PART II

SUMMARY

OF THE REQUEST FOR AUTHORIZATION OF GM FOOD AND GM FEED IN ACCORDANCE WITH ATICLES 5 AND 17 OF REGULATION (EC) NO. 1829/2003

GLUFOSINATE AMMONIUM-TOLERANT OILSEED RAPE TRANSFORMATION EVENT T45

A. GENERAL INFORMATION

1. Details of application

a) Member State of application: United Kingdom
b) Application number: Not available at the date of application
c) Name of the product (commercial and other names): Seed of genetically modified oilseed rape (*Brassica napus*) with tolerance to glufosinate ammonium, derived by traditional breeding methods from crosses between GM oilseed rape transformation event T45 (OECD code ACS-BNØØ8-2) and non-GM oilseed rape cultivars.
d) Date of acknowledgement of valid application: Not available at the date of application

2. Applicant

a) Name of applicant: Bayer CropScience GmbH
b) Address of applicant: Bayer CropScience GmbH Industriepark Höchst, K 607 D-65926 Frankfurt a.M **E-mail address:** info@bayercropscience.com
c) Name and address of the person established in the Community who is responsible for the placing on the market, whether it be the manufacturer, the importer or the distributor, if different from the applicant (Commission Decision 2004/204/EC Art 3(a)(ii)): T45 will be imported and processed in the EU by the same groups who import, process and distribute commodity oilseed rape today.

3. Scope of the application

☒ GM plants for food use

☐ Food containing or consisting of GM plants

☐ Food produced from GM plants or containing ingredients produced from GM plants

☒ GM plants for feed use

☐ Feed containing or consisting of GM plants

☐ Feed produced from GM plants

☒ Import and processing (Part C of Directive 2001/18/EC)

☐ Seeds and plant propagating material for cultivation in Europe (Part C of Directive 2001/18/EC)

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

Yes ☒	No
If *yes*, specify Food additives produced from T45 oilseed rape were notified in the EU as existing food additives within the meaning of Article 8 (1)(b) of Regulation (EC) 1829/2003, authorised under Directive 89/107/EEC and complying with the relevant specifications laid down under this legislation. Feed materials produced from T45 oilseed rape were also notified as existing feed falling within the scope of Article 20(1)(b) of Regulation (EC) No 1829/2003, namely as feed materials which are produced from a genetically modified organism (GMO).	

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

Yes ☒	No ☐
If *no*, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC	

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

Yes ☒	No ☐
If *yes*, specify: notification No. C/GB/99/M5/2. This notification is to replace 2001/18 notification No. C/GB/04/M5/4.	

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

Yes ☒	No ☐

If *yes*, specify:

Country	Submit Type	Granted
Canada	CFIA Unconfined Release	1997
	CFIA Novel Feed	1997
	Health Canada Novel Food	1997
USA	FDA Feed and Food Safety	1997
	USDA Import and Growing	1998
Mexico	Ministry of Health	2001
China	Nong Ji An Zheng Zi (Import only)	2004
Japan	MHW Food Clearance (T45)	1997
Australia	ANZFA Clearance (Food)	2002
New Zealand	OGTR Environment	2003
Korea	Korea Food & Drug Administration	2005
	Rural Development Administration	2005

8. General description of the product

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

The recipient plant belongs to the species, *Brassica napus* L. The genetic modification intends to confer the tolerance to the herbicide glufosinate ammonium through the genetic locus defined as T45. LibertyLink® oilseed rape varieties are developed by traditional breeding methods from crosses between T45 and non-GM oilseed rape adapted for planting in the oilseed rape production regions of North America.

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

Agricultural production of oilseed rape requires weed control, and successful weed control depends upon combinations of management practices. For oilseed rape production, farmers use the planting of weed-free seed, crop rotation to break weed cycles, seed bed preparation, conservation tillage programs and the application of one or more herbicides.

Growing LibertyLink oilseed rape allows to use an effective post-emergent herbicide and to avoid the precautionary pre-emergence herbicide treatments. It allows for postponing weed control operations and herbicide use until really necessary, contributing an important tool in Integrated Crop

Management. In addition it has eliminated the dependence of growers on the use of soil incorporated herbicides allowing for conservation tillage practices to be more widely adopted in the culture of canola in western Canada.

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

T45 was first commercialized in Canada and the USA in 1998.

Bayer Crop Science has discontinued the sale of T45 derived lines by its retailers and deregistered as of 2003 all T45 lines that it has produced with the exception of a single line that has remaining inventory (LL2393). Stock of all other T45 lines has been recalled from distribution and destroyed. The only remaining T45 line for sale in 2005 is LL2393 until inventory is exhausted.

T45 seed will be imported, processed and distributed in the European Union (EU) for all uses as any other oilseed rape (food, feed and industrial uses) excluding cultivation.

Rapeseed products derived from event T45 (rapeseed meal and rapeseed oil) will be imported in the EU.

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

In the EU, oilseed rape meal is used as high protein feed supplement for livestock and poultry.

Oilseed rape oil is an important vegetable oil source. Oilseed rape products derived from event T45 will be imported in the EU from Canada as commodity and could be used for downstream purposes as food, feed and industrial products identically to non-GM oilseed rape.

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 oilseed rape today remain adequate for the handling of glufosinate ammonium-tolerant T45 varieties.

When genetically modified oilseed rape is placed on the EU market (including co-mingled with non-genetically modified oilseed rape during use, storage and handling), the corresponding batch will be labelled and handled according to the legislation in application in the EU, in particular the Regulation No. 1830/2003 (EC).

e) Any proposed packaging requirements:

Seed containing T45 will be packaged as any other oilseed rape.

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:

T45 does not harbour characteristics that require specific labelling. Hence, no additional labelling is proposed on top of the GM labelling requirements foreseen in regulations (EC) 1829/2003 and 1830/2003.

g) Unique identifier for the GM plant (Regulation (EC) 65/2004; does not apply to applications concerning only food and feed produced from GM plants, or containing ingredients produced from GM plants): ACS-BNØØ8-2.
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 T45 is suitable for food, feed and industrial uses in all regions of the EU.

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

Taking into account the low amount of T45 grown in Canada, it is expected that the fraction of T45 in imported oilseed rape commodities is very small. The safety profile in terms of human and animal health and environmental impact of seeds of T45 and conventional oilseed rape are identical and do not constitute a hazard. The case of accidental spillage of non-processed T45 seeds, in transit or at the processing facility, has been 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:	*Brassicaceae*
b) Genus:	*Brassica*
c) Species:	*napus*
d) Subspecies:	*oleifera.*
e) Cultivar/breeding line or strain:	AC Excel
f) Common name:	oilseed rape

2 a. Information concerning reproduction

(i) Mode(s) of reproduction

Autogamous and allogamous reproduction: oilseed rape is a crop capable of both self-pollination (approx. 70%) and cross-pollination (approx. 30%). The pollen, which is heavy and sticky, can be transferred from plant to plant through physical contact between neighbouring plants and by wind and insects.

(ii) Specific factors affecting reproduction

Pollination is affected by temperature (insect visits), humidity (pollen viability) and wind (pollen dispersal). The spring-type *B. napus* is not very drought tolerant. Air and soil temperatures influence plant growth and productivity. The optimum temperature for maximal growth and development of spring-type oilseed rape is just over 20°C, and it is best grown between 12°C and 30°C. Pollinating insects, in particular honeybees (*Apis mellifera*) and bumblebees (*Bombus* sp.), play a major role in *B. napus* pollination. In crops that flower later in the season, insect pollination is more important in cross-pollination due to higher temperatures.

(iii) Generation time

The generation time in agronomic ecosystems is normally about 4 - 5 months for spring sown crops or 10 - 11 months for autumn sown crops.

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

Successful hybrid formation depends not only on the sexual compatibility of the recipient species (whether the same or related species) but the two species must flower simultaneously, share the same insect pollinator (if insect pollinated) and be sufficiently nearby for the transfer of viable pollen. The consequences of successful transfer will depend on the sexual fertility of the hybrid progeny, vigour and the fertility of subsequent generations or their ability to propagate vegetatively.

The possibility of gene flow from oilseed rape (*Brassica napus*) to wild relatives under natural conditions has been reported, mostly under optimal conditions, on four species: *Brassica rapa* (synonym *Brassica campestris*), *Brassica juncea*, *Hirschfeldia incana*, *Raphanus raphanistrum*.

Although it was stressed to be a very rare event, pollen flow to *Sinapis arvensis* was reported recently.

The frequency of gene flow from oilseed rape to wild relatives under natural conditions is considered very low, the fitness of the interspecific hybrids is generally reduced compared to the parents and the stable introgression of a new trait in the weed species genome is confirmed to be extremely difficult.

3. Survivability

a) Ability to form structures for survival or dormancy

Oilseed rape is an annual plant. Seeds are formed as structures enhancing survival. They can persist in soil through dormancy for several years if they were ploughed in deeper soil. Cultivation of the soil usually terminates this dormancy.

b) Specific factors affecting survivability

The survival ability of the seeds is affected by soil conditions such as temperature and moisture content.

4. Dissemination

a) Ways and extent of dissemination

The two differentiated reproductive structures suitable for dispersal of oilseed rape genes in the environment are the seed and pollen.

- **Seed dispersal** could occur during transport, at sowing and essentially before and during harvest.
- **Pollen dispersal** studies conclude that, although pollen can be blown by wind or carried away by insect pollinators over large distances, the bulk of cross-pollination occurs over very short distances. Successful pollination declines exponentially with increasing distance between the pollen source and the nearest recipient plant.

b) Specific factors affecting dissemination

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

Pollen dispersal in oilseed rape is mainly affected by wind and insects. Pollinating insects, in particular honeybees (*Apis mellifera*) and bumblebees (*Bombus* sp.) play a major role in *B. napus* pollination. The dynamics of bee mediated pollen movement depend on the quantity of pollen available (size and density of donor population) and the size and location of the receiving populations, as well as environmental conditions and insect activity.

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

Since the second world war, rapeseed production in Europe and Canada has increased dramatically as a result of improved oil and meal quality. China, India, Europe and Canada are now the top producers.

Today two species of *Brassica* (*B. napus* and *B. rapa*) have commercialised varieties with double low characteristics (low erucic acid content in the oil and very low glucosinolate content in the meal), characteristics desirable for high-quality vegetable oil and high quality animal feed.

B. napus is grown as a winter annual in regions where winter conditions do not result in very low temperatures. In North America and Northern Europe, a spring biotype of *B. napus* that requires no vernalisation prior to flowering is grown.

Oilseed rape is now one of the major global sources of vegetable oil and the major crop grown in Europe for the production of vegetable oil. In 2004 the total cultivation area of rapeseed in the world is approx. 26 million hectares, with approx. 15 million hectares in Asia (particularly India and China), 5,3 million hectares in North America (mainly Canada), 4,4 million hectares in the EU and 1,1 million hectares in Australia. In the EU the main producers are Germany (1 279 000 ha), France (1 117 000 ha, United Kingdom (557 000 ha) and Poland (500 000 ha).

Of the compatible wild relatives *Brassica rapa* (synonym *Brassica campestris*), *Brassica* juncea and *Raphanus raphanistrum* are present throughout Europe. *Hirschfeldia incana* has been reported in southern Europe; rarer in central and northern Europe.

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

Oilseed rape is commercially grown in the Member States.

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

Oilseed rape is known to interact with other organisms in the ecosystem including a range of **beneficial and pestiferous arthropods, bacteria, fungi, surrounding weed species, animals and humans**.

The crop has been cultivated in Member States for decades and has a history of safe use. Concerns about the nutritional safety of erucic acid in oilseed rape oil and of glucosinolates in oilseed rape meal led to the development of varieties of oilseed rape which have combined low levels of both glucosinolates and erucic acid (also known as "double low" varieties), characteristics desirable for high-quality vegetable oil and high quality animal feed.

Oilseed rape is not considered harmful or pathogenic to animals or humans; however, the plant does produce a small amount of natural antinutritional factors such as **erucic acid, glucosinolates** and **phytic acid.** Erucic acid levels in oil are well below the safety threshold. Concerning feed, with the exception of phytic acid, all the antinutritionals are subject to neutralisation during processing.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification

The genetic modification was performed by *Agrobacterium* mediated introduction of the chimeric gene denoted as P*35S*::*pat*::T*35S*.

2. Nature and source of the vector used

Plasmid pHOE4/Ac(II) is a derivative of pPCV002 (itself a derivative of the vector PiAN7 and pRK2), which was constructed in *Escherichia coli*, and thereafter transferred to a suitable *Agrobacterium tumefaciens* strain.

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

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

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

Source	Approximate Size (Kb)	Reference	Intended function
Synthetic DNA containing the Left border repeat from pTiAch5	0.04	Gielen *et al.*, 1984	None, remaining part of the vector
P35S: promoter region from the Cauliflower Mosaic Virus 35S transcript	0.53	Pietrzak *et al.*, 1986	Regulatory sequence for high level constitutive expression in the plant
Synthetic	0.03		Polylinker sequence
pat: the coding sequence of the bialaphos resistance gene of *Streptomyces viridochromogenes.*	0.55	Strauch *et al.*, 1993	Herbicide tolerance and selectable marker
Synthetic	0.02		Polylinker sequence
T35S: terminator region from the Cauliflower Mosaic Virus 35S transcript	0.20	Pietrzak *et al.*, 1986	Polyadenylation signal
Synthetic	0.01		Polylinker sequence
Synthetic DNA containing the Right border repeat from pTiT37	0.06	Depicker *et al.*, 1982	None; remaining part of the vector

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.

Gielen J., De Beuckeleer M., Seurinck J., Deboeck F., De Greve H., Lemmers M., Van Montagu M., Schell J. 1984. The complete nucleotide sequence of the TL-DNA of the *Agrobacterium tumefaciens* plasmid pTiAch5. The EMBO Journal 3, 835-846.

Pietrzak M., Shillito R.D., Hohn B., Potrykus I. 1986. Expression in plants of two bacterial antibiotic resistance genes after protoplast transformation with a new plant expression vector. Nucleic Acids Res. 14, 5857-5868.

Strauch E., Arnold W., Alijah R., Wohlleben W., Pühler A., Eckes P.. 1993. Phosphinothricin-resistance gene active in plants, and its use. European patent 275957 B1.

D. INFORMATION RELATING TO THE GM PLANT

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

All LibertyLink® crops are tolerant to commercial herbicides containing glufosinate ammonium (active form is L-glufosinate). Their herbicide tolerance is based upon the naturally occurring *pat* gene, isolated from soil microbes that produce L-phosphinothricin, a bacterial metabolite with antimicrobial and herbicidal activity. Glufosinate ammonium is the synthetic salt of this natural herbicide. Activity of the *pat* gene protects the microbe as it makes L-phosphinothricin. In a similar manner, expression of the *pat* gene in plants allows survival after a foliar spray with glufosinate ammonium herbicide. The *pat* gene codes for the enzyme phosphinothricin-acetyl-transferase (PAT) that acetylates L-phosphinothricin (also known as L-glufosinate) to an inactive form. The PAT protein is a highly specific enzyme with only this one function. If left in its L-isomer form, phosphinothricin disrupts the normal process of amino acid synthesis and results in a lethal build-up of ammonium in the microbe or plant cell. In a manner not unlike an inadvertent over-fertilisation of a plant, glufosinate ammonium herbicides cause sensitive plants to release internal ammonia, leading to rapid plant death.

Oilseed rape varieties based on transformation event T45 make the PAT protein mainly in their green leaf tissue. When sprayed with glufosinate ammonium herbicides, the T45 plants can continue to grow while surrounding weeds rapidly die.

Several formulations of glufosinate ammonium are commercially used in many regions of the world. Registered trade names include Liberty®, Ignite®, Finale® and Basta®. Registered uses in Europe include non-selective weed control in the floor of orchards and vineyards and desiccation of potatoes and oilseed rape prior to harvesting. LibertyLink® crops currently on the market in certain areas include varieties of corn, cotton, canola and soybean. None of them are cultivated in the EU.

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 glufosinate ammonium-tolerant, oilseed rape event T45 contains one copy of the *pat* gene.

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

Although the genetic modification was intended to insert a DNA fragment, 48 bp were deleted (target site deletion) upon integration of the T-DNA in the genomic DNA. Homology searches revealed that this piece of DNA most likely does not belong to a coding sequence.

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 has integrated in a single genetic locus in the oilseed rape nuclear genome (chromosome).

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

The characterisation of the inserted sequences in event T45 confirmed the presence of one copy of the *pat* gene cassette, and also the absence of vector backbone. There are no antibiotic resistance markers present in T45.

3. Information on the expression of the insert

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

The amount of PAT protein in seed of T45 has an upper limit of approximately 1 µg/g dry weight.

b) Parts of the plant where the insert is expressed

Linked to the plant promoter, *35S*, the expression of the *pat* gene is targeted to green tissue of the plant. Expression level was measured by northern blot analysis and PAT protein specific ELISA.

From published experience with the 35S promoter in cotton and rice, T45 plants were expected to show high levels of *pat* expression in the leaves, and lesser amounts in the other organs. Indeed, we found clear RNA expression in leaves, and, to a lesser extend, in seed. It was found that PAT protein constituted up to and 1 µg/g dry weight in seeds. PAT protein comprises up to 0.0027% of the total crude protein in seeds of event T45. ELISA reactive PAT protein was not found in the non-transgenic control oilseed rape organs.

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

a) Reproduction

The trait of herbicide tolerance had no effect as the mode and rate of reproduction are by seed production and are the same as for conventional oilseed rape.

b) Dissemination

Dissemination of the plants happens through the seed stage. The trait may also be conveyed via the pollen stage. No differences in dissemination capacity have been observed between genetically modified and non-genetically modified plants.

Studies show that the genetic modification did not modify the characteristics of the plants that could have an impact on seed dispersal.

c) Survivability

Survival is essentially determined at the seed stage. There is no indication of any change in seed characteristics as a result of the genetic modification. No difference in survival was recorded at the vegetative stage.

Although non-genetically modified oilseed rape as well as genetically modified oilseed rape can be volunteers in the following crops, current agricultural practices (including cultivation, rotation, selective herbicides) are able to control both modified and unmodified volunteer rape plants.

d) Other differences

The only biologically significant difference observed in field evaluations is that oilseed rape varieties based upon transformation event T45 are tolerant to Liberty® herbicide, active ingredient glufosinate ammonium.

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

The trait is inherited as a single dominant gene. To demonstrate the stability of the inserted DNA, Southern blot analysis was completed for different generations.

The isolated DNA was digested with the *Hpa*I restriction enzyme, which has only one recognition site in the T-DNA. Probing *Hpa*I restricted genomic DNA with the *pat* gene cassette showed the two expected bands in all T45 samples. These bands represent the junctions between transgenic sequences and plant DNA sequences upstream and downstream of the T-DNA insert They were identical in all samples.

The resulting Southern blots demonstrate the molecular stability of the oilseed rape event T45 at the genetic level over multiple generations.

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 T45 to bacteria could occur.

b) Plant to plant gene transfer

There is no evidence of genetic transfer and exchange under natural conditions with organisms other than those with which oilseed rape is able to produce fertile crosses through sexual reproduction. There are no indications that the potential for successful exchange has changed due to the genetic modification. The possibility of gene flow to wild relatives under natural conditions has been reported, mostly under optimal conditions, on four species *Brassica rapa*, *Brassica juncea*, *Hirschfeldia incana*, *Raphanus raphanistrum*.

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

Compositional analysis for seed compared T45 and the reference varieties.

7.2 Production of material for comparative assessment

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

The geographic range included the main oilseed rape growing regions of Saskatchewan and Alberta, Canada. Seed samples were collected from two growing seasons (2000 and 2004), 12 locations, three treatments from almost every location, and a 3 to 4-fold replication per treatment. The three treatments consisted of: a) non-transgenic oilseed rape grown using conventional herbicide weed control, b) transgenic oilseed rape grown using conventional herbicide weed control, and c) transgenic oilseed rape grown with Liberty® herbicide weed control.

b) The baseline used for consideration of natural variations

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

7.3 Selection of material and compounds for analysis

Bayer CropScience undertook a systematic review of the composition of the seed derived from T45. 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 oilseed rape. These are proximates, amino acids, fatty acids, micronutrients such as vitamins and minerals, and antinutrients such as erucic acid, glucosinolates and phytic acid. The data demonstrate that rapeseed from T45 has the same nutritional composition as its non-transgenic counterpart, and values for nutritional components fall within the range of values reported for commodities in commerce.

Rapeseed oil is a high-quality cooking oil, due to its balance in unsaturated fatty acids, high alpha linolenic acid (an omega-3 fatty acid), and high tocopherol (vitamin E) content. The lipid profile is preserved in T45. The fatty acid and tocopherol levels in the transgenic rapeseed oil samples are similar to the respective conventional rapeseed oil samples and within the range reported by the literature.

Antinutritional factors common to oilseed rape were measured in oilseed rape seed and meal and are well below acceptable levels, and similar to levels in conventional oilseed rape.

7.4 Agronomic traits

Throughout the field testing history of T45 there were no differences observed that could be attributed to pleiotropic effects of the *pat* gene insertion. Neither did T45 differ from the reference variety in nutritional, 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. Field studies were conducted in Canada in 1995, 1996, 1997 and 2004. A summary of the comparisons between T45 and the reference oilseed rape varieties is provided in Table 2.

There is no indication in the data of agronomic performance that T45 is unlike oilseed rape that is currently grown and consumed.

Table 2. Summary of parameters evaluated in the comparison of varieties containing T45 and the parent and reference varieties

Characteristic	Parameters	Finding
Plant morphology	Plant height Maturity Lodging resistance Seed yield	Same as recipient variety
Reproductive traits	Flower morphology Days to 50% flowering Days to finish flowering Days to maturity	Same as recipient variety
Field performance	Emergence Establishment Vigour Height Yield Rate of growth (days to 50% flowering)	Same as recipient variety
Pest and disease resistance	Severity rating for naturally occurring pathogens	Same as recipient variety
Fecundity	Seed yield Seed index (1000 seed weight)	Same as recipient variety
Persistence	Competing ability Invasive potential	Same as recipient variety
Nutritional composition of seed	Proximates, amino acids, minerals, vitamin E, fatty acids	Same as recipient variety
Antinutritional components	Erucic acid, glucosinolates, phytic acid	Same as recipient variety

7.5 Product specification

The derived food is rapeseed oil and the derived feed the by-products of seed processing (e.g. rapeseed meal).

Glufosinate ammonium-tolerant oilseed rape transformation event T45 has been conventionally bred into varieties with adaptation to the various zones of oilseed rape cultivation (T45 varieties). T45 varieties belong to the species, *Brassica napus* L. and are distinguished from other oilseed rape only by tolerance to the herbicide, glufosinate ammonium, the genetic locus defined as T45 and the presence of the PAT protein.

7.6 Effect of processing

The T45 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 oilseed rape 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 (rapeseed meal, crude rapeseed oil) were found to be equivalent to other oilseed rape.

Processing using heat, for example cooking, high pressure steam, plus solvents, alkali treatments, degrades the PAT protein. In crude and refined rapeseed oil, the PAT protein is not detected.

7.7 Anticipated intake/extent of use

The intake of rapeseed oil in the diet of the EU is not anticipated to change with the introduction of T45 varieties. Oilseed rape and oilseed rape products derived from T45 varieties are not different in quality or nutritional composition from the rapeseed products now consumed. No change in the use patterns for oilseed rape is anticipated. No potential dietary and nutritional impacts have been identified for oilseed rape and oilseed rape products derived from T45 varieties.

The *per capita* consumption of rapeseed oil for the European diet is 7,6 g/day. The extremes of rapeseed oil consumption in the member States include 0,3 g/person/day in Spain and 31,4 g/person/day in Sweden. The *per capita* consumption in Canada is 37,2 g/day.

7.8 Toxicology

7.8.1 Safety assessment of newly expressed proteins

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

- The coding sequence of the *pat* gene is derived from a common soil microbe not known to be a pathogen.
- The PAT protein is quickly degraded and denatured in simulated gastric and intestinal fluids of domestic animals and humans.
- The PAT enzyme is highly substrate specific. It acts on its target, glufosinate ammonium but it does not act on glutamate, the closest structural analogue of L-glufosinate.
- There were no adverse effects found in mice, even at a high dose level of the PAT protein, after intravenous administration.

7.8.2 Testing of new constituents other than proteins

No other constituent than the PAT protein is novel and no changes in composition of oilseed rape were discovered by chemical analysis.

7.8.3 Information on natural food and feed constituents

Natural constituents of oilseed rape have not been changed in T45. Extensive compositional analysis was undertaken, taking into consideration the OECD "Consensus Document on Key Nutrients and Key Toxicants in Low Erucic Acid Rapeseed (Canola)". Equivalence in the whole seed was demonstrated for all proximates, fibre compounds, and the total amino acids. Good agreement between the findings for T45, the comparator and the baseline support the conclusion of compositional equivalence to oilseed rape currently in commerce.

7.8.4 Testing of the whole GM food/feed

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

The broiler chicken is an economically significant and widely distributed food animal. The species used is based upon commercial practice and is very sensitive to detect differences in nutrient quality because of its rapid growth (15-fold increase in body weight over the first 21 days). This study showed no indications that neither the event T45 nor the transformation process itself, has adverse effects on feeding, growth or general health. Moreover, no negative impacts of the nutritional quality of the event T45 were observed on poultry.

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

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

The PAT protein has no homology with any known allergen, toxin or antinutrient.

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

The PAT protein forms only an extremely minor part of the crude protein fraction in T45, making it unlikely to become a food allergen, which tend to be major proteins.

7.9.2 Assessment of allergenicity of the whole GM plant or crop

Oilseed rape (*Brassica napus* L.) is not considered an allergenic food.

Plants are known to naturally produce toxins and allergens that often serve the plant as natural defence compounds against pests and pathogens. The inclusion of rapeseed products in human food or animal feed is limited due to the presence of some antinutrients that could act as toxic compounds. These antinutritional and toxic factors are erucic acid, glucosinolates and phytic acid. Erucic acid is present in the oil and glucosinolates are present in the meal and the seed. Breeding efforts have reduced the levels of both erucic acid and glucosinolates resulting in “double zero” varieties (Europe) and “canola”-type varieties (Canada). In Europe, “double zero” rapeseed varieties are defined as those producing seed with a maximum glucosinolate content of 25 µmoles/g (seed weight) and with a moisture content of 9% and, having erucic acid content of not more than 2% of the total fatty acid content. Canola is defined as having less than 2% erucic acid in the oil and less than 30 µmol/g glucosinolates in the air-dried, oil-free meal. AC Excel, the recipient variety of T45, meets these criteria. The transformation process did not result in levels significantly different from the recipient variety.

Therefore, rapeseed oil and meal are currently considered not to contain common food toxins or antinutritional components of concern for human and animal health, because either the product only has minor amounts of these active compounds or their levels decrease (or they even disappear) during processing.

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. Therefore, no allergic reaction is expected from its current use pattern.

7.10 Nutritional assessment of GM food/feed

7.10.1 Nutritional assessment of GM food

The introduced trait in T45 is intended for agronomic benefits. Extensive compositional analysis was undertaken, taking into consideration the OECD "Consensus Document on Key Nutrients and Key Toxicants in Low Erucic Acid Rapeseed (Canola)". No change in the nutritional composition was intended and upon extensive analysis, none was found.

The oilseed rape oil is for human consumption, the protein rich meal is meant for animal feeding. The nutritional composition of the seed, and certain processed products were found to be equivalent to other oilseed rape by chemical analysis. The key nutrients, fatty acids and vitamin E (tocopherol), which are the principal components of rapeseed oil, were investigated. The lipid profile is preserved in T45, and the fatty acid levels in the transgenic rapeseed oil samples are similar to the respective conventional rapeseed oil samples and within the range reported by the literature.

Rapeseed oil from T45 has the same nutritional composition as its non-transgenic counterpart, and values for nutritional components fall within the range of values reported for commodities in commerce.

7.10.2 Nutritional assessment of GM feed

Extensive compositional analysis was undertaken, taking into consideration the OECD "Consensus Document on Key Nutrients and Key Toxicants in Low Erucic Acid Rapeseed (Canola)". The by-products of rapeseed processing (rapeseed meal and rapeseed hulls) can be used in animal feed. Oilseed rape contains some antinutritional factors, most of which are concentrated in the meal fraction. The antinutritional factors include glucosinolates and phytic acid. With the exception of phytic acid, all of the antinutritional factors are subject to heat denaturation. Rapeseed meal is typically subjected to a moist heat treatment to facilitate oil removal. This treatment denatures proteins and further reduces the content of glucosinolates. Antinutritional factors common to oilseed rape were measured in whole seed and rapeseed meal and are well below acceptable levels, and similar to levels in conventional oilseed rape.

7.11 Post-market monitoring of GM food/feed

No post-market monitoring plan is required for GM food/feed produced from T45. Traditional comparators were used in the comparative analysis (7.1-3). The intent of the genetic modification was for agronomic benefit (7.4), no change in the nutritional composition or value was intended and no change was identified (7.6, 10). No health claims are intended and T45 will not be marketed as an alternative to or replacement for traditional oilseed rape (7.5). T45 has no specific properties that might increase the dietary intake compared to traditional oilseed rape (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 T45 (7.8-10).

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

Not applicable. There are no target organisms.

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

9.1 Persistence and invasiveness

A review of the reproductive and vegetative fitness finds that T45 compares to its parent variety in all aspects except for the tolerance to glufosinate ammonium herbicide. Studies have found no indication of increased persistence or invasiveness of T45.

9.2 Selective advantage or disadvantage

None. Agronomic performance shows no disadvantage. The only circumstance in which a selective advantage could happen would be if some plants from escaped seed would be sprayed with glufosinate ammonium. The likelihood that some escaped seed would germinate is low because crushing facilities that handle oilseed rape are located in industrial areas at seaports or along the river Rhine. In addition the herbicide glufosinate ammonium is not likely to be used in the vicinity of seed storage facilities, processing plants or waterways, areas where such an escape might occur.

9.3 Potential for gene transfer

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

Sequence analysis of elite event T45 confirmed (Section D.2), the insertion of one copy of the *pat* gene cassette only and also the absence of vector backbone sequences. T45 does not contain either an origin of replication from plasmid pHOE4/Ac(II) or any sequences responsible for an enhanced frequency of recombination. Furthermore the introduced *pat* gene is under the control of the 35S promoter, which is not functional in bacteria. Considered altogether, these facts make the possibility of gene transfer from plants of T45 to bacteria to be unlikely.

Plant to plant gene flow. Gene flow to other oilseed rape crop is possible in production areas of Europe. Impacts of out-crossing to other cultivated oilseed rape can be managed with isolation distances in commercial production.

The possibility of gene flow to wild relatives under natural conditions has been reported, mostly under optimal conditions, on four species *Brassica rapa*, *Brassica juncea*, *Hirschfeldia incana*, *Raphanus raphanistrum*. There are no indications that the potential for successful exchange with these organisms through sexual reproduction, has changed due to the genetic modification.

Likelihood of gene flow. Gene flow can occur into an adjacent oilseed rape crop. However, the rate is dependent on proximity, weather conditions, insect activity and flowering period.

The frequency of gene flow to wild relatives under natural conditions is considered very low, the fitness of the interspecific hybrids is generally reduced compared to the parents and the stable introgression of the herbicide tolerance trait in the weed species genome is confirmed to be extremely difficult.

T45 is not intended to be grown in Europe. The only chance for T45 plants to exchange pollen with oilseed rape grown in Europe would be the unintended release through a seed spill as a result of import.

Consequence of gene flow. The transfer of the *pat* gene into cultivated oilseed rape will not exacerbate problems of weed control or adversely impact agriculture. Glufosinate ammonium is used mainly in agricultural areas in Europe, and the weed management of roadsides and the yards of processing facilities based on the use of glufosinate ammonium is not common practice.

As a consequence, the establishment of a lasting feral oilseed rape population dominated by T45 is unlikely, and the likelihood that T45 would be introduced into the environment is very low and not higher than conventional oilseed rape. No adverse impact to biodiversity was identified.

9.4 Interactions between the GM plant and target organisms

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

9.5 Interactions of the GM plant with non-target organisms

Three possible interactions with other organisms were examined. The genetic modification, tolerance to the herbicide, glufosinate ammonium, does not change the interaction of GM oilseed rape varieties with other organisms in the absence of herbicide application. Under agricultural conditions when the herbicide is used: i.) some advantage may be gained in plant population dynamics; ii.) in habitats outside agriculture, the interaction with other plant communities is like any other oilseed rape; iii.) no changes could be identified in interactions with non-target organisms in the environments under which glufosinate ammonium tolerant oilseed rape will be cultivated (Canada). Under agricultural conditions, with direct comparisons of herbicide application, insect population diversity and measures of sensitivity to natural pathogens of oilseed rape found no advantage for the transgenic event T45.

a) Effects on biodiversity in the area of cultivation
   The scope of the present application does not include cultivation in Europe and is limited to "import and processing" in EU. In the area of cultivation (NA), T45 may establish in the environment and, thereby, modify the biodiversity only under pressure of selection in an area treated with glufosinate ammonium. Furthermore it might transfer the trait via pollen flow to other cultivated oilseed rape and wild relatives in the vicinity and contribute to their establishment and modification of the biodiversity too. However extensive environmental risk assessment has been carried out with T45 in various countries and approvals have been granted in the USA, Canada and Australia.

b) Effects on biodiversity in other habitats
   Most of the oilseed rape grain that is imported from North America is processed in crushing plants at the seaport or along the river Rhine. These areas probably do not provide conditions for oilseed rape populations to establish. Moreover, the EU crushing industry is HACCP compliant, covering safety, operating and environmental issues.
   The safety profile in terms of human and animal health and environmental impact of grains of T45 and conventional oilseed rape are identical and do not constitute a hazard.
   The case of accidental spillage of non-processed T45 grains, in transit or at the processing facility, has been foreseen in the post market monitoring plan (see paragraph 11.4).

c) Effects on non-target organisms
   There are no non-target organisms specific to T45 compared to non-genetically modified oilseed rape. There are no observed effects of the herbicide-tolerant oilseed rape on non-target organisms. Careful monitoring of trial areas in Canada has shown no evidence of adverse effects on wildlife or insects that frequent canola fields. However, the Farm Scale Evaluations in the UK did point to some shifts in fauna and flora as a result of the application of glufosinate ammonium as compared to conventional herbicide application regimes. These effects arise from the crop management regimes associated with these GMHT crops (i.e. the herbicide application) and are not a direct consequence of the way the crops have been bred.

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 T45. Seed of T45 has the same nutritional quality as rapeseed in commerce. The plants of T45 have the same qualities as other oilseed rape. No toxic or allergic effect from handling T45 has been observed on workers in the field since 1993, year of its first field release.

9.7 Effects on animal health

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

To support the finding of nutritional equivalence and to demonstrate bioavailability, poultry were fed diets containing oilseed rape 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 meal in the tested animal species.

Birds or small rodents might feed on oilseed rape in the field. Seed of transformation event T45 is not antinutritional or toxic for animals and no effects on animal health are expected.

9.8 Effects on biogeochemical processes

Potential effects on biogeochemistry were assessed indirectly in agronomic studies designed to identify best agronomic practices for growing glufosinate ammonium-tolerant oilseed rape. For example, studies to evaluate the fitness of the event found that oilseed rape varieties containing the transformation event, T45 are not different in seed or oil yield response to soil composition than comparable oilseed rape varieties.

Chemical analysis of the components in seed found no or no major differences in the mineral composition and thus no reason to consider mineral utilisation from the soil to be different or more intense than for conventional oilseed rape.

Moreover, the scope of the present application does not include cultivation of T45 in Europe and is limited to “import and processing” in the EU.

9.9 Impacts of the specific cultivation, management and harvesting techniques

T45 varieties will be grown principally in Canada and enters the EU by import as commodity rapeseed. Crushing, processing and consumer packaging are accomplished in the EU. No new crushing or processing activities are required for T45.

Oilseed in agricultural production requires weed control and successful weed control depends upon combinations of management practices. For rapeseed production, farmers use the planting of weed-free seed, crop rotation to break weed cycles, seed bed preparation, conservation tillage programs and the application of one or more herbicides.

The Liberty® oilseed rape system provides several advantages for farmers. Growing LibertyLink oilseed rape allows to use an effective post-emergent herbicide with positive environmental characteristics and to avoid the precautionary pre-emergence herbicide treatments. It allows for postponing weed control operations and herbicide use until really necessary, contributing an important tool in Integrated Crop Management. In addition it has eliminated the dependence of growers on the use of soil incorporated herbicides allowing for conservation tillage practices to be more widely adopted in the culture of canola in western Canada.

Moreover, the scope of the present application does not include cultivation of T45 in Europe and is limited to “import and processing” in the EU.

10. Potential interactions with the abiotic environment

No interaction with the abiotic environment is foreseen that would differ from oilseed rape now in cultivation and in commerce. Lesser soil erosion may be a benefit of the cultivation of T45 as farmers growing it will be able to practice minimum tillage and conservation tillage systems.

Moreover, the scope of the present application does not include cultivation of T45 in Europe and is limited to “import and processing” in the EU.

11. Environmental monitoring plan (not if application concerns only food and feed produced from GM plants, or containing ingredients produced from GM plants and if the applicant has clearly shown that environmental exposure is absent or will be at levels or in a form that does not present a risk to other living organisms or the abiotic environment)

11.1 General (risk assessment, background information)

The scope of this application is the import of seed derived from T45 for food, feed and industrial uses. No authorisation for growing is requested in the Member States of the EU.

Based on the conclusions of the environmental risk assessment (e.r.a.), monitoring can address the identified potential risks of the GMO to human health or the environment on a case-by-case basis, and confirm the related assumptions in the e.r.a. This is referred to as case-specific monitoring.

The identification of potential adverse effects of the GMO on human health and the environment, which were not anticipated in the e.r.a., can be addressed under the general surveillance.

11.2 Interplay between environmental risk assessment and monitoring

Because there are no adverse effects identified relating to import of herbicide-tolerant T45, the resulting monitoring to perform is limited to a general surveillance of potential adverse effects, immediate or delayed, direct or indirect, of the GMO on human health and/or the environment which are not covered in the e.r.a.

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

Since no risk has been identified, there is no need for a case-specific monitoring plan.

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

The scope of this application is the import of seed derived from T45 for food, feed and industrial uses, no authorization for growing is requested at the moment in the Member States of the EU. The general surveillance will be focused on those domains involved from import to crushing facilities. The identification of possible unanticipated adverse effects of the GMO on human or livestock health and/or the environment, which were not anticipated in the e.r.a., can be addressed under the general surveillance.

Parameters to evaluate

General surveillance intends to identify the unanticipated adverse effects. However, because of the unanticipated character it is difficult to formulate the parameters to be assessed or to be measured. Because these parameters are usually not part of a routine observation, data are probably reported in such a way not adequate in terms of statistical power. In addition, because of the unanticipated character, no existing baseline data are probably available, which makes a comparative analysis impossible. Maybe at the best, reference can only be made to knowledge or experience of the observer.

However, general surveillance performed by the combination of organisations, networks and/or company monitoring programmes intends to include all key parameters covering species/ecosystem biodiversity, soil functionality, sustainable agriculture, or plant health.

Implementing general surveillance

Upon approval of T45 in the EU, Bayer CropScience will ensure that awareness of the GM crop is made widely available through stakeholders by providing key information, and will invite these stakeholders to participate in general surveillance:

- Inform European operators, especially traders and processors of bulk mixtures of oilseed rape grain, that T45 has been authorized in the EU for import and use thereof as any other oilseed rape, excluding cultivation in the EU;
- Supply European operators, especially traders and processors of bulk mixtures of oilseed rape grain, with information about T45 products and their safety in accordance with the requirements of Directive 2001/18/EC, relating to the Placing on the Market of the GM crop;
- Inform European operators involved in the import of oilseed rape grain that labelling of products for the European market must be executed in accordance with article 4 and 5 of Regulation (EC) 1830/2003 of the European parliament and of the Council of 22 September 2003 concerning traceability and labelling of GMOs and traceability of food and feed products produced from GMOs and amending Directive 2001/18/EC;
- Supply European operators involved in the import of oilseed rape grain with the OECD Unique Identifier Code:

  T45: ACS-BNØØ8-2

- Review with European operators involved in the import and processing of oilseed rape grain seed the existing measures to minimize grain spillage and clean-up practices in the frame of good manufacturing practices and environmental management systems already in place for crushing facilities and ports in the EU;
- Invite European operators involved in the import and processing of oilseed rape grain, to provide regular feedback on the general surveillance;
- Request from European operators involved in the import and processing of oilseed rape grain, to report in timely fashion any unanticipated adverse effects associated with the use of the product, so that decisive (if necessary remediating) action can be taken, including risk-reducing measures;
- In addition, company experts will actively screen for information on the product which could be publicly available on the web or published in literature and to inform the Competent Authority and Commission in case adverse effects will be reported, in particular with respect to human, animal and/or environmental safety;
- Provide to European operators involved in the import and processing of oilseed rape grain, the reference to the Register: http://europa.eu.int/comm/food/food/biotechnology/authorisation/commun_register_en.htm

In addition, 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.

Existing surveillance systems

Receiving environment

Those people and networks best suited to surveillance of the broader receiving environment in which the grain derived from a GM crop is transported and processed would be those whose day-to-day work gives them regular experience of this environment

Human and livestock health

Those people and networks having regular contact with handlers, processors, users, and farm livestock, are best suited for surveillance of any unanticipated human occupational health and livestock health effects.

Primary sources of surveillance information

The grain import and distribution network

To meet the requirements of the Traceability and Labelling regulations, shipments of grain derived from GMO crops will be identified as such in the invoice and import documents. The industry is experienced in tracking shipments with full documentation of the origin of the grain.

Key external networks

The use of existing networks to provide surveillance information is seen as a key aspect of ensuring that sufficient observers are available to identify and report possible unanticipated adverse effects, as well as ensuring methodological consistency and optimising the expenditure of resources. This would include existing observation programmes in the receiving environment, occupational health and livestock welfare.

Other sources of surveillance information

Although not a formal part of the surveillance plan, it is appropriate to note that there is an extensive information network, with global reach, which will provide additional information on possible unanticipated adverse effects arising from the use of GM crops. These include new and rapid means of access to information from across the globe through telecommunications, the media and Internet access. Through these means, many groups, including agronomists, ecologists, health professionals, and the general public now have unprecedented access to reports on the use world-wide of GM crops. In addition, electronic discussion sites, for example those of WHO, OECD, FAO, and consumer organisations, are valuable sources of information and communication for professionals and, in many cases, the general public.

Information collection and analysis

Surveillance information will be collected from three primary sources:

1. Feedback from selected networks can be gained by an active surveillance in collaboration with organisations and/or networks.
2. Passive surveillance will be recorded via the collection of voluntary briefings of operators.
3. Ongoing record keeping of reported potential adverse effects and other relevant information received via direct contacts with Bayer CropScience.

Evaluation of potential adverse effects

Where scientific evaluation of the observation confirms the possibility of an unanticipated adverse effect, this would be investigated further to establish a correlation, if present, between the use of the GM crop and the observed effect. The analysis should consider the consequence of the observed effect and remedial action, if necessary, should be proportionate to the significance of the observed effect.

11.5 Reporting the results of monitoring

Bayer CropScience propose to submit general surveillance reports on an annual basis, following the initial placing on the market (first import). A final report will be made at the end of the consent.

Indirect effects refer to a causal chain of events with an effect on human health and the environment. Observations of indirect effects might, in some cases, be delayed. Since surveillance will also include the observation of potential indirect and/or delayed effects, we propose to include a report covering potential indirect or delayed effects at the stage of re-evaluation or at the end of a given consent in the case where Bayer CropScience does not apply for a renewal. An evaluation of the need for additional, post-consent surveillance will be included in such a report.

If information that confirms an adverse effect which alters the existing risk assessment becomes available to the notifier from users or other sources, Bayer CropScience is required immediately to inform the Competent Authority which gave consent for marketing of the GM crop, and in collaboration with the Competent Authority, to evaluate the information and, if necessary, to take proportional measures necessary to protect human or livestock health and/or the environment. Bayer CropScience will submit a Report, consisting of a scientific evaluation of the potential adverse effect and a conclusion on the safety of the product. The report will also include, where appropriate, the measures that were taken to ensure the safety of human or livestock health and/or the environment.

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

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

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

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

a) Notification number

UK: GB/95/R19/7, GB/96/R19/11 and GB/97/R19/14
Sweden: B/SE/98/1070 and B/SE/99/469

b) Conclusions of post-release monitoring

Volunteers managed by current agricultural practices.

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.

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

a) Release country

T45 was first commercialized in Canada and the USA in 1998. Bayer Crop Science has discontinued the sale of T45 derived lines by its retailers and deregistered as of 2003 all T45 lines that it has produced with the exception of a single line that has remaining inventory (LL2393). Stock of all other T45 lines has been recalled from distribution and destroyed. The only remaining T45 line for sale in 2005 is LL2393. Sales in 2004 were proximately 9600 acres and sales for 2005 are expected to be less than half the 2004 amount or 4000 acres. Therefore sales for 2005 will be less than 0.05 % of canola seeded acres. It can be expected that sales for 2006 season will be again be less or near zero as remaining inventory is exhausted.

USA (field release since 1996, no longer regulated since 1998)
Authority overseeing the releases: United States Department of Agriculture (USDA)
Information on the releases at www.aphis.usda.gov/
Canada (field release since 1993, feed approval 1995, food approval 1997)
Authority overseeing the releases: Canadian Food Inspection Agency (CFIA), Plant Biotechnology Office
Information on the releases at http://www.inspection.gc.ca/english/plaveg/bio/pbobbve.shtml.

b) Authority overseeing the release

See E.2.a.

c) Release site See. E.2.a
d) Aim of the release See E.2.a., Field releases for breeding and variety development, technical developments for best agronomic practices and oilseed rape integrated pest management systems have been conducted.
e) Duration of the release The generation time in agronomic ecosystems is normally about 4 - 5 months for spring sown crops.
f) Aim of post-releases monitoring Volunteer T45 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 can be managed by the usual agronomic practices for oilseed rape.
i) Results of the release in respect to any risk to human health and the environment No risk to human health or the environment has been indicated by the field release experience.

3. Links (some of these links may be accessible only to the competent authorities of the Member States, to the Commission and to EFSA):

a) Status/process of approval The JRC websites http://gmoinfo.jrc.it /gmc_browse.asp and http://gmocrl.jrc.it/statusofdoss.htm provide publicly accessible links to up-to-date databases on the regulatory progress of notifications under Directive 2001/18/EC and Regulation (EC) No 1829/2003.
b) Assessment Report of the Competent Authority (Directive 2001/18/EC) Not yet available
c) EFSA opinion Not yet available
d) Commission Register (Commission Decision 2004/204/EC) Not yet available
e) Molecular Register of the Community Reference Laboratory/Joint Research Centre Information on detection protocols will likely be posted at www.gmo-crl.jrc.it/
f) Biosafety Clearing-House (Council Decision 2002/628/EC www.bch.biodiv.org/

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

www.gmoinfo.jrc
Reference notification C/GB/04/M5/4