# Application for renewal of the authorisation for continued marketing of existing food additives, feed materials and feed additives produced from GT73 oilseed rape that were notified according to Articles 8(1)(b) and 20(1)(b) of Regulation (EC) No 1829/2003 on genetically modified food and feed

# Part II

# Summary

## A. GENERAL INFORMATION

### 1. Details of application

**a) Member State of application**

Not applicable.

**b) Notification number**

Not available at the time of submission.

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

The name of the product is Roundup Ready® oilseed rape.

The Monsanto development code for this genetically modified oilseed rape is GT73. GT73 varieties are marketed under the name of the variety, in association with the trademark Roundup Ready® oilseed rape, indicating that GT73 oilseed rape[1] is tolerant to glyphosate, the active ingredient in Roundup® herbicides.

**d) Date of acknowledgement of notification**

Not available at the time of submission.

### 2. Applicant

**a) Name of applicant**

Monsanto Company, represented by Monsanto Europe S.A.

**b) Address of applicant**

| | |
|---|---|
| Monsanto Europe S.A. | Monsanto Company |
| Avenue de Tervuren 270-272 | 800 N. Lindbergh Boulevard |
| B-1150 Brussels | St. Louis, Missouri 63167 |
| BELGIUM | U.S.A. |

**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))**

GT73 is produced in other world areas and is imported and used in the European Union by operators that have traditionally been involved in the commerce, transport and use of oilseed rape-derived products in the EU.

[1] Hereafter referred to as GT73.

® Roundup and Roundup Ready are registered trademarks of Monsanto Technology LLC.

**3. Scope of the application**

**( ) GM plants for food use**

**( ) Food containing or consisting of GM plants**

**(x) Food produced from GM plants or containing ingredients produced from GM plants**

**( ) GM plants for feed use**

**( ) Feed containing or consisting of GM plants**

**(x) 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 ( x )** |
| **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 ( x )** | **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 ( x ) | No ( ) |
|---|---|

**If *yes*, specify**

An application for the import and use of GT73 grain under Directive 90/220/EEC was submitted in 1998 to the Dutch Competent Authority. A consent was granted on 31 August 2005 by the European Commission, but has yet to come into force.

In 1995, Monsanto provided the UK Advisory Committee on Novel Foods and Processes (ACNFP) with a complete dossier on GT73 oilseed rape, including information demonstrating that oil from GT73 oilseed rape is equivalent to rapeseed oil currently on the market. Based on the opinion of the UK Competent Authority, in 1997 Monsanto notified foods and food ingredients produced from GT73, specifically refined oil, to the European Commission according to Article 5 of Regulation N°258/97 on novel foods and novel food ingredients.

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

| Yes ( x ) | No ( ) |
|---|---|

**If *yes*, specify**

GT73 has been notified and evaluated by numerous international regulatory authorities, which granted its approval in Canada, U.S.A., Japan, Australia, Mexico, China, Taiwan and Korea.

**8. General description of the product**

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

GT73 was developed by Monsanto Company, using *Agrobacterium tumefaciens*-mediated tranformation, to introduce the *goxv247* and the *cp4 epsps* expression cassettes into the oilseed rape genome. GT73 produces the glyphosate oxidoreductase (GOXv247) protein, derived from the bacterium *Ochrobactrum anthropi* strain LBAA, and the 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) protein from *Agrobacterium* sp. strain CP4 (CP4 EPSPS), which confer tolerance to glyphosate.

In countries where GT73 is cultivated, it enables the farmer to use Roundup herbicides for effective control of weeds during the growing season and to take advantage of the favourable environmental and safety characteristics of its active ingredient glyphosate.

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

This application is for renewal of the authorization for continued marketing of existing food additives, feed materials and feed additives produced from GT73 oilseed rape that were notified according to Articles 8(1)(b) and 20(1)(b) of Regulation (EC) No 1829/2003 on genetically modified food and feed.

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

GT73 oilseed rape existing products will continue to be traded and used in the European Union in the same manner as commercial oilseed rape and by the same operators currently involved in the storage, transport, processing and use of 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**

GT73 is substantially equivalent to conventional oilseed rape, except for its tolerance to glyphosate, which is a trait of agronomic interest. This oilseed rape was shown to be as safe and nutritious as conventional oilseed rape. Therefore, GT73-derived products will continue to be stored, packaged, transported, used and handled in the same manner as current commercial oilseed rape. No specific conditions are warranted or required for the food and feed use of GT73.

**e) Any proposed packaging requirements**

GT73 is substantially equivalent to conventional oilseed rape, except for its tolerance to glyphosate. Therefore, GT73-derived products will continue to be used in the same manner as other oilseed rape and no specific packaging is required. (For labelling, *see* question 8.(f)).

**f) A proposal for labelling in accordance with Articles 13 and 25 of Regulation (EC) 1829/2003. In the case of GMOs, food and/or feed containing, 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.**

In accordance with Regulations (EC) No 1829/2003 and 1830/2003, the current labelling threshold of 0.9% will continue to be applied for the marketing of GT73-derived products.

Operators are currently required to label foods and feeds derived from GT73 with the words "produced from genetically modified oilseed rape". In the case of products for which no list of ingredients exists, operators shall continue to ensure that an indication that the food or feed product is produced from GMOs is transmitted in writing to the operator receiving the product.

Operators handling or using GT73-derived foods and feeds in the EU are required to be aware of the legal obligations regarding traceability and

labelling of these products. Given that explicit requirements for the traceability and labelling of GMOs and derived foods and feeds are laid down in Regulations (EC) No 1829/2003 and 1830/2003, and that authorized foods and feeds shall be entered in the Community Register, operators in the food/feed chain are fully aware of the traceability and labelling requirements for GT73.

Therefore, no further specific measures are to be taken by the applicant.

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

Not applicable.

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

Not applicable.

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

Misuse of GT73 is unlikely, as the proposed food and feed uses for this oilseed rape include all the current food and feed uses of conventional oilseed rape. Therefore, any measures for waste disposal and treatment of products derived from GT73 are equivalent to those already in place for any conventional oilseed rape variety. No specific conditions are warranted or required for the placing on the market of GT73 for food and feed use.

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

**1. Complete name**

**a) Family name**

Brassicaceae (formerly Cruciferae)

**b) Genus**

*Brassica*

**c) Species**

*napus*

**d) Subspecies**

oleifera

**e) Cultivar/breeding line**

Westar

**f) Common name**

oilseed rape

**2. a) Information concerning reproduction**

***(i) Mode(s) of reproduction***

*Brassica napus*, oilseed rape, reproduces sexually. It is predominantly self-pollinated, although outcrossing occurs to a significant extent. The amount of outcrossing depends upon several parameters, such as weather conditions, pollinator activity, floral characteristics, synchrony of flowering, breeding system and pollen competitiveness and it has been reported to occur at an average rate of 30%. Oilseed rape is insect pollinated, primarily by honey bees (*Apis melifera*) and bumblebees (*Bombus* sp.), but wind pollination is also of importance. Flowering of oilseed rape is indeterminate and the stigma is usually receptive to pollination up to three days after opening of the flowers. Following pollination and fertilization, the ovary elongates and forms pods (siliques) containing 25 or more seeds. As seeds mature, they turn from green to black or reddish brown.

***(ii) Specific factors affecting reproduction***

The optimal temperature for vegetative growth is about 20°C. Reproduction is favored by dry weather conditions, which increases the activity of insect pollinators. Water availability is also of particular importance, particularly during the period of seed ripening.

***(iii) Generation time***

The generation time (seed to seed) ranges from about 6 months for spring sown oilseed rape up to 11 months for autumn sown (winter) oilseed rape.

**2 b) Sexual compatibility with other cultivated or wild plant species**

Studies have demonstrated that crosses between *B. napus* and other species occur with varying degrees of difficulty. Outcrossing from *B. napus* to other *B. napus* plants, to *B. rapa* (synonym *B. campestris*) and to *B. juncea* has been demonstrated to occur naturally under field conditions. Under artificial conditions, including manual crosses, ovary culture techniques and high foreign pollen pressure, interspecific hybrids may be produced with other species, but these have often been shown to be low in fitness and often sterile. The interspecific crosses are more successful when *B. napus* is used as the female parent and when the species have at least one genome in common.

***i). Hybridization with cultivated oilseed rape varieties***

*B. napus* is principally a self-pollinating crop which is also able to cross with other plants of the same species. Pollen movement is by means of wind and insects, mainly bees. Frequency of intraspecific outcrossing is variable in its conclusions, which reflects the fact that pollinator activity, planting density, genotype, weather, timing of flowering and distance from the pollinator source have an impact on outcrossing. Values have been reported as high as 30%.

***ii). Crosses between B. napus and other* Brassica *species***

1. *Brassica rapa* (synonym *B. campestris*)

*B. napus* and *B. rapa* are known to be sexually compatible under open pollination conditions. Outcrossing frequencies are higher when *B. rapa* occurs as a weed within *B. napus* crops.

While gene transfer from *B. napus* to *B. rapa* is known to occur under controlled conditions, the likelihood of natural introgression of genes from *B. napus* is less certain.

2. *Brassica oleracea*

Natural hybridization with *B. oleracea* has not been reported. Even with artificial techniques, hybridizations are very difficult to achieve and have been more successful when *B. napus* was used as the seed (female) parent. It is unlikely therefore, that interspecific hybrids with *B. oleracea* will occur under open pollination conditions.

*3.* *Brassica juncea*

Successful hybridization with *B. napus* has been reported under experimental field conditions using mixed stands of *B. napus* and *B. juncea*. Pollen viability of the $F_1$ hybrid plants is generally low (less than 10%).

*4.* *Brassica nigra*

The production of hybrids under field conditions has been unsuccessful. With manual crosses, interspecific hybrids were produced, usually when *B. napus* was used as the female parent. The resulting hybrid seed and backcrossed progeny, however, exhibited low fertility or sterility and reduced survival characteristics.

*5.* *Brassica carinata*

Hybrid seed has been produced by manual crosses with *B. napus* and was most successful when *B. napus* was used as the female parent. Fertility and seed production were generally low.

***iii). Crosses between B. napus and other genera in the Brassicaceae***

Other studies have been reported in the literature which examine the possibility of hybridization between *B. napus* and other genera within the Brassicaceae. These genera include *Diplotaxis*, *Erucastrum*, *Hirschfeldia*, *Raphanus*, and *Sinapis*.

1. *Diplotaxis* species

Many hybridizations with *B. napus* have been attempted, but only *D. erucoides*, *D. muralis*, and *D. tenufolia* have been successful in producing hybrid seed under artificial conditions. The likelihood of producing hybrids with *Diplotaxis* species under natural conditions appears to be low.

2. *Erucastrum gallicum*

The potential for generation of fertile hybrids between *E. gallicum* and *B. napus* will be lower in frequency than for viable hybrid generation from *Raphanus raphanistrum* and *B. napus*. Although crosses have been successfully obtained in the laboratory, these have resulted in less competitive offspring with low viability. Moreover, *E. gallicum* itself is lowly competitive and highly self-fertile. Therefore, this species would likely not have the opportunity to cross with *B. napus* under field conditions.

3. *Hirschfeldia incana* (synonym *B. adpressa*)

Hybrid seeds have been produced under field conditions, although the experiments favored hybrid seed production by interplanting male sterile *B. napus* and fully fertile *H. incana*. Manual crosses between *H. incana* and *B. napus* exhibit poor fertility, whether *B. napus* is used as the male or female parent.

4. *Raphanus* species

Manual hybridizations with *Raphanus* species have generally been unsuccessful. In field experiments similar to those conducted with *H. incana* (above), however, hybrid seeds were obtained from crosses between male sterile *B. napus* and female *R. raphanistrum* plants.

5. *Sinapis* species

No hybrids between *B. napus* and *Sinapis* species have been produced under field conditions, and interspecific hybrid production under artificial conditions has also proven to be extremely difficult.

6. Others

No reports of other weedy relatives of *B. napus,* such as *Capsella bursa-pastoris* (shepherd's purse), *Thlaspi arvense* (field penny-cress), *Lepidium* sp., *Cardaria draba* (hoary cress), *Neslia paniculata* (ball-mustard), *Sisymbrium officinale* (hedge mustard) and *Erysimum cheiranthoides* (treacle mustard) successfully hybridizing with oilseed rape have been reported.

***iv) Crosses between sexually compatible relatives of B. napus and other genera in the Brassicaceae***

Crosses between *B. rapa* and the cultivated *Brassica* species *B. juncea* and *B. oleracea,* although unlikely, have been successful in producing viable seed, hence, indirect gene transfer to these species cannot be excluded. Conversely, there are no reports of hybrid seed production between *B. rapa* and the weedy species *B. nigra*, when *B. rapa* is used as pollinator. The reverse cross under controlled conditions, however,

produced seed at very low frequency (1 per 2000 pollinations) and the $F_1$ plants were much easier to backcross to *B. rapa*. Therefore gene flow is more likely from *B. nigra* to *B. rapa* than the reverse, which is considered unlikely. Gene flow from *B. rapa* to the weedy species *S. arvensis* has been shown to be very unlikely, since reciprocal crosses under controlled conditions failed to produce any seed.

Crosses between *B. juncea* and *B. nigra* have been successful at low frequency, particularly if *B. juncea* is used as the seed (female) parent. Open pollination of the $F_1$ progeny and backcrossing to *B. juncea* produced plants with low fertility. Backcrossing was easier with *B. juncea* than with *B. nigra*, and the high chromosome numbers of the hybrid progeny suggest that the offspring of this interspecific cross are likely to revert to the cultivated amphidiploid species. Hybrids between *B. juncea* and *S. arvensis* were also only successful, when *B. juncea* was used as the seed parent and the progeny were poorly fertile. Gene flow from *B. juncea* to *S. arvensis* is considered to be highly unlikely.

## 3. Survivability

### a) Ability to form structures for survival or dormancy

Oilseed rape is an annual crop and seeds are the only survival structures since natural regeneration from vegetative tissue is not known to occur.

Regrowth from oilseed rape seeds (volunteers) is often observed in crops grown in rotation with oilseed rape, since seed dormancy of surviving seeds is usually broken by cultivation. In most cases oilseed rape volunteers are easily controlled by current agronomic practices.

Volunteers may also be present in non-cropped disturbed ecosystems, such as field margins, roadsides and railway lines, where they have to compete with existing weeds. Oilseed rape is not considered an environmentally hazardous colonizing species and volunteers are easily displaced by other plants, unless those habitats are disturbed on a regular basis. Moreover, these oilseed rape roadside populations are often prevented from reaching maturity by mowing or by chemical treatment.

### b) Specific factors affecting survivability

Survival is favoured by the late harvesting of the oilseed rape crop, when pods are mature and more susceptible to natural shattering. Immediate and deep cultivation also favours seed dormancy and survival in the soil. In undisturbed habitats oilseed rape plants show poor survival characteristics; regular disturbance is needed for the establishment of oilseed rape plants from seeds in natural habitats.

## 4. Dissemination

### a) Ways and extent of dissemination

Oilseed rape dissemination can occur by means of seeds and pollen. The seeds have no special or specific adaptations to facilitate widespread dispersal (they are not wind transported and have no structures to allow them to stick to animal fur) and so any shattered seed will remain in close proximity to the site of production. Further dissemination may occur by means of fauna or machinery.

Oilseed rape may also be dispersed by pollen (wind and insects, mainly bees), and eventually cross with other sexually compatible plants. This has been described in Section B.2.b.

### b) Specific factors affecting dissemination

*See* Section B.4.a.

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

Cultivated oilseed rape species are believed to originate from the Mediterranean area, but have been cultivated for thousands of years in Asia and the Indian subcontinent. Oilseed rape has been cultivated in northwestern Europe since the thirteenth century, initially as a source of fuel, although its widespread use as a source of food and animal feed is more recent.

## 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

Not applicable, as oilseed rape is grown in Europe.

## 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 has a history of safe use, being used in foods and feedstuffs. It is grown mainly for the production of oil, which represents more than 40% of the seed weight. The oil is separated from the seed by crushing and processing, and is used predominantly in cooking oils, margarines and fats. The oil is also used as a source of fuel. The protein-rich meal remaining following crushing is employed as a feedstuff for livestock.

The seeds contain varying levels of two naturally occurring toxicants, erucic acid and glucosinolates, depending on the variety grown. High erucic acid rapeseed oil has been shown to have cardiopathic potential in experimental animals. Oil from the low erucic acid oilseed rape varieties grown today is free of cardiopathogenicity, except in certain strains of rat. The glucosinolates are considered to be antinutritients because they

are precursors to isothiocyanates, thiocyanates and nitriles. Conversion of glucosinolates into these compounds requires hydrolysis which can be facilitated by the enzyme myrosinase, a naturally occurring protein in oilseed rape. Feeding studies using swine, cattle, poultry and rats have shown a correlation between toxic effects (as indicated by growth performance, reproduction, goitrogenicity, liver hypertrophy, hemorrhage and palatability) and the levels of glucosinolates in the meal. Commercial processing of oilseed rape usually allows glucosinolates to remain intact, but because intestinal microflora may achieve some hydrolysis of glucosinolates, nutritionists have encouraged breeders to work toward the elimination of glucosinolates.

Significant progress has been made in recent years to reduce the levels of these substances through classical breeding approaches. Canadian oilseed rape which contains low levels of erucic acid (less than 2% of the total fatty acids in the oil) and alkyl glucosinolates (less than 30 µmol/g in the defatted meal) may be sold under the Canola trademark. For certified seed of "double zero" varieties listed in the Common Catalogue of Varieties of Agricultural Plant Species, the European Commission established the maximum glucosinolate content of 25 µmole/g seeds (moisture content 9%) and the erucic acid content below 2% of the total fatty acid content.

Other substances which may restrict the use of oilseed rape meal in animal feedstuffs are tannins, saponins and sinapine.

## C. INFORMATION RELATING TO THE GENETIC MODIFICATION

### 1. Description of the methods used for the genetic modification

A disarmed *Agrobacterium tumefaciens* plant transformation system including the double-border, binary vector PV-BNGT04 was used to produce GT73.

### 2. Nature and source of the vector used

The PV-BNGT04 vector used for the transformation of oilseed rape to produce GT73 is presented in Table 1.

**Table 1. Summary of genetic elements in the plasmid PV-BNGT04**

| Genetic element [1,2] | Position on plasmid (bp) | Function (reference) |
|---|---|---|
| Right border | 8928-9284 | DNA region derived from *Agrobacterium* containing the right border sequence involved in the transfer of the T-DNA |
| Intervening sequence | 9285-9317 | Synthetic sequence, polylinker. |
| P-*FMV* | 9318-9881 | The *35S* promoter from a modified Figwort Mosaic Virus |
| Intervening sequence | 9882-9910 | Synthetic sequence, polylinker. |
| TS-*CTP1* | 9911-10174 | DNA sequence encoding the N-terminal chloroplast transit peptide, derived from the small subunit 1A of the ribulose-1,5-bisphosphate carboxylase gene from *Arabidopsis thaliana*, present to direct the GOXv247 protein to the chloroplast |
| CS-*goxv247* | 10175-11470 | A synthetic glyphosate oxidoreductase (*gox*) gene variant number 247 based on the glyphosate oxidoreductase gene isolated from *Ochrobactrum anthropi* strain LBAA |
| Intervening sequence | 11471-11491 | Synthetic sequence, polylinker. |
| Intervening sequence | 1-16 | Synthetic sequence, polylinker. |
| T-*E9* | 17-659 | 3' nontranslated region of the pea ribulose-1,5-bisphosphate carboxylase, small subunit (*rbcS*) *E9* gene |
| Intervening sequence | 660-713 | Synthetic sequence, polylinker. |
| P-*FMV* | 714-1393 | The *35S* promoter from a modified Figwort Mosaic Virus |
| TS-*CTP2* | 1394-1621 | DNA sequence encoding the N-terminal chloroplast transit peptide from the *Arabidopsis thaliana epsps* gene |
| CS-*cp4 epsps* | 1622-2989 | Coding sequence for the synthetic CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) from *Agrobacterium* sp. strain CP4. |
| Intervening sequence | 2990-3031 | Synthetic sequence, polylinker. |
| T-*E9* | 3032-3674 | 3' nontranslated region of the pea ribulose-1,5-bisphosphate carboxylase small subunit (*rbcS*) *E9* gene |
| Intervening sequence | 3675-3731 | Synthetic sequence, polylinker. |

| | | |
|---|---|---|
| Left border | 3732-4173 | DNA region derived from *Agrobacterium* containing the left border sequence involved in the transfer of the T-DNA. |
| Intervening sequence | 4174-4259 | Synthetic sequence, polylinker. |
| OR-*ori V* | 4260-4656 | Origin of replication from the broad host range plasmid RK2 for plasmid maintenance in *Agrobacterium* |
| Intervening sequence | 4657-6164 | Synthetic sequence, polylinker. |
| CS-*rop* | 6165-6356 | Coding sequence for the repressor of primer (ROP) protein for maintenance of plasmid copy number in *E. coli* |
| Intervening sequence | 6357-6773 | Synthetic sequence, polylinker. |
| OR-*ori-PBR322* | 6774-7402 | Origin of replication from pBR322 for plasmid maintenance in *E. coli* |
| Intervening sequence | 7403-7902 | Synthetic sequence, polylinker. |
| *aadA* | 7903-8791 | Bacterial gene encoding an aminoglycoside-modifying enzyme, 3' (9)-O-nucleotidyl-transferase from the transposon Tn*7* |
| Intervening sequence | 8792-8927 | Synthetic sequence, polylinker. |

[1] Intervening sequences are not regarded as genetic elements.

[2] P – Promoter; TS – Targeting sequence; CS – Coding sequence; T – 3' nontranslated transcriptional termination and polyadenylation signal sequence; B – Border region; OR – Origin of replication.

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

The genetic elements of PV-BNGT04 intended for insertion into the oilseed rape genome comprised between the T-DNA borders are, from the right border region, a transcriptional promoter (P-*FMV*), a chloroplast transit peptide sequence (TS-*CTP1*), the *goxv247* coding sequence (CS-*goxv247*) and a 3' nontranslated sequence from the *RbcS* gene (T-*E9*). These elements together constitute the *goxv247* expression cassette which is followed by the *cp4 epsps* expression cassette. The latter is constituted by a transcriptional promoter (P-*FMV*); a chloroplast transit peptide sequence (TS-*CTP2*), the *cp4 epsps* coding sequence (CS-*cp4 epsps*) and a 3' nontranslated sequence from the *RbcS* gene (T-*E9*).

A detailed description of the genetic elements present in the T-DNA is provided below.

T-DNA Borders

Plasmid PV-BNGT04 contains right border and left border regions that delineate the portion of DNA to be incorporated into the oilseed rape genome and are necessary for the efficient transfer of the T-DNA into the plant cell. These border regions were derived from *Agrobacterium tumefaciens* plasmids.

Promoter

The same constitutive promoter, P-*FMV*, was used to drive expression of both *goxv247* and *cp4 epsps* expression cassettes, producing the GOXv247 and CP4 EPSPS proteins conferring glyphosate tolerance. P-*FMV* is a constitutive promoter containing the *35S* sequence of a modified Figwort Mosaic Virus.

*CTP* targeting sequences

A chloroplast transit peptide sequence (TS-*CTP*) was fused upstream of the *goxv247* and *cp4 epsps* coding sequences to facilitate import of the newly translated proteins into the chloroplast, the site of aromatic amino acid biosynthesis and glyphosate mode of action.

- The *CTP1* sequence, fused to the *goxv247* coding sequence, codes for a transit peptide derived from the small subunit 1A of *Arabidopsis thaliana* ribulose-1,5-bisphosphate carboxylase. The *CTP1* DNA sequence encodes an 89 amino acid peptide that is fused to the N-terminus of the GOXv247 protein.
- The *CTP2* sequence, fused to the *cp4 epsps* coding sequence, codes for the *Arabidopsis thaliana* EPSPS chloroplast transit peptide. The *CTP2* DNA sequence encodes a 77 amino acid peptide that is fused to the N-terminus of the CP4 EPSPS protein.

Transit peptides are typically cleaved from the translated polypeptide following delivery to the plastid.

*goxv247 and cp4 epsps* coding sequences

The *gox* gene encodes the glyphosate oxidoreductase (GOX) protein. GOX imparts glyphosate tolerance by degrading glyphosate *in planta*. GOX and GOXv247, a variant of GOX, are more than 99% identical. GOX was isolated from *Ochrobactrum anthropi* (formerly *Achromobacter*) sp. strain LBAA, and catalyzes the breakdown of glyphosate into aminomethylphosphonic acid (AMPA) and glyoxylate. The GOXv247 protein produced by GT73 effectively inactivates the herbicide and enables growth when GT73 plants are treated with glyphosate.

The *cp4 epsps* gene from *Agrobacterium* sp. strain CP4, a common soil-borne bacterium, has been sequenced and shown to encode a 47.6 kDa EPSPS protein consisting of a single polypeptide of 455 amino acids. EPSPS catalyzes the conversion of shikimate-3-phosphate (S3P) and phosphoenolpyruvate (PEP) into 5-enolpyruvyl-shikimate-3-phosphate (EPSP), an intermediate required for the production of aromatic amino acids. Most native plant and microbial EPSPS enzymes are sensitive to glyphosate which blocks the biosynthesis of EPSP, thereby depriving plants of essential amino acids that are necessary for growth and development. The CP4 EPSPS protein produced in glyphosate-tolerant plants is functionally identical to endogenous plant EPSPS enzymes, with the exception that CP4 EPSPS naturally displays reduced affinity for glyphosate relative to endogenous plant EPSPSs. Therefore, the presence of CP4 EPSPS in glyphosate-tolerant plants reconstitutes the shikimic acid pathway allowing plants to continuously synthesize aromatic amino acids even in the presence of glyphosate.

*E9* transcription termination sequence

The coding sequences in both expression cassettes are followed by the T-*E9* DNA sequence derived from *Pisum sativum*, containing the 3' nontranslated region of the pea ribulose-1,5-bisphosphate carboxylase, small subunit (*RbcS*) *E9* gene that directs transcriptional termination and polyadenylation of the mRNA.

## D. INFORMATION RELATING TO THE GM PLANT

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

GT73 contains one intact copy of the *goxv247* and *cp4 epsps* expression cassettes encoding the GOXv247 and CP4 EPSPS proteins, which confer tolerance to glyphosate. Glyphosate has excellent weed control capabilities and well-known, favorable environmental and safety characteristics. However, the sensitivity of crop plants to glyphosate has prevented the in-season use of this herbicide over-the-top of crops. The extension of its use to allow in-season application in major crops such as oilseed rape provides a novel weed control option for farmers.

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

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

The insert in GT73 was characterized using Southern blot methods. Specifically, the insert number (number of insertions of the integrated DNA within the oilseed rape genome), the copy number (the number of copies of the integrated DNA within one insertion site), the integrity of the inserted *goxv247* and *cp4 epsps* expression cassettes and the presence or absence of plasmid backbone sequence was assessed. The data show that GT73 contains one copy of the insert at a single insertion site hosting both *goxv247* and *cp4 epsps* intact expression cassettes. No additional elements from the transformation vector PV-BNGT04, linked or unlinked to the *goxv247* and *cp4 epsps* expression cassettes, were detected in the genome of GT73. Additionally, backbone sequence from the plasmid PV-BNGT04 was not detected.

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

Not applicable.

**c) Chromosomal location(s) of insert(s) (nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination**

The inheritance of the glyphosate-tolerance trait in GT73 follows Mendelian principles. This indicates that the insert is stably integrated in the nuclear genome and is neither located in the mitochondria nor in the chloroplasts.

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

PCR and DNA sequence analyses were conducted on the GT73 insert. The insert sequence analysis confirmed that the organization of the elements within GT73 is identical to that of plasmid PV-BNGT04, as anticipated by the results of the molecular characterization.

## 3. Information on the expression of the insert

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

GT73 produces two functional proteins, GOXv247 and CP4 EPSPS, both providing tolerance to glyphosate. GOXv247 and CP4 EPSPS protein levels in tissues derived from GT73 were determined by ELISA. The levels of the GOXv247 and CP4 EPSPS proteins in seeds and leaves were measured in tissues collected from GT73 samples produced in multiple Canadian and European field trials during different growing seasons from 1992 to 1996.

Taken together, the results of the Canadian and European field trials show that the mean expression levels in seed were in the range of 0.12 to 0.21 µg/mg fresh weight and 0.02 to 0.05 µg/mg fresh weight for the GOXv247 and CP4 EPSPS proteins, respectively. Analysis in leaf tissue gave a mean expression level of 0.03 µg/mg fresh weight for CP4 EPSPS, while the mean expression level of GOXv247 ranged from 0.06 to 0.13 µg/mg fresh weight.

Generally, it can be concluded that the GOXv247 and CP4 EPSPS protein expression levels measured in each tissue are comparable across all growing seasons and geographies.

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

The expression of the GOXv247 and CP4 EPSPS proteins occurs throughout the plant since the *FMV* promoter drives constitutive expression of the encoded proteins.

As seed is the most relevant tissue for the food and feed safety assessment, protein levels in this tissue were estimated in multiple Canadian and European field trials.

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

### a) Reproduction

Based on centuries of experience, oilseed rape should not be regarded as a significant weed and is not invasive in undisturbed habitats or natural ecosystems. In agricultural habitats, re-growth from oilseed rape seeds (volunteers) is often observed in crops grown in rotation with oilseed rape. However, in most cases volunteers are easily controlled by current agronomic practices. The *goxv247* and *cp4 epsps* coding sequences integrated in the GT73 genome encode the GOXv247 and CP4 EPSPS proteins, respectively, which confer tolerance to glyphosate. This genetic modification is not expected to alter the phenotypic characteristics of oilseed rape.

However, extensive studies have been conducted with GT73 and its progeny in Canada and Europe to determine the phenotypic behaviour of GT73 compared to Westar (a conventional oilseed rape variety with similar background genetics to GT73). Every test was conducted such

that a direct comparison to Westar grown side-by-side at each field site was made.

On the basis of the studies conducted, it is possible to conclude that no differences in the mode or rate of reproduction, dissemination, survivability or other agronomic, phenotypic or ecological characteristics are expected in GT73 and that GT73 is equivalent to conventional oilseed rape in its phenotypic and agronomic behaviour, except for the glyphosate-tolerance trait.

**b) Dissemination**

*See* Section D.4.a.

**c) Survivability**

*See* Section D.4.a.

**d) Other differences**

*See* Section D.4.a.

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

The *cp4 epsps* and *gox* genes have been shown to be stably integrated into a nuclear chromosome based on Southern blot analysis, expression data and Mendelian segregation ratios (over several generations) from crosses between GT73 and conventional oilseed rape.

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

**a) Plant to bacteria gene transfer**

No elements known to be involved in DNA mobility have been included in the inserted DNA. Therefore, in comparison to conventional oilseed rape, no changes are to be expected in the ability of the GM plant to exchange genetic material with bacteria.

**b) Plant to plant gene transfer**

Based on the observation that reproductive morphology in GT73 is unchanged compared to conventional oilseed rape and that pollen production and pollen viability were unaffected by the genetic modification, the out-crossing frequency to other oilseed rape varieties or to wild relatives would be unlikely to be different for GT73, when compared to conventional oilseed rape varieties.

However, the scope of the current application does not include the cultivation of GT73 varieties in the EU.

## 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**

GT73 was compared to Westar, a conventional spring oilseed rape variety with background genetics similar to GT73. In addition, GT73 winter oilseed rape varieties obtained by backcrossing GT73 into two conventional winter oilseed rape varieties, Libero and Composite Hybrid, were compared to Libero and Composite Hybrid.

### *7.2 Production of material for comparative assessment*

**a) number of locations, growing seasons, geographical spread and replicates**

As a part of the program to assess the food and feed safety of GT73, extensive compositional analyses were conducted on seeds obtained from Canadian field trials during the 1992 and 1993 growing seasons (seven and four locations, respectively) and from European field trials during the 1994, 1995 and 1995-1996 growing seasons (three, three and six locations, respectively). The locations used for these field trials are representative of the majority of oilseed rape growing regions in Canada and Europe.

GT73 and Westar spring oilseed rape varieties were employed in the field trials conducted in the 1992, 1993, 1994 and 1995 growing seasons. In the 1995-1996 growing season, GT73 winter oilseed rape varieties obtained by backcrossing GT73 into two winter oilseed rape varieties, Libero and Composite Hybrid, were grown to generate samples for compositional analyses.

The conventional varieties Westar, Libero and Composite Hybrid served as controls.

The results of all analyses show that GT73 seeds and processed fractions (toasted meal and refined, bleached, deodorized oil) are not different from the conventional oilseed rape seeds or fractions. Furthermore, the levels of antinutrients in GT73 toasted meal are at or below levels currently found in commercial oilseed rape and are comparable to the levels of antinutrients measured in toasted meal from conventional oilseed rape. On the basis of all the information presented, it is possible to conclude that GT73 is compositionally equivalent to conventional oilseed rape and to establish the safety and the wholesomeness of this product for human and animal health.

**b) the baseline used for consideration of natural variations**

Compositional equivalence between GT73 and Westar was established by comparing GT73 to Westar grown in the same field trials, but also by referring to the extensive database available for Westar which gathers the information collected from several years

of oilseed rape official trials required for registration of all new Canadian canola varieties (Co-Op Tests[2]) in multitude locations and growing seasons. This comparison was conducted in order to better observe the inherent variability of Westar.

### *7.3 Selection of material and compounds for analysis*

The oilseed rape constituents selected for the analyses in the compositional studies were chosen on the basis of their nutritional and antinutritional proterties. Although the OECD consensus document on key nutrients and key toxicants of oilseed rape plants did not exist at the time when the field studies were conducted, all key nutrients and antinutrients were analyzed.

### *7.4 Agronomic traits*

The set of agronomic observations, described in Section D.4, supports the conclusion that from an agronomic and phenotypic (morphological) point of view, GT73 is equivalent to conventional oilseed rape, with the exception of the introduced glyphosate-tolerance trait.

### *7.5 Product specification*

GT73 contains two functionally intact expression cassettes encoding the GOXv247 and CP4 EPSPS proteins, respectively, which both confer tolerance to glyphosate. Food and feed produced from GT73 will continue to be imported into the EU in mixed shipments of oilseed rape products, produced in other world areas, for use by operators that have traditionally been involved in the commerce, processing and use of oilseed rape and oilseed rape-derived products in the EU.

The presence of the glyphosate-tolerance trait in oilseed rape-derived products can be identified by employing different techniques. Southern blot or PCR techniques can identify the inserted nucleotide sequence, while ELISAs have been developed to detect the presence of the GOXv247 or CP4 EPSPS proteins in specific tissues. A GT73-specific PCR assay allowing the identification and the quantification of GT73 was provided to the Joint Research Center (JRC) acting as the Community reference Laboratory (CRL). The GT73 method validation report was published on 8 February 2007[3].

### *7.6 Effect of processing*

As GT73 is compositionally equivalent to conventional oilseed rape, the use of GT73 for the production of foods and feeds is not expected to be different from that of conventional oilseed rape. The production and processing of GT73 does not differ from the production and processing of the equivalent foods and feeds, originating from conventional oilseed rape.

[2] Canadian Cooperative Rapeseed Test

[3] http://gmo-crl.jrc.it/summaries/RT73_val_report.pdf

### *7.7 Anticipated intake/extent of use*

As GT73 is nutritionally equivalent to conventional oilseed rape in commerce and as the introduced agronomic trait is not expected to alter patterns or volumes of oilseed rape consumption, this oilseed rape is not expected to be more or less attractive for use as food or feed or for processing. Therefore, anticipated dietary intake of oilseed rape-derived foods and feeds is not expected to be altered upon renewal of the authorization of GT73 for food and feed use. GT73 is currently replacing a portion of the oilseed rape supply such that its intake or use represents some fraction of the total oilseed rape and oilseed rape-derived products used.

### *7.8 Toxicology*

#### *7.8.1 Safety assessment of newly expressed proteins*

GT73 contains the *goxv247* and *cp4 epsps* expression cassettes that produce the GOXv247 and CP4 EPSPS proteins, respectively. The assessment of human and animal safety of the GOXv247 and CP4 EPSPS proteins includes (i) the safety of the donor organisms, *Ochrobactrum anthropi* strain LBAA and *Agrobacterium* sp. strain CP4; (ii) the similarity of the GOXv247 and CP4 EPSPS proteins to other proteins with a history of safe use; (iii) the bioinformatic comparisons of the GOXv247 and CP4 EPSPS proteins to known toxic or pharmacologically active proteins and (iv) an acute oral toxicity study with the GOXv247 and CP4 EPSPS proteins in mice.

The *gox* donor organism, *Ochrobactrum anthropi* sp. strain LBAA, is not a food source, but *Ochrobactrum anthropi* is reported to be one of the most frequently occurring bacteria in the rhizosphere. Since only one gene, *i.e. gox*, was transferred from *Ochrobactrum anthropi* to oilseed rape, and the sequence of the DNA transferred to the host is completely known, characteristics of this donor species do not warrant further tests. These considerations, as well as the properties and safety of the GOXv247 protein discussed further below in this section, lead to the conclusion that there is no safety concern regarding the source of the GOXv247 protein. *Agrobacterium* sp. strain CP4 was chosen as the donor organism because this bacterium exhibited tolerance to glyphosate by producing a naturally glyphosate-tolerant EPSPS protein. The bacterial isolate, CP4, was identified by the American Type Culture Collection as an *Agrobacterium* species. *Agrobacterium* species are not known for human or animal pathogenicity and are not commonly allergenic.

GOXv247 is similar to enzymes that are ubiquitous in both eukaryotes and prokaryotes and therefore benefit from a history of safe use. The CP4 EPSPS protein is a member of the EPSPS family, a well-known class of proteins that are ubiquitous in nature, as they are present in algae, plants, fungi and bacteria, but not in animals. The similarity of the CP4 EPSPS protein to EPSPSs in a variety of foods supports extensive human consumption of the family of EPSPS proteins and the lack of health concerns.

Finally, the GOXv247 and CP4 EPSPS proteins have been shown not to be homologous to known toxins or pharmacologically-active proteins and no indications of toxicity were reported in mice administered the GOXv247 or CP4 EPSPS proteins by oral gavage.

On the basis of the information presented, it is therefore possible to conclude that the GOXv247 and CP4 EPSPS proteins are safe and pose no concerns for humans, animals and the environment.

*7.8.2 Testing of new constituents other than proteins*

Oilseed rape has a long history of safe use and consumption around the world. As described in Section D.7.1, GT73 has been shown to be compositionally equivalent to conventional oilseed rape. Therefore, no testing of any constituent other than the introduced proteins is indicated.

*7.8.3 Information on natural food and feed constituents*

Oilseed rape is known to contain a number of natural anti-nutritional analytes, such as glucosinolates, erucic acid, sinapine and phytic acid. These antinutrients were evaluated in GT73 compositional analyses and their levels were demonstrated to be comparable in GT73 and in conventional oilseed rape.

*7.8.4 Testing of the whole GM food/feed*

The data presented in Section D.7.1 establish that GT73 is compositionally equivalent to conventional oilseed rape. In addition, the safety for humans and animals of the newly expressed GOXv247 and CP4 EPSPS proteins has been demonstrated on the basis of extensive characterization, history of safe use, lack of structural similarities with known protein toxins and allergens, absence of acute toxicity in oral gavage studies in rodents and rapid digestion in simulated gastric and intestinal fluids.

The GOXv247 and CP4 EPSPS proteins produced in GT73 are shown to be safe for consumption by humans and animals. The safety of GT73 has been confirmed by multiple animal feeding studies.

### *7.9 Allergenicity*

*7.9.1 Assessment of allergenicity of the newly expressed protein*

It is unlikely that the GOXv247 and CP4 EPSPS proteins will cause allergenic concerns due to the following considerations: (1) the GOXv247 and CP4 EPSPS proteins are not glycosylated, which strengthens the hypothesis that they are no allergens; (2) the GOXv247 and CP4 EPSPS proteins are extremely labile to peptic and tryptic digestion, a characteristic shared among proteins with a history of safe consumption; (3) the bioinformatic analysis confirmed that the GOXv247 and CP4 EPSPS proteins show no structurally significant amino acid sequence similarity to any known protein allergens; (4) the GOXv247 and CP4 EPSPS proteins

constitute only a small portion of the total protein content in GT73 seed. Therefore, these proteins are unlikely to be allergenic proteins. Thus, using the best methodology available when the safety assessment for GT73 was initially conducted, it can be concluded that the allergenic potential of the GOXv247 and CP4 EPSPS proteins is negligible and therefore, these proteins do not pose a significant allergenic risk.

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

Oilseed rape is not known to be allergenic. GT73 has been demonstrated to be substantially equivalent to conventional oilseed rape, except for the GOXv247 and CP4 EPSPS proteins, which have been demonstrated not to have characteristics of an allergen. Therefore, GT73 is considered not to have allergenic potential.

### *7.10 Nutritional assessment of GM food/feed*

*7.10.1 Nutritional assessment of GM food*

As described in Section D.7.1, GT73 was shown to be compositionally equivalent to conventional oilseed rape. The introduced glyphosate-tolerance trait is of agronomic interest and is not intended to change any nutritional aspects of this oilseed rape. Therefore, anticipated dietary intake of oilseed rape-derived foods is not expected to be altered in the EU and no nutritional imbalances are expected as a result.

*7.10.2 Nutritional assessment of GM feed*

GT73 was demonstrated to be compositionally equivalent to conventional oilseed rape. The safety assessment of GT73 showed that this glyphosate-tolerant oilseed rape does not pose any adverse effects for humans and animals. Animal feeding studies were nonetheless conducted with GT73 in several vertebrate animals and established the nutritional equivalence of this oilseed rape to conventional oilseed rape for use as feed. These studies further confirmed the absence of any pleiotropic or unanticipated effects resulting from the introduction of the glyphosate-tolerance trait into the oilseed rape genome.

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

There are no intrinsic hazards related to GT73 as no signs of adverse or unanticipated effects have been observed in a number of safety studies, including animal feeding studies using doses of administration that are orders of magnitude above expected consumption levels. The pre-market risk characterization for food and feed use of GT73 demonstrates that the risks of consumption of GT73-derived products are consistently negligible and no different from the risks associated with the consumption of conventional oilseed rape. As a consequence, specific risk management measures are not indicated, and post-market monitoring of the use of oilseed rape for food and feed is not considered appropriate.

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

Not applicable, as neither the GMO, nor the food and feed containing or consisting of the GMO, are within the scope of this renewal application under Regulation (EC) No 1829/2003.

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

Not applicable, as neither the GMO, nor the food and feed containing or consisting of the GMO, are within the scope of this renewal application under Regulation (EC) No 1829/2003.

## 10. Potential interactions with the abiotic environment

Not applicable, as neither the GMO, nor the food and feed containing or consisting of the GMO, are within the scope of this renewal application under Regulation (EC) No 1829/2003.

## 11. Environmental monitoring plan (not if application concerns only food and feed produced from GM plants, or containing ingredients produced from GM)

Not applicable, as neither the GMO, nor the food and feed containing or consisting of the GMO, are within the scope of this renewal application under Regulation (EC) No 1829/2003.

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

Southern blot or PCR techniques can be employed for the detection and identification of the inserted nucleotide sequences. ELISAs have been developed and can be used to detect the GOXv247 and CP4 EPSPS proteins in individual plants. A GT73-specific PCR assay allowing the identification and the quantification of GT73 has been provided to the Joint Research Center (JRC) acting as the Community reference Laboratory (CRL). The GT73 method validation report was published on 8 February 2007[4].

[4] http://gmo-crl.jrc.it/summaries/RT73_val_report.pdf

## 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**

Notifications under Part B of Directive 90/220/EEC have been made in Belgium, France, Germany and the UK between 1990 and 1996.

| Country | Notification numbers |
|---|---|
| Belgium | B/BE/92/W1A-CON; B/BE/93/W19-CON; B/BE/93/W2; B/BE/92/W22; B/BE/94/W18D; B/BE/95/WSP10; |
| France | B/FR/97/10/08; B/FR/95/02/16-CON; B/FR/95/02/02; B/FR/93/05/04; B/FR/93/12/06; B/FR/99/01/09; B/FR/95/01/11; B/FR/94/05/05; B/FR/95/05/12; B/FR/96/06/04; B/FR/97/07/04; B/FR/95/05/11; B/FR/96/06/03; B/FR/97/07/02; B/FR/95/05/09; B/FR/96/05/05; B/FR/99/06/06; B/FR/95/05/10; B/FR/96/06/02; B/FR/97/07/03; B/FR/96/06/07-CON |
| Germany | B/DE/96/50; B/DE/97/70; B/DE/99/108; |
| UK | B/GB/94/R5/2-CON; B/GB/95/R5/6; B/GB/97/R24/2; B/GB/97/R22/9; B/GB/98/R22/13; B/GB/95/R22/3; B/GB/96/R22/6 |

**b) Conclusions of post-release monitoring**

The results of field trials with GT73, undertaken to assess agronomic performance, efficacy and selectivity, yield potential, residues determination, compositional analysis and breeding, showed no significant evidence that GT73 is likely to cause any adverse effects to human or animal health or to the environment.

**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)**

Post-release general surveillance provided no significant evidence that GT73 is likely to pose any risk of adverse effects to human or animal health or to the environment.

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

**a) Release country**

| Country | Authority that granted the approval |
|---|---|
| U.S.A. | United States Department of Agriculture (January 1994) |
| Canada | Agriculture and Agri-food Canada (March, 1995) |
| Australia | Office of the Gene Technology Regulator (December 2003) |

In addition to the countries listed above, GT73 and derived products are approved for import and consumption in eight additional countries representing key export markets for U.S. and Canadian produced oilseed rape, including the EU-25.

**b) Authority overseeing the release**

See question E.2.(a).

**c) Release site**

All major oilseed rape growing regions in North-America and in Australia, listed under Section E.2.(a).

**d) Aim of the release**

Commercial release for all uses as traditional oilseed rape.

**e) Duration of the release**

Commercial release. Please see Section E.2.(a).

**f) Aim of post-releases monitoring**

Extensive pre-market risk assessment did not provide evidence of adverse effects potentially associated with the cultivation, handling or use of GT73, indicating that a requirement for post-release monitoring would not be appropriate.

In addition, GT73 is commercialized alongside stewardship programmes, involving downstream stakeholders in the use of this oilseed rape, in order to ensure the implementation of good agricultural practice in its cultivation and to ensure a channel of communication in the unlikely event that unanticipated adverse effects might occur.

**g) Duration of post-releases monitoring**

Please see Section E.2.(f).

**h) Conclusions of post-release monitoring**

Please see Section E.2.(f).

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

Post-marketing experience provided no significant evidence that GT73 or derived products would be the cause of any adverse effects to human health or to the environment.

**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://gmo-crl.jrc.it/statusofdoss.htm and the EFSA website http://www.efsa.europa.eu/en/science/gmo/gm_ff_applications.html provide publicly accessible links to up-to-date databases on the regulatory progress of notifications under Directive 2001/18/EC and applications under Regulation (EC) No 1829/2003, including the Monsanto dossier for GT73.

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

http://gmoinfo.jrc.it/csnifs/C-NL-98-11_RiskAssessment.pdf

**c) EFSA opinion**

http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/gmo_opinions/174.Par.0001.File.dat/opinion_gmo05_ej29_gt73_en1.pdf

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

http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

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

Information on detection protocols is posted at http://gmo-crl.jrc.it/

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

The publicly accessible portal site of the Biosafety Clearing-House (BCH) can be found at http://bch.biodiv.org/

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

EFSA provides a link to the publicly accessible summary of this application under Regulation (EC) No 1829/2003 at http://www.efsa.europa.eu/en/science/gmo/gm_ff_applications.html.