Journal (2006) 99, pp. 1-100).

11.2 Interplay between environmental risk assessment and monitoring

The scope of this application is the authorisation of GTxLL 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 GTxLL cotton seed products in the EU.

An environmental risk assessment (e.r.a.) was carried out for GTxLL 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 GTxLL 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 GTxLL cotton.

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

The scientific evaluation of the characteristics of GTxLL 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 GTxLL 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 GTxLL 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 GTxLL cotton. Bayer CropScience will provide appropriate technical information on GTxLL 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 GTxLL cotton can be established.

11.5 Reporting the results of monitoring

In accordance with Regulation (EC) No 1829/2003, the authorisation holders are responsible to inform the European Commission of the results of the general surveillance.

If information that confirms an adverse effect of GTxLL cotton and that alters the existing risk assessment becomes available, the authorisation holders will immediately investigate and inform the European Commission. The authorisation holders, in collaboration with the European Commission, and based on a scientific evaluation of the potential consequences of the observed adverse effect, will define and implement management measures to protect human and animal health or the environment, as necessary. It is important that the remedial action is proportionate to the significance of the observed effect.

The authorisation holders 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 GTxLL cotton.

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

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

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

The detection method for GTxLL cotton is based on the validated detection methods that are available for GHB614, LLCotton25 cotton.

The detection method for GTxLL cotton has been sent to the Community Reference Laboratory (CRL) (http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm) of the Joint Research Centre of the European Commission (EC-JRC) for the purpose of experimental testing and validation.

Appropriate control samples have also been made available to the JRC-CRL.

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

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

a) Notification number

There is no history of release of GHB614 x LLCotton25 in the EU.

b) Conclusions of post-release monitoring

Not applicable.

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

Not applicable.

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

a) Release country

GHB614 x LLCotton25 has been field tested extensively in the USA (permit numbers07-065-110n; 07-065-111n; 08-254-116n; 08-010-104rm; 09-030-127n; 09-050-104n; 09-096-101n), Mexico (permit numbers 0043_2007; 0054_2007; 0055_2007; 0056_2007; 0019_2008; 0020_2008;0022_2008; 0023_2008) and South Africa (permit numbers 17/3(2/08/251); 17/3(4/09/190)).

b) Authority overseeing the release

USA: United States Department of Agriculture (USDA)
Mexico: Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria (SENASICA)
South-Africa: Biosafety Directorate, Department of Agriculture, Forestry & Fisheries

c) Release site

USA: Information on the releases at www.aphis.usda.gov/
Mexico: Chihuahua, La Laguna, Sonora and Tamaulipas.
South-Africa: Limpopo province

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 x LLCotton25 plants in subsequent season.
g) Duration of post-releases monitoring One or two seasons, until no volunteers observed.
h) Conclusions of post-release monitoring 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 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/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) A notification for GHB614 x LLCotton25 according to Directive 2001/18/EC has not been submitted by Bayer CropScience.
c) EFSA opinion Not available at the time of submission of this application.
d) Commission Register (Commission Decision 2004/204/EC) Not available at the time of submission of this application.
e) Molecular Register of the Community Reference Laboratory/Joint Research Centre 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 http://bch.biodiv.org/
g) Summary Notification Information Format (SNIF) (Council Decision 2002/812/EC) http://gmoinfo.jrc.it/