PART II

SUMMARY

OF THE REQUEST FOR RENEWAL, ACCORDING TO ARTICLES 11 AND 23, OF THE AUTHORIZATIONS NOTIFIED UNDER ARTICLES 8(1)(A) AND 20(1)(B) OF REGULATION (EC) NO. 1829/2003

GLUFOSINATE AMMONIUM-TOLERANT GENETICALLY MODIFIED OILSEED RAPE MS8/RF3

FOR DERIVED FOOD AND FEED PRODUCTS

A. GENERAL INFORMATION

1. Details of application

a) **Member State of application**: The European Commission
b) **Application number:** Not available at the date of application
c) **Name of the product (commercial and other names):** Food (oil) and Feed (meal) derived from the cultivation of oilseed rape varieties containing the MS8/RF3 traits. • The female line containing event MS8 and all progeny derived through traditional breeding crosses with non-genetically modified oilseed rape. • The male line (fertility restoration) containing event RF3 and all progeny derived through traditional breeding crosses with non-genetically modified oilseed rape. • The hybrid seeds from traditional crossings between parental lines containing events MS8 and RF3. • Hybrid seeds are commercialised for cultivation in Canada and the USA under the trade name InVigor® oilseed rape
d) **Date of acknowledgement of valid application:** Not available at the date of application

2. Applicant

a) **Name of applicant:** Bayer CropScience AG
b) **Address of applicant:** Bayer CropScience AG Alfred-Nobel-Strasse 50 D - 40789 Monheim am Rhein

Germany **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)): MS8/RF3 derived products will be imported and used in the EU in the same way as the equivalent products from other commercial oilseed rape and by the same groups who import 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	

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: The notification C/BE/96/01 has been submitted according to Directive 2001/18/EC and positively reviewed by the European Food Safety Authority (EFSA). The decision has been granted by the European Commission on March 26, 2007. A notification has been submitted according to Reg (EC) 258/97 and substantial equivalence has been	

granted by the Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin (BgVV) on September 30, 1999.

Regulation EC/1829/2003 specifies that products which have been lawfully placed on the market in the Community before the date of application of that Regulation may continue to be placed on the market, used and processed provided that those products are notified to the European Commission before October 18th, 2004.

In the case of MS8/RF3, the transitional measures identified above are applicable to the product oil and meal and a notification under Article 8(1)(a) and Article 20(1)(b) of Regulation EC/1829/2003 has been submitted accordingly on 5 September 2004. See Community Register for more information.

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

Yes ☒		No ☐	

If yes, specify:

Australia/New Zealand		**Food**	**9-May-02**
		Feed	**25-Jul-03**
	(cultivation)	**Environment**	**25-Jul-03**
Canada		**Food**	**12-Mar-97**
		Feed	**21-Oct-96**
	(cultivation)	**Environment**	**27-Oct-96**
South Africa		**Food**	**12-Dec-01**
		Feed	**12-Dec-01**
South Korea		**Food**	25-Feb-05
		Environment	28-Jun-05
United States		**Food**	**18-Sep-98**
		Feed	**22-Mar-99**
	(cultivation)	**Environment**	**22-Mar-99**
Mexico		**Food**	**21-Oct-04**
		Feed	**Not regulated**
China		**Food**	**Sep, 06**
		Feed	**1-Sep-06**
Japan	**MS8**	**Food**	**31-Mar-01**
		Feed	**27-Mar-03**
	(cultivation)	**Environment**	**22-Sep-06**
	RF3	**Food**	
		Feed	**27-Mar-03**
		Environment	**Pending**
	MS8/RF3	**Food**	**31-Mar-01**
		Feed	**27-Mar-03**
		Environment	**Pending**
EU		**Food**	**30-Sep-99**
		Existing products	**18-Apr-2005**
	(import and processing)	**Environment**	**26-Mar-07**

8. General description of the product

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

The recipient organism was a commercial spring variety of oilseed rape cultivated in USA and Canada, which has been genetically modified to introduce a pollination control system (hybrid system), linked to a herbicide tolerant trait.

Pollination control:

Oilseed rape is a crop capable of undergoing both self-pollination (70%) as well as cross-pollination (30%). Therefore a system to ensure only cross-pollination is required for producing hybrids from two distinct parents. The SeedLink® hybridisation system allows that the female plants are pollinated by the desired male plants. It is based on:

A female line obtained by the unique combination of a natural catabolic activity, a ribonuclease (Barnase protein produced by the *barnase* gene), and a DNA sequence limiting its expression to a specific stage and time during the development of the anthers. This female line does not produce pollen and thereby prevents self-pollination and enables the production of hybrids.

A fertility restoration line (male line) harbouring a highly specific inhibitor (Barstar protein produced by the *barstar* gene) of the introduced ribonuclease (Barnase protein). Full fertility restoration is obtained after a cross between the female line and the fertility restoration line. Fertility restoration ensures that the hybrid seed is itself fully fertile in the farmer's field.

The resulting hybrid oilseed rape varieties have higher yields than conventional varieties, while their consistent growth and even ripening make harvesting easier.

Herbicide tolerance:

The SeedLink® hybridisation system is combined with the LibertyLink® trait of tolerance to Liberty® herbicide (active ingredient glufosinate-ammonium), through the PAT protein (produced by the *bar* gene) that degrades the herbicide. Liberty® enables farmers to use a broad spectrum herbicide with favourable environmental and safety characteristics and to avoid the precautionary pre-emergence herbicide treatments. The ability to postpone weed control operations and herbicide applications until really necessary represents an important tool for Integrated Crop Management. Farmers are thus given the flexibility to tolerate flora in their fields that do not pose a threat to either the quality or the yield of their crop.

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

Oilseed rape products derived from MS8/RF3 will be imported and distributed in the European Union for all uses as any other Oilseed rape products (oil for food use, meal for feed uses).

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

In the EC, oilseed rape oil is an important vegetable oil source and can be used also for biodiesel. The meal is used primarily for animal feed. The import, processing, and industrial use together with the use of the grain as feed are authorised according to Dir. 2001/18/EC.

The processed product (oil for human consumption and meal for animal consumption) will be used for downstream purposes 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 renewal of

the authorisation. All standard practices applicable to oilseed rape oil and meal products today remain adequate for the handling of oil and meal derived from MS8/RF3 varieties.

When the processed product is placed on the EU market, 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:

Food and feed products produced from MS8/RF3 varieties, grown in North America and Canada, are substantially equivalent to traditional oilseed rape products and will therefore be used in the same manner as other oilseed rape. Consequently no specific packaging is foreseen.

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:

MS8/RF3 does not have 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):

Not applicable as the scope of this application is food and feed produced from MS8/RF3.

The UIC provided under Dir. 2001/18/EC are:

MS8: ACS-BNØØ5-8
RF3: ACS-BNØØ3-6
MS8xRF3: ACS-BNØØ5-8 x ACS-BNØØ3-6

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 MS8/RF3 is suitable for food, feed and industrial uses in all regions of the European Union.

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

The safety profile in terms of human and animal health and environmental impact of derived products of MS8/RF3 and conventional oilseed rape are identical and do not constitute a hazard.

No specific conditions are warranted or required for the placing on the market of MS8/RF3 either for food and feed.

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

1. Complete name

a) Family name:	*Cruciferae*
b) Genus:	*Brassica*
c) Species:	*napus*
d) Subspecies:	oleifera
e) Cultivar/breeding line or strain:	various
f) Common name:	oilseed rape

2 a. Information concerning reproduction

(i) Mode(s) of reproduction

The flowers are self-compatible. Reproduction is sexual: 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

Temperature (insect visits), humidity (pollen viability) and wind.
Pollinating insects, in particular honeybees (*Apis mellifera*) and bumblebees (*Bombus* sp.) play a major role in *B. napus* pollination.

(iii) Generation time

Between 6 and 12 months.

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

Successful hybrid formation depends not only on the sexual compatibility between the plants (whether the same or related species) but the two plants 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 five species: *Brassica rapa* (synonym *Brassica campestris*), *Brassica juncea*, *Hirschfeldia incana*, *Raphanus raphanistrum* and *Sinapis arvensis*.

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 during several years if they are 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

Two development stages are relevant for dissemination: pollen and seeds.

- Pollen: oilseed rape pollen grains, which are heavy and sticky, can be transferred from plant to plant through physical contact between neighbouring plants and by wind and insects. Although pollen can be blown by wind or carried away by insect pollinators over large distances, the bulk of cross-pollination has been observed to occur over very short distances. Successful pollination declines exponentially with increasing distance between the pollen source and the nearest recipient plant.

- Seeds: oilseed rape seeds are small and may be left in and near the field (essentially seeds from shattered seed pods, or leaked from the transport equipment) or may be carried away (essentially seeds that leaked from the transport carriers).

b) Specific factors affecting dissemination

Pollen dissemination 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.

There is no specific factor affecting seed dissemination (oilseed rapeseeds have no special adaptations to encourage transport), which is mainly due to human 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 crop 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.

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 the crop is grown normally 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 neither pathogenic nor harmful. There are no major interactions with the ecosystem except for being a crop. Oilseed rape serves as an abundant supply of nectar for foraging insects such as honeybees.

Oilseed rape plants or seeds may be occasionally consumed by flea beetles, animal browsers (e.g. rabbits) and birds.

A number of diseases (e.g. *Sclerotinia sclerotiorum*) may infest the crop.

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 zero" varieties), characteristics desirable for high-quality vegetable oil and high quality animal feed.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification

Insertion of genetic material by *Agrobacterium tumefaciens* mediated transformation.

2. Nature and source of the vector used

Female line MS8 - plasmid pTHW107 contains between the left and right borders:

1. PTA29-*barnase*-3'nos:

- the tapetum cell-specific promoter PTA29 from *Nicotiana tabacum*
- the *barnase* gene from *Bacillus amyloliquefaciens*
- part of the 3' non-coding region (3' nos) of the nopaline synthase gene of *Agrobacterium tumefaciens*

2. PssuAra-*bar*-3'g7:

- the PssuAra promoter from *Arabidopsis thaliana*
- the *bar* gene isolated from *Streptomyces hygroscopicus*
- the 3' untranslated sequence of the TL gene 7 of *Agrobacterium tumefaciens*

Male line RF3- plasmid pTHW118 contains between the left and right borders:

1. PTA29-*barstar*-3'nos:

- the tapetum cell-specific promoter PTA29 from *Nicotiana tabacum*
- the *barstar* gene from *Bacillus amyloliquefaciens*
- part of the 3' non-coding region (3' nos) of the nopaline synthase gene of *Agrobacterium tumefaciens*

2. PssuAra-*bar*-3'g7:

- the PssuAra promoter from *Arabidopsis thaliana*
- the *bar* gene isolated from *Streptomyces hygroscopicus*
- the 3' untranslated sequence of the TL gene 7 of *Agrobacterium tumefaciens*

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

Table 1 Genetic Elements of T-DNA Component of pTHW107

Definition	Source	Size (bp)	Function
Right border sequence	*A. tumefaciens*	25	T-DNA integration
Polylinker sequence	Synthetic	72	Plasmid cloning
Terminating signal from TL-DNA gene 7	*A. tumefaciens*	212	Stop signal
Polylinker sequence	Synthetic	21	Plasmid cloning
Glufosinate tolerance gene	*S. hygroscopicus*	552	Selectable marker and herbicide tolerance
Promoter	*A. thaliana*	1726	Constitutive promoter targeting expression mainly to green tissue
Polylinker sequence	Synthetic	50	Plasmid cloning
Polyadenylation region of nopaline synthase gene	*A. tumefaciens*	261	Stop signal
Terminating signal of barnase gene	*B. amyloliquefaciens*	112	Stop signal
Ribonuclease gene	*B. amyloliquefaciens*	336	Male sterility
Promoter	*N. tabacum*	1510	Expression only in anthers
Polylinker sequence	Synthetic	44	Plasmid cloning
Left border sequence	*A. tumefaciens*	25	T-DNA integration

Table 2 Genetic Elements of T-DNA Component of pTHW118

Definition	Source	Size (bp)	Function
Right border sequence	*A. tumefaciens*	25	T-DNA integration
Polylinker sequence	Synthetic	28	Plasmid cloning
TL-DNA sequence	*A. tumefaciens*	37	None
Polylinker sequence	Synthetic	7	Plasmid cloning
Terminating signal from TL-DNA gene 7	*A. tumefaciens*	212	Stop signal
Polylinker sequence	Synthetic	21	Plasmid cloning
Glufosinate tolerance gene	*S. hygroscopicus*	552	Selectable marker and herbicide tolerance
Promoter	*A. thaliana*	1726	Constitutive promoter targeting expression mainly to green tissue
Polylinker sequence	Synthetic	50	Plasmid cloning
Polyadenylation region of nopaline synthase gene	*A. tumefaciens*	261	Stop signal
Polylinker sequence	Synthetic	21	Plasmid cloning
Terminating signal of *barstar* gene	*B. amyloliquefaciens*	40	Stop signal
Ribonuclease inhibitor gene	*B. amyloliquefaciens*	273	Fertility Restoration
Promoter	*N. tabacum*	1510	Expression only in anthers
Polylinker sequence	Synthetic	45	Plasmid cloning
Left border sequence	*A. tumefaciens*	25	T-DNA integration

D. INFORMATION RELATING TO THE GM PLANT

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

Pollination control system (female line Ms8 and male (fertility restoration) line Rf3)

The female line MS8 contains a *barnase* gene (origin *Bacillus amyloliquefaciens*) coding for a ribonuclease expressed only in the tapetum cells during anther development that leads to lack of viable pollen.

The male (fertility restoration) line RF3 contains a *barstar* gene (origin *Bacillus amyloliquefaciens*) coding for an inhibitor of *barnase* expressed only in the tapetum cells during anther development that leads to restoration of fertility in the hybrid plant.

Herbicide tolerance

Both the female and male lines (and the resulting hybrid) contain a *bar* gene (bialaphos resistance, origin *Streptomyces hygroscopicus*) coding for phosphinotricin acetyl transferase conferring tolerance to herbicides based on glufosinate ammonium. The *bar* gene is driven by a plant promoter that is active in all green tissues of the plant.

2. Information on the sequences actually inserted or deleted

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

In line Ms8 the inserted DNA has been shown to consist of a single copy of T-DNA insert.

In line Rf3 there is a T-DNA copy arranged in an inverted repeat structure with a second, incomplete T-DNA copy. The second copy includes a functional part of promoter PTA29, the coding region of *barstar*, the 3' nos and a non-functional part of promoter PssuAra.

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

Not relevant.

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

In both MS8 and RF3, based on Southern and segregation analyses, it was demonstrated that the DNA has integrated in a single genetic locus in the oilseed rape nuclear genome (chromosomes).

Following analyses of the regions flanking the insert there is no indication of insertion of T-DNA in a functional gene.

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

See 2a.

3. Information on the expression of the insert

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

Linked to the plant promoter PssuAra, the expression of the *bar* gene is mainly targeted to green tissue of the plant.

The plant promoter PTA29 allows the activity of the *barnase* and the *barstar* genes to be limited in time (only when flowering, during anther development) as well as place (tapetum cells of the pollen sac).

Expression level was measured by Northern blot analysis and PAT protein specific ELISA. The PAT protein activity was assessed by enzymatic assays.

However, the scope of the current application covers oil and meal derived from MS8/RF3 only, and does not involve the environmental release of the GM plants.

b) Parts of the plant where the insert is expressed

The scope of the current application covers oil and meal derived from MS8/RF3 only, and does not involve the environmental release of the GM plants. Therefore, the following information related to the expression of the insert can be considered as mainly informative.

Linked to the plant promoter PssuAra, the expression of the *bar* gene is mainly targeted to green tissue of the plant (e.g. leaves). The PAT protein can also be detected in very low amounts in dry seed (approx. 0.1 µg/g seed).

The plant promoter PTA29 allows the activity of the *barnase* and the *barstar* genes to be limited in time (only when flowering, during anther development) as well as place (tapetum cells of the pollen sac). The Barnase and the Barstar proteins are not detected in seeds.

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

a) Reproduction

Reproduction occurs through seed production. In the female line MS8 there is no pollen production.

In the male line RF3 and the hybrid line MS8xRF3 the mode and rate of reproduction are similar to the recipient plant.

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, with the exception of the female line being incapable of releasing pollen.

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

- no differences in seed shattering ability have been observed between the genetically modified oilseed rape plants and non-genetically modified oilseed rape.
- the shape and size of the seeds is identical to that of the original non-genetically modified variety; there is no development of structures facilitating transport (such as hairs or needles);
- the germination ability (a key-parameter to test seed dormancy) and evolution of germination ability of the seeds of the genetically modified oilseed rape did not differ from their non-genetically modified counterpart (cf. field trials and germination tests);
- no differences in regrowth ability have been observed between the genetically modified and non-genetically modified oilseed rape under greenhouse and field conditions.

c) Survivability

Survival is essentially determined at the seed stage. There is no indication on 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 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 female, male and hybrid lines have been made tolerant to the Liberty® herbicide (active ingredient glufosinate ammonium) and can therefore survive treatment with glufosinate ammonium.

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

Based on phenotypic and molecular techniques it was shown that the genes are stable and follow standard 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

Not applicable. However no aspect of the nature of the genetic elements used gives any indication that a transfer from MS8/RF3 to bacteria could occur.

b) Plant to plant gene transfer

Not applicable. The scope of the current application covers oil and meal derived from MS8/RF3 only, and does not involve the environmental release of the GM plants.

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

MS8xRF3 was compared with its parent variety Drakkar.

7.2 Production of material for comparative assessment

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

Plant variety descriptors and agronomic performance traits were studied in a total of 12 locations in season 2001 & 2002.

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 variety, Drakkar.

7.3 Selection of material and compounds for analysis

The analysis of the compounds was based on international accepted guidelines (OECD).

The results of the composition analysis of MS8xRF3 in comparison with the conventional oilseed rape variety demonstrate substantial equivalence and do not indicate a need for further analysis of selected compounds of MS8xRF3 derived products.

7.4 Agronomic traits

Data for agronomic, compositional and nutritional assessment were generated at 12 field trial locations in Belgium, performed in 2001 and 2002. The field trials were sowed and cultivated to demonstrate the agronomic performance of the Liberty treated and untreated F1 MS8xRF3 hybrids in relation to the non-transgenic counterpart. The second objective was to generate seed material for compositional and nutritional analyses.

The trials were located at different stations on different soil types, with 4 replicates and a Complete Randomized Block Design. Different treatments are performed; the non-transgenic control conventionally treated, the transgenic LL OSR MS8xRF3 conventionally treated and the transgenic LL OSR MS8xRF3 treated with glufosinate ammonium (Liberty).

The agronomic performance of the MS8/RF3 product and its non-transgenic counterpart were monitored from germination until harvest for a number of key agronomic parameters, such as establishment, vigour, flowering start, flowering end, height, maturity, lodging and yield.

There were no significant differences between the Liberty® treated MS8xRF3, not Liberty® treated MS8xRF3 and the non-transgenic counterpart for all agronomic parameters except for the vigour after Liberty® treatment. This vigour reduction however quickly disappeared and was no longer apparent at the onset of flowering.

7.5 Product specification

The import of the grain, the processing and the use of grain for feed purposes are authorized according to the Commission Decision concerning the placing on the market (Dir. 2001/18)

Rapeseeds are only used in the human diet after processing into food grade vegetable oil. Because of the presence of several anti-nutritional factors the use of rapeseed oil was until 1950 limited to industry. Since the introduction of erucic acid free varieties rapeseed oil can be used in the food sector. Whereas in 1974, 70% of the European rapeseed was used for industrial purposes, nowadays 96% is further processed for food use. Oil from low erucic acid rapeseeds is used in a variety of food applications including: salad oil, frying fat, baking shortening and tablespreads (margarine). Beside the oil, there are no other products from OSR that enter the food chain.

The main side product from oil processing, the mechanical extracted or solvent extracted meal, is an important source of protein in animal feeding. This is true since the introduction of the double zero cultivars with low glucosinolate contents. OSR meal is mixed with soybean meal or field peas. Low erucic acid rapeseed meal is used as protein feed for all classes of livestock. It has relatively high fibre content, because it contains about 30% of hull material. Depending on the fibre content it is only acceptable in low inclusion rates for monogastric animals (15% of the total diet). When it is used as the sole protein source in a ruminant diet, the inclusion rate is a maximum of 30% of the total diet. In addition to the meal, crushed seeds and the oil can be used in animal diets.

7.6 Effect of processing

As MS8/RF3 is substantially equivalent to traditional oilseed rape in commerce, the same production process applied to oilseed rape will be used for the grain derived from MS8/RF3 varieties. The genetic modifications were not aimed at changing the processing methods.

7.7 Anticipated intake/extent of use

Oilseed rape and oilseed rape products derived from MS8/RF3 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 MS8/RF3 varieties.

The total consumption of rapeseed oil for the EU (25) was 5 476 000 mT in 2005, accounting for more than 1/3 of total vegetable oil consumption. The extremes of rapeseed oil consumption in the member States include 2 276 000 mT in Germany, 629 000 mT in The United Kingdom and 622 000 mT in France (FEDIOL, 2007).

In 2005 daily intake for rapeseed and mustard seed together varied from 0,18 gram per capita in Portugal to 63,28 gram in the Austria (FAOStat, 2007).

7.8 Toxicology

7.8.1 Safety assessment of newly expressed proteins

The safety of these events, including the proteins, has been assessed. The proteins encoded by the introduced genes are not toxic to mammals and present no unacceptable risk to human safety, and no risk specific to the expression of the new proteins in the same plant can be anticipated.

The PAT protein is the only newly-expressed protein present in MS8 x RF3 seed. Barnase and Barstar proteins are only expressed in the tapetum cells of the flower buds and therefore will not occur in food or feed derived from MS8 x RF3 seed

There is no dietary intake of PAT protein via oilseed rape products by humans, since food grade oil is the only oilseed rape product that enters the human food chain and PAT protein was not detected in any oil product derived from MS8xRF3.

7.8.2 Testing of new constituents other than proteins

Not applicable

7.8.3 Information on natural food and feed constituents

Natural constituents of oilseed rape have not been changed.

7.8.4 Testing of the whole GM food/feed

Based on the fact that the extensive comparative compositional analysis of MS8xRF3 oilseed rape provided no indication for unintended effects of the genetic modification under consideration, additional animal safety or nutrition studies were not required (EFSA opinion, 2005).

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

The PAT protein is the only newly-expressed protein present in MS8 x RF3 seed. Barnase and Barstar proteins are only expressed in the tapetum cells of the flower buds and therefore will not occur in food or feed derived from MS8 x RF3 seed. The PAT protein has been previously evaluated for its safety in the context of other applications for the placing on the market of GM crops expressing PAT. Independently it has been investigated whether the identical stretches of six or more contiguous amino acids were shared by transgenic proteins expressed in genetically modified crops and allergenic proteins. In the case of PAT encoded by the *bar* gene of *Streptomyces hygroscopicus*, no identities of six or more amino acids were observed by these authors. BCS also showed the absence of amino acid sequence homology of the three newly-expressed proteins with known allergens and toxins.

7.9.2 Assessment of allergenicity of the whole GM plant or crop

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

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.

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 deodorized 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 conclusion from the compositional analyses of MS8xRF3 seeds and the comparison between the analyzed values with reference data from the respective chemistry reference guidelines is that events MS8xRF3 are found to be compositionally and nutritionally equivalent to its traditional non-transgenic counterpart and that there is no impact on the nutritional value of the rapeseeds caused by the genetic transformation.

7.10.2 Nutritional assessment of GM feed

The conclusion from the compositional analyses of MS8xRF3 seeds and the comparison between the analyzed values with reference data from the respective chemistry reference guidelines is that events MS8xRF3 are found to be compositionally and nutritionally equivalent to its traditional non-transgenic counterpart and that there is no impact on the nutritional value of the rapeseeds caused by the genetic transformation.

7.11 Post-market monitoring of GM food/feed

Ms8 x Rf3 oilseed rape is, from a nutritional point of view, equivalent to conventional oilseed rape and will be used as any other oilseed rape. Therefore no post-market monitoring of the GM food/feed products is required.

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

Not applicable as this application under Regulation (EC) No 1829/2003 includes the renewal of the food and feed authorizations, specifically oil and meal, produced from MS8xRF3 for uses equivalent to any other oilseed rape.

The import, processing, industrial uses and the grain as feed are authorized according to Dir. 2001/18/EC.

9.1 Persistence and invasiveness

Not applicable

9.2 Selective advantage or disadvantage

Not applicable

9.3 Potential for gene transfer

Not applicable

9.4 Interactions between the GM plant and target organisms

Not applicable

9.5 Interactions of the GM plant with non-target organisms

Not applicable

9.6 Effects on human health

Not applicable

9.7 Effects on animal health

Not applicable

9.8 Effects on biogeochemical processes

Not applicable

9.9 Impacts of the specific cultivation, management and harvesting techniques

Not applicable

10. Potential interactions with the abiotic environment

Not applicable as this application under Regulation (EC) No 1829/2003 includes the renewal of the food and feed authorizations, specifically oil and meal, produced from MS8xRF3 for uses equivalent to any other oilseed rape.

The import, processing, industrial uses and the grain as feed are authorized according to Dir. 2001/18/EC.

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)

Not applicable as the EFSA opinion document on the Post Market Environmental Monitoring (PMEM) of genetically modified plants[1] has excluded an environmental monitoring plan (including general surveillance) in the case of non-viable GM material (*e.g.* derived products not containing any living GMOs).

An environmental monitoring plan exists and is operational according to the conditions mentioned in the Decision according to Dir. 2001/18/EC which relates to the import and processing of the grain.

11.1 General (risk assessment, background information)

Not applicable

11.2 Interplay between environmental risk assessment and monitoring

Not applicable

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

Not applicable

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

Not applicable

11.5 Reporting the results of monitoring

Not applicable

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.

[1] Opinion of the Scientific Panel on Genetically Modified Organisms on the Post Market Environmental Monitoring (PMEM) of genetically modified plants, The EFSA Journal (2006), 319, 1-27

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

Not applicable as this application under Regulation (EC) No 1829/2003 includes the renewal of the food and feed authorizations, specifically oil and meal, produced from MS8xRF3 for uses equivalent to any other oilseed rape. The environmental releases are provided in the framework of the Dir. 2001/18 submission (C/BE/96/01). See also the SNIF related to this submission.
a) Notification number Not applicable
b) Conclusions of post-release monitoring Not applicable
c) Results of the release in respect to any risk to human health and the environment (submitted to the Competent Authority according to Article 10 of Directive 2001/18/EC) Not applicable

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

a) Release country Not applicable
b) Authority overseeing the release Not applicable
c) Release site Not applicable
d) Aim of the release Not applicable
e) Duration of the release Not applicable
f) Aim of post-releases monitoring Not applicable
g) Duration of post-releases monitoring Not applicable
h) Conclusions of post-release monitoring

Not applicable
i) Results of the release in respect to any risk to human health and the environment Not applicable

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 Regulation (EC) No 1829/2003.
b) Assessment Report of the Competent Authority (Directive 2001/18/EC) SBB: http://www.biosafety.be/gmcropff/EN/TP/SBB_NotificationC_BE_96_01.html
c) EFSA opinion http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/1178.html
d) Commission Register (Commission Decision 2004/204/EC) http://ec.europa.eu/food/dyna/gm_register/gm_register.cfm?gm_id=15
e) Molecular Register of the Community Reference Laboratory/Joint Research Centre Information on detection protocols are 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) Not available at the time of submission