PART II

Request for Authorization

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

Insect resistant and glufosinate tolerant cotton event T304-40 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: EFSA-GMO-NL-2011-97
c) Name of the product (commercial and other names): T304-40 Cotton (OECD ID BCS- GHØØ4-7) Seed of genetically modified cotton (*Gossypium hirsutum*) with resistance to certain lepidopteran pests and tolerance to herbicide products containing the active ingredient glufosinate ammonium.
d) Date of acknowledgement of valid application: Not available at the date of application

2. Applicant

a) Name of applicant: Bayer CropScience AG, represented by Bayer BioScience NV
b) Address of applicant: Bayer CropScience AG represented by Bayer BioScience NV Alfred-Nobel-Strasse 50 Technologiepark 38 D - 40789 Monheim am Rhein B-9052 Gent Germany 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)): T304-40 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 T304-40 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: Authorisation requested for cultivation and commercial use in USA and Argentina. Authorisations requested for food, feed and industrial uses in Australia & New Zealand, Canada, Japan, Korea, Mexico and Colombia	

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 hirsutum.* The genetic modification controls certain lepidopteran cotton pests and confers tolerance to the herbicide glufosinate ammonium. T304-40 cotton varieties are developed by traditional breeding methods from crosses between T304-40 and conventional cotton adapted for planting in the temperate cotton production regions of the Americas. Glufosinate ammonium is a non-selective, foliar applied, broad-spectrum and post emergent herbicide.

The introduced insect resistance trait in T304-40 cotton is conferred by the insecticidal crystal protein, Cry1Ab, from the common soil bacterium, *Bacillus thuringiensis* subsp. *berliner* (*B.t. berliner*). The Cry1Ab protein, encoded by the *cry1Ab* gene, is effective in controlling lepidopteran larvae such as cotton bollworm larvae (CBW, *Helicoverpa zea*) and tobacco budworm larvae (TBW, *Heliothis virescens*), which are common pests of cotton. *Bacillus thurigiensis* (Bt) crystal proteins turn into active proteins once they are processed in the lumen of the insect larvae. The Cry1Ab protein in T304-40 cotton is a synthetic coding sequence that includes only the N-terminal region of the proprotein bearing the active protein.

The *bar* gene has been isolated from *Streptomyces hygroscopicus*, a microorganism that produces bialaphos. Bialaphos or its synthetically produced component glufosinate ammonium has phosphinothricin as the active ingredient. Phosphinothricin acts by the inhibition of a specific amino acid biosynthesis pathway in plants. It is a potent inhibitor of glutamine synthetase (GS), an enzyme that plays a central role in the assimilation of ammonia and in the regulation of the nitrogen metabolism in the plant. Phosphinothricin based herbicides (Basta®, Finale®, Rely®) are highly effective against plants, but are safe to humans and animals and are rapidly biodegraded in the environment. The PAT enzyme metabolizes glufosinate to an inactive acetylated derivative ensuring glufosinate ammonium tolerance in T304-40 cotton.

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 T304-40 and 2) cottonseed products derived from T304-40 cotton.

1) T304-40 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 T304-40 cotton (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:

T304-40 grain and cottonseed products derived from T304-40 cotton 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 cotton 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 insect resistant and herbicide tolerant, T304-40 cotton varieties.

When genetically T304-40 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:

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:

T304-40 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- GHØØ4-7

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 T304-40 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 T304-40 and conventional cottons are identical and do not constitute a hazard.

The case of accidental spillage of non-processed T304-40 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:	T304-40 cotton
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 cross-pollination may take place when pollinators are present.

(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

The cultural cycle for cotton ranges from less than 100 days, to 200 growing days from seedling emergence to maturity depending on the variety. Rainfall, temperature, sunshine and spring warming, all have an impact on optimal growth.

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

Two differentiated reproductive structures are suitable for the dispersal of cotton genes in the environment:

1. Seed dispersal. It could occur during transport, at planting and essentially before and during harvest.
2. Pollen dispersal. A number of 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 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 Greece and Spain; and is grown in limited surfaces 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

The genetic modification was performed by *Agrobacterium tumefaciens* mediated transformation.

2. Nature and source of the vector used

The vector pTDL008 is derived from pGSC1700

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

Symbol	**Definition**	**Source**	**Size (bp)**	**Reference**	**Function**
LB	Left border repeat	*Agrobacterium tumefaciens*	24	Zambryski, 1988	*Cis*-acting element for T-DNA transfer
3'me1	Terminating signal of *cry1Ab* gene	*Flaveria bidentis*	936	Marshall *et al*., 1996	Stop signal
cry1Ab	Insect resistance *cry1Ab* gene	*Bacillus thuringiensis*	1853	Höfte *et al*., 1986	Insect resistance
5'e1	Leader sequence	*Oryza sativa*	60	Michiels *et al*., 1992	High level constitutive expression, especially in cotton leaves and squares
Ps7s7	Duplicated promoter	subterranean clover stunt virus	1041	Boevink *et al*., 1995	
P35S3	Promoter	cauliflower mosaic virus	857	Odell *et al*., 1985	High level constitutive expression
bar	Glufosinate ammonium-tolerance *bar* gene	*Streptomyces hygroscopicus*	551	Thompson *et al*., 1987	Herbicide tolerance and selectable marker

3'nos	Terminating signal of *bar* gene	*Agrobacterium tumefaciens*	309	Depicker *et al*., 1982	Stop signal
RB	Right border repeat	*Agrobacterium tumefaciens*	24	Zambryski, 1988	*Cis*-acting element for T-DNA transfer

- Boevink P., Chu P.W.G. and Keese P. 1995. Sequence of Subterranean Clover Stunt Virus DNA: Affinities with the Geminiviruses. Virology 207, 354 – 361.
- Depicker A., Stachel S., Dhaese P., Zambryski P., Goodman H.M.1982. Nopaline synthase: transcript mapping and DNA sequence. Journal of Molecular and Applied Genetics, 1, 561-573.
- Höfte H., de Greve H., Seurinck J., Jansens S., Mahillon J., Ampe C., Vandekerckhove J., Vanderbruggen H., van Montagu M., Zabeau M., Vaeck M. 1986. Structural and functional analysis of a cloned delta endotoxin of Bacillus thuringiensis berliner 1715. European Journal of Biochemistry, 161, 273-280.
- Marshall J.S., Stubbs J.D., Taylor W.C. 1996. Two genes encode highly similar chloroplastic NADP-malic enzymes in Flaveria. Plant Physiology, 111, 1251-1261
- Michiels F., Morioka S., Scheirlinck T., Komari T. 1992. Stamenspecific promoters from rice. Patent Application WO92/13956A1 (20 AUG-1992) PLANT GENETIC SYSTEMS N.V. (BE).
- Odell J.T., Nagy F., Chua N.-H. 1985. Identification of DNA sequences required for activity of the Cauliflower Mosaic Virus 35S promoter. Nature, 313, 810-812
- Thompson C.J., Rao Movva N., Tizard R., Crameri R., Davies J., Lauwereys M., Botterman J. 1987. Characterization of the herbicide resistance gene bar from *Streptomyces hygroscopicus*. The EMBO Journal, 6, 2519-2523
- 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

T304-40 cotton (*Gossypium hirsutum*) plants express an insecticidal crystal protein, Cry1Ab, from the common soil bacterium, *Bacillus thuringiensis* subsp. *berliner* (*B.t. berliner*) and the PAT protein from the soil microorganism, *Streptomyces hygroscopicus* which confers tolerance to glufosinate ammonium.

The Cry1Ab protein is effective in controlling lepidopteran larvae such as cotton bollworm larvae (CBW, *Helicoverpa zea*) and tobacco budworm larvae (TBW, *Heliothis virescens*), which are common pests of cotton.

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

Southern blot, PCR and sequence analysis demonstrated that the insect resistant and herbicide tolerant T304-40 cotton contains a partial 3'me1 terminator, followed by two partial copies of the *cry1Ab* gene cassette in a tail-to-tail orientation, one cassette containing only part of the Ps7s7 promoter and the other one containing only part of the 3'me1 terminator, and a partial copy of the *bar* gene cassette, in which only part of the 3'nos terminator is present. One of the *cry1Ab* cassettes contains only part of the Ps7s7 promoter and the second *cry1Ab* cassette contains only part of the 3'me1 terminator.

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

The characterization of the inserted sequences in T304-40 cotton demonstrated that the insect resistant and herbicide tolerant T304-40 cotton contains a partial 3'me1 terminator, followed by two partial copies of the *crylAb* gene cassette in a tail-to-tail orientation, one cassette containing only part of the Ps7s7 promoter and the other one containing only part of the 3'me1 terminator, and a partial copy of the *bar* gene cassette, in which only part of the 3'nos terminator is present. One of the *cry1Ab* cassettes contains only part of the Ps7s7 promoter and the second *cry1Ab* cassette contains only part of the 3'me1 terminator, and also the absence of vector backbone.

There are no antibiotic resistance markers present in T304-40 cotton

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

Not relevant

3. Information on the expression of the insert

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

Commercial-level insect resistance depends on the expression of the Cry1Ab protein in leaves and the reproductive organs of T304-40 cotton. Therefore the activity of the *cry1Ab* gene is ensured by the presence of two promoters in the T304-40 cotton: the constitutive duplicated promoter region derived from the subterranean clover stunt virus genome segment 7 (Ps7S7) and the leader sequence of the tapetum specific E1 gene of rice (*Oryza sativa*).

The cauliflower mosaic virus (35S) promoter, as a constitutive promoter with high activity in the leaves drives the expression of the *bar* gene.

b) Parts of the plant where the insert is expressed

Expression level of the proteins produced in T304-40 (Cry1Ab and PAT) cotton were measured by protein specific ELISA. Tissue samples were harvested at different growth stages from greenhouse grown cotton.

T304-40 cotton was also expected to show high levels of Cry1Ab protein expression in flowering organs.

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

a) Reproduction

The traits of insect resistance and 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 T304-40 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

The characteristics of T304-40 cotton that could have an impact on survivability, such as germination rate and vigour remain unchanged when compared to the conventional non-GM counterpart.

d) Other differences

The only biologically significant difference observed in field evaluations is that T304-40 cotton varieties are resistant to certain insect pests of the Lepidoptera family and are tolerant to glufosinate-ammonium herbicides.

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 analyses were completed for plants of different generations, different environments and from crosses into different genetic backgrounds.

The isolated DNA was digested with the restriction enzyme EcoRV, which has one recognition site in the transforming DNA. Probing EcoRV restricted genomic DNA with the cry1Ab probe will yield a 5' integration fragment of ca. 3100 bp, an internal fragment of 3476 bp and a 3' integration fragment of ca. 6800 bp. All three integration fragments were observed in all tested tested DNA samples.

The resulting Southern blots demonstrate the molecular stability of the T304-40 cotton at the genetic level over multiple generations, different locations, and in different 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 T304-40 cotton to bacteria could occur.

b) Plant to plant gene transfer

Analysis of the basic parameters relating to reproductive fitness of T304-40 cotton was performed in field trial studies in the Spain during the 2007 and 2008 growing seasons. For all parameters evaluated, T304-40 cotton was found to be unchanged compared to the conventional cotton, thereby confirming that the potential for gene transfer from T304-40 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

Choice of the comparator

T304-40 cotton was compared to its parent variety, Coker 315.

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 Louisiana, Mississippi and Texas and Cataluña (Spain) in 2007 and Cataluña and Andalucia (Spain) in 2008.
Seed samples were collected from two growing seasons (2007 and 2008). In each location three treatments were done, and a 3-fold replication per treatment. The three treatments consisted of: a) conventional cotton grown using conventional herbicide weed control, b) T304-40 cotton grown using conventional herbicide weed control, and c) T304-40 cotton grown with glufosinate ammonium 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 commercial varieties present in the field trials at the Spanish locations, from published literature, as well as from the values for the non GM counterpart variety, Coker 315.

7.3 Selection of material and compounds for analysis

Bayer CropScience undertook a systematic review of the composition of the seed derived from T304-40. 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 T304-40 has the same nutritional composition as its non GM counterpart, and values for nutritional components fall within the range of values reported for commodities in commerce.

7.4 Agronomic traits

Throughout the field testing history of T304-40 cotton there were no differences observed that could be attributed to pleiotropic effects of the *cry1Ab* and *bar* gene insertion. Neither did T304-40 cotton 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 2007 and 2008 in Cataluña and Andalucia.

There is no indication in the data of agronomic performance that T304-40 cotton differs from the cotton that is currently grown and consumed (except the intended traits insect resistance and herbicide tolerance)

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).

Insect resistant and glufosinate tolerant T304-40 cotton has been conventionally bred into an array of varieties with adaptation to the various zones of cotton cultivation. T304-40 varieties belong to the species, *Gossypium hirsutum* L. and are distinguished from other cotton only by resistance to some lepidopteran pests and to tolerance to glufosinate ammonium herbicides.

7.6 Effect of processing

The T304-40 cotton 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 Cry1Ab and the PAT proteins, which was not detected in toasted meal and crude or refined oil.

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 T304-40 cotton varieties. Cottonseed and cottonseed products derived from T304-40 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 T304-40 cotton.

7.8 Toxicology

7.8.1 Safety assessment of newly expressed proteins

The Cry1Ab and PAT proteins are not toxic to mammals and do not possess any of the characteristics associated with food allergens. Findings to support this conclusion include:

- The *cry1Ab* gene which encodes the Cry1Ab protein is derived from *Bacillus thurigiensis* (*Bt*). The *Bt* crystal proteins are ubiquitous in nature and almost a century of studies of insecticidal proteins has brought a detailed understanding of their structure and function. The *bar* gene, which encodes the PAT protein, is derived from *Streptomyces hygroscopicus* which is a common soil saprophytic bacterium not known to be pathogenic to humans and animals.
- the Cry1Ab and PAT proteins are quickly degraded in simulated gastric and intestinal fluids of domestic animals and humans and by heat;
- No potential N-glycosylation site was identified for the PAT amino acid sequence and seven potential N-glycosylation sites were identified for the Cry1Ab protein.
- the PAT enzyme is highly substrate-specific. It acetylates its target, glufosinate-ammonium, but not glutamate, the closest structural analogue of L-glufosinate ammonium or other L-amino acids;
- exposure to Cry1Ab protein via an oral route was assessed in mice at a high dose of 2000 mg/kg body weight. In addition exposure to PAT protein via parenteral route was assessed in mice at a high dose of 10 mg/kg body weight. These tests confirmed that the Cry1Ab and the PAT proteins are not acutely toxic.
- a repeated dose oral toxicity study in rats with the PAT protein, encoded by the *pat* gene, further confirmed absence of toxicity for the PAT protein. A similar study was not performed for Cry1Ab as this protein is well known and proteins sharing high degree of identity to the Cry1Ab protein from T304-40 has been used in other genetic modifications.
- A 90 day rat feeding study was performed to confirm the absence of any harmful effect due to the inclusion in the diet of T304-40 cotton.

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 Cry1Ab and the PAT proteins are novel and equivalence in composition of cotton was confirmed by chemical analysis.

7.8.3 Information on natural food and feed constituents

Natural constituents of cotton have not been changed in T304-40 cotton. 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 T304-40, the non GM counterpart support the conclusion of compositional equivalence to cotton currently in commerce.

7.8.4 Testing of the whole GM food/feed

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 T304-40 nor the gene insertion process itself, has adverse effects on feeding, growth or general health. Moreover, no negative impacts of the nutritional quality of T304-40 cotton were observed on poultry.

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

The total amino acid sequence of the Cry1Ab and PAT protein were compared to that of known toxins and allergens listed in the existing large reference databases (Uniprot_Swissprot, Uniprot_TrEMBL, PDB, DAD and GenPept) and in the Bayer toxin database. Based on these *in silico* results, no evidence for any similarity to known toxic or allergenic proteins was found.

An epitope sequence homology search of the Cry1Ab and PAT proteins. No sequence similarities with an allergenic epitope were observed.

The Cry1Ab and PAT proteins form only an extremely minor part of the crude protein fraction in T304-40 cotton 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 in the case of T304-40.

7.10 Nutritional assessment of GM food/feed

7.10.1 Nutritional assessment of GM food

The introduced traits in T304-40 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 T304-40, and the fatty acid levels in the cottonseed oil samples are similar to those of the conventional cottonseed oil samples and within the range of the reported in the literature.

Cottonseed oil from T304-40 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 T304-40 has been demonstrated in a zootechnical study with chicken and with an additional 90 day feeding study with Wistar rats.

7.11 Post-market monitoring of GM food/feed

No post-market monitoring plan is required for GM food/feed produced from T304-40 cotton. The non GM cotton variety Coker 315, 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 T304-40 will not be marketed as an alternative to or replacement for traditional cotton (D7.5). T304-40 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 T304-40 (D.7.8-10).

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

Cotton derived from event T304-40 expresses the Cry1Ab and the PAT proteins that confer resistance to certain lepidopteran pests and confer tolerance to the glufosinate ammonium herbicide. These lepidopteran insects may be considered as targets organisms which interact with the T304-40 cotton plants.

However, the scope of this application is food and feed, import and processing of the T304-40 cotton and does not include cultivation in the EU. Therefore, no interactions between T304-40 cotton plants and lepidopteran insects are expected.

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 T304-40 compares to its non GM counterpart variety Coker 315 in all aspects except for the insect resistance and herbicide tolerance. Subsequent season monitoring for volunteers has found no indication of increased persistence or invasiveness of T304-40.

9.2 Selective advantage or disadvantage

None. The new traits allow the T304-40 cotton plants to survive sprays with glufosinate and resist to certain Lepidoptera attacks. Under pressure of selection in an area with target pests and treated with glufosinate, T304-40 may establish in the environment and, thereby, modify the biodiversity. Furthermore it might transfer the traits via pollen flow to other cultivated cotton (no wild relative of cotton is present in Europe) in the vicinity and contribute to their establishment and modification of the biodiversity too. However the scope of this application is not for cultivation in Europe and the only way for T304-40 for growing in Europe is after unintentional release into the Environment. 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

T304-40 cotton is not intended to be grown in Europe at the moment. The only chance for T304-40 plants to exchange pollen with cotton grown in Europe would be the unintended release through a seed spill as a result of import.

Ports and crushing facilities are located in industrial areas where growing conditions are unlikely to support the growth of cotton. In addition it is a standard practice in these areas to destroy any weed and feral plants, which would hinder the movement of vehicles and equipments.

The only foreseeable chance for T304-40 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 cotton typically require some form of treatment to ensure adequate germination: heat treatment and a sulfuric acid delinting treatment to remove fuzz or linters from the seed coat (the delinted seed is also known as 'black' seed). Cotton seed and fuzzy seed germinate poorly, probably because the lint and linters attached to the seed coat limit contact with soil thereby inhibiting imbibing soil moisture. Seeds that may escape during transport do not give rise to persistent populations due to the seed treatment requirements. The need for significant moisture also prohibits growth of escapes in many locations. Even in areas with significant rainfall, escaped cotton has not been able to establish due to its poor colonizing ability.

Cotton is a domesticated crop that requires human intervention to survive in non-cotton production areas. Since cotton is an exotic species in the EU and has not become a weed pest over many centuries, there is no expectation that a new cotton variety with two traits would enhance that risk by becoming weedy in non-cotton production areas. The transfer of the *Cry1Ab* and *bar* gene into cultivated cotton will not exacerbate problems of weed control or adversely impact agriculture.

9.4 Interactions between the GM plant and target organisms

Glufosinate ammonium herbicide tolerance of T304-40 cotton, is an agronomic trait with the intended commercial effect to expand weed management options for cotton. This trait has no effect on any other organisms. As a consequence, there are no target organisms in the case of herbicide tolerance of T304-40.

The insect protection trait of T304-40 provides control against certain key cotton pests of the lepidopteran family. In case T304-40 enters the environment the target organisms may develop resistance to the insecticidal Cry1Ab protein. However, the scope of this application is for authorization of T304-40 cotton for food and feed uses, as well as import and processing and does not include authorization for cultivation of T304-40 cotton seeds in the EU. As a consequence, exposure to the environment will be limited to unintended release of the T304-40 cottonseed, which could occur via incidental spillage during transportation and processing. Taking into consideration the poor survival characteristics of conventional cotton under most European non-agricultural conditions and the fact that T304-40 cotton will be imported as mostly non-viable seed, a likelihood that imported T304-40 will establish a feral cotton population and will interact with potential target organisms affecting their insecticidal properties can be considered as negligible.

9.5 Interactions of the GM plant with non-target organisms

To evaluate the interaction between the GM plant and the non-target organisms a field study was conducted in Andalucia in 2009.

The results of these studies show that results from both sites are very similar and comparable. If effects were identified they could be attributed to the insecticide treatment and not to the T304-40 cotton. It can be concluded that the use of T304-40-cotton has no impact on the non-target arthropod-fauna.

Comparing insect populations on T304-40 and conventional cotton plants, no influence of *Cry1Ab* and *bar* gene expression was observed over the entomofauna of the cotton crop in any plant stage.

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 T304-40. As discussed in section D.7, cotton seed of T304-40 has the same nutritional quality as cotton in commerce. The plants of T304-40 have the same qualities as other cotton. No toxic or allergic effect from handling T304-40 has been observed on workers in the field since 2007, 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. This findings were confirmed by a 90 day feeding study performed with Wistar rats.

T304-40 cotton is not more anti-nutritional or toxic for animals than conventional cotton 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 insect-resistant glufosinate-tolerant cotton. For example, studies to evaluate the fitness of the event found cotton varieties containing T304-40 are not different in seed or lint yield 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 utilization from the soil to be different than for conventional cotton

Nevertheless the scope of this application does not include cultivation.

9.9 Impacts of the specific cultivation, management and harvesting techniques

The scope of this application does not include cultivation in the EU and therefore no impact on the cultivation, management and harvesting techniques is expected.

10. Potential interactions with the abiotic environment

The traits introduced in T304-40 cotton are not intended to modify the interactions of the plant with the abiotic environment. The intended commercial effect of T304-40 is to protect cotton from certain Lepidoptera and expand weed management options for the crop.

Moreover the scope of the present application does not include cultivation in Europe.

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 GTxLLxB2 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 T304-40 cotton for import, processing, food and feed use in the European Union (EU) under Regulation (EC) No. 1829/2003[1]. The scope of the application does not include authorisation for the cultivation of T304-40 seed products in the EU.

An environmental risk assessment (e.r.a.) was carried out for T304-40 cotton according to the principles laid down in Annex II to Directive 2001/18/EC and Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC. The scientific evaluation of the characteristics of T304-40 in the e.r.a. (Section D.9 and D.10 of this application) 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 T304-40 cotton relative to:

- Persistence and invasiveness
- Selective advantage or disadvantage
- Potential for gene transfer
- Interactions between the GM plant and target organisms
- Interactions of the GM plant with non-target organisms
- Effects on human health
- Effects on animal health
- Effects on biogeochemical processes
- Impacts of the specific cultivation, management and harvesting techniques
- Potential interactions with the abiotic environment.

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

As discussed in Section 2, the scientific evaluation of the characteristics of T304-40 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 T304-40 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)

4.1 Approach

General surveillance is not based on a particular hypothesis and it should be used to identify the occurrence of unanticipated adverse effects of the viable GMO or its use for human and animal health or the environment that were not predicted in the e.r.a.

The scope of this application is the authorisation of T304-40 cotton for import, processing, food and feed uses. The scope of the application does not include authorisation for the cultivation of T304-40 cotton.

Therefore, exposure to the environment will be limited to unintended release of T304-40 cotton, which could occur for example via substantial losses during loading/unloading of the viable commodity including T304-40 cottonseed destined for processing into animal feed or human food products. Exposure can be controlled by clean up measures and the application of current practices used for the control of any adventitious cotton plants, such as manual or mechanical removal and the application of herbicides (with the exception of glufosinate ammonium herbicide).

However and in order to safeguard against any adverse effects on human and animal health or the environment that were not anticipated in the e.r.a., general surveillance on T304-40 cotton will be undertaken for the duration of the authorisation. The general surveillance will take into consideration, and be proportionate to, the extent of imports of T304-40 cotton and use thereof in the Member States.

In order to increase the possibility of detecting any unanticipated adverse effects, a monitoring system will be used, which involves the authorisation holder and operators handling and using viable T304-40 cotton seed. The operators will be provided with guidance to facilitate reporting of any unanticipated adverse effect from handling and use of viable T304-40 cotton seed.

A detailed description of the methodology proposed for general surveillance of T304-40 cotton is provided in Section 4.6.

4.2 Baselines

Since the intended use of T304-40 cotton is the same as that of any other commercial cotton, the procedures for the import, handling and processing of cotton seed will be the same and have been considered in the development of the monitoring plan. The baseline and controls for general surveillance will rely on the historical knowledge and experience with non-GM cotton as comparable reference where necessary.

4.3 Time-period

General surveillance of T304-40 cotton will be undertaken for the duration of the authorisation period for T304-40 for import and processing.

4.4 Assigning responsibilities

The authorisation holder is responsible for ensuring that the monitoring plan is put in place and properly implemented in accordance with the conditions of the authorisation.

The authorization holder shall be in the position to give evidence to the Commission and the competent authorities of the Member States:

- That the monitoring networks as specified in the monitoring plan collect the information relevant for the monitoring of T304-40 cotton

- That the members of these networks have agreed to make available that information to the authorisation holder before the date of the submission of the monitoring report.

The third parties involved in the general surveillance will report any potential unanticipated adverse effects to the authorisation holder, who will immediately investigate and inform the European Commission in accordance with Regulation (EC) No 1829/2003, as described in Section 5.

4.5 Existing systems

Primary sources of information
The authorisation holder is not involved in commodity trade with T304-40 cotton. The monitoring methodology hence needs to be predominantly based on collaboration with third parties, such as operators involved in the import, handling and processing of viable T304-40 cotton seed. They are exposed to the imported viable T304-40 cotton and therefore are the best placed to observe and report any unanticipated adverse effects in the framework of their routine surveillance of the commodities they handle and use.

Since traders may commingle T304-40 cotton with other commercial cotton, including authorised GM cotton, the authorisation holder is working together with other members of the plant biotechnology industry within the European Association of Bioindustries (EuropaBio) and trade associations representing the relevant operators in order to implement a harmonised monitoring methodology. The following networks are currently involved:

⇒ *Importers / Traders*
COCERAL is the European association representing the cereals, rice, feedstuffs, oilseeds, oils and fats and agro-supply trade in the European Union. Its members are the national trade organisations that represent collectors, distributors, exporters, importers and agribulk storers of the above mentioned commodities in the majority of Member States. The main importers of cereals and feedstuffs into the EU are members of COCERAL.
Also see: http://www.coceral.com/cms/beitrag/10010169/227870.

⇒ *Silo Operators*
UNISTOCK is the European association representing professional storekeepers for agribulk commodities within the EU. It regroups representatives from 11 Member States and is itself a member of COCERAL. Commodity imports enter the EU by sea and transit through sea-port silos. The main storekeepers managing these silos are members of UNISTOCK.
Also see: http://www.coceral.com/cms/beitrag/10010260/232602

⇒ *Processors*
FEDIOL, the federation of the EU Oil and Protein Meal Industry, represents the interests of the European crushers of oilseeds meals producers and vegetable oils producers/processors. Its members represent 80% of the EU industry and hold 147 oilseeds processing and vegetable oils and fats production facilities across Europe.
Also see: http://www.fediol.be/1/main1.php.

These associations represent the majority of European operators importing, handling and processing viable cotton commodity. They work closely together with a continuous and efficient flow of communication between them, particularly, through the documentation that needs to accompany any shipment containing GMOs in accordance with the labelling and traceability requirements of Regulation (EC) No 1830/2003, and are therefore best placed to observe and report any unanticipated adverse effects.

Other networks consisting of operators further down the food and feed chain have not been selected for the general surveillance of viable T304-40, because they focus on processed, non-viable material.

Additional sources of information
In addition to the aforementioned existing monitoring systems, extensive independent research by scientists with a wide range of expertise is another valuable source of information on potential adverse effects arising from the use of GMOs. The authorisation holder will actively screen relevant reports and peer-reviewed publications on the use of T304-40 cotton, in order to identify potential unforeseen adverse effects linked to T304-40 cotton.

4.6 Monitoring Methodology

The authorisation holder, together with other members of the plant biotechnology industry and EuropaBio, will implement general surveillance of viable GM cotton, including T304-40, with the help of the selected networks described in Section 4.5.

The different parties agreed on a general framework for monitoring of GMOs, including T304-40, as follows:

⇒ The authorisation holder represented by EuropaBio will:

- Agree with the operators before adding or amending activities that fall under their responsibility in accordance with the proposed monitoring plan.
- Inform operators concerning the authorisation, safety and general characteristics of T304-40 cotton and of the conditions as to general surveillance
- Set up and maintain a website dedicated to operators including detailed information on T304-40 cotton. The website, hosted on the EuropaBio website under www.europabio.org/InfoOperators, contains the following information:

  - An introduction to the purpose of the website
  - A table giving an overview of all currently approved GM plant products subject to general surveillance
  - A profile for every approved GM plant product providing documentation on characteristics and safety, positive EFSA opinion(s) and Commission Decision(s) authorising the GM plant product in the EU
  - A contact point at EuropaBio for information exchange on any of the GM plant products

  The website will be regularly updated in order to further facilitate and ensure a transparent process for general surveillance and easy access to relevant information for operators.

- Contact the selected networks of operators annually reminding them of their agreement to report on any unanticipated adverse effects (or absence thereof).

⇒ The selected networks of operators (European trade associations) will:

- Inform and remind their member organisations and companies on an annual basis:

  - to monitor for potential unanticipated adverse effects
  - that, in the framework of their management or safety standards (ISO, HACCP, …), procedures must be in place and implemented to limit losses and spillage of viable CROP and to routinely eradicate adventitious populations on their premises – any such adventitious populations, resisting routine eradication procedures, shall be treated as potential adverse effects
  - to inform and remind their own member companies of this requirement

- to report back any adverse effect reported to them to the European trade associations

- Report to the authorisation holders directly or via EuropaBio
- at least annually, regardless whether an adverse effect was observed or not
- immediately any adverse effects reported to them.

Consequently, the European trade associations COCERAL, UNISTOCK and FEDIOL will notify EuropaBio of the results of the general surveillance on an annual basis. EuropaBio will forward this report to the respective authorisation holders for inclusion in their annual report to the European Commission, as described in Section 5.

The general surveillance information reported to and collected by the authorisation holder from the European trade associations or other sources will be analysed for its relevance. Where information indicates the possibility of an unanticipated adverse effect, the authorisation holder will immediately investigate to determine and confirm whether a significant correlation between the effect and T304-40 cotton can be established. If the investigation establishes that T304-40 cotton was present when the adverse effect was identified, and confirms that T304-40 cotton is the cause of the adverse effect, the authorisation holder will immediately inform the European Commission, as described in Section 5.

11.5 Reporting the results of monitoring

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

If information that confirms an adverse effect of T304-40 cotton and that alters the existing risk assessment becomes available, the authorisation holder will immediately investigate and inform the European Commission. The authorisation holder, in collaboration with the European Commission and based on a scientific evaluation of the potential consequences of the observed adverse effect, will define and implement management measures to protect human and animal health or the environment, as necessary. It is important that the remedial action is proportionate to the significance of the observed effect.

The authorisation holder 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 T304-40 cotton.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of T304-40 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 of Regulation (EC) No 1829/2003. Confidential parts of such report shall be submitted in separate documents.

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

The detection method for T304-40 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

Releases of T304-40 cotton have been notified under Part B of the Directive 2001/18/EC in Spain in 2007 (B/ES/01/39) and 2008 (B/ES/08/40; B/ES/08/37), 2009 (B/ES/09/32) and 2010 (B/ES/10/25).

b) Conclusions of post-release monitoring

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 human health or environmental risks were observed after the field trials.

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

a) Release country :

T304-40 has been field tested in the USA since 2005 under permit numbers 05-040-06n, 05-091-08n, 05-189-07n, 06-047-02n, 06-068-03n, 07-044-102n, 07-059-104n, 07-065-117n, 08-254-117n, 08-254-118n, 08-036-127n, 08-022-101n, 09-033-102n, 09-033-103n, 09-096-103n, 09-253-102n.

T304-40 has been also field tested in Argentina.

T304-40 has been field tested in Spain

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 T304-40 cotton 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.ec.europa.eu/gmp_browse.aspx and http://gmo-crl.jrc.ec.europa.eu/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 T304-40 cotton 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.ec.europa.eu/
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.ec.europa.eu/