PART II

Request for Authorization of Glufosinate Ammonium-Tolerant Genetically Modified Oilseed Rape

MS8, RF3 and MS8xRF3

in accordance with article 5 of Regulation (EC) N° 1829/2003

A. GENERAL INFORMATION

1. Details of application

a) Member State of application: Belgium
b) Application number: EFSA-GMO-BE-2010-81
c) Name of the product (commercial and other names): Glufosinate ammonium-tolerant genetically modified MS8, RF3 and MS8xRF3 oilseed rape. The unique identifiers assigned to MS8/RF3[1] oilseed rape are: MS8: ACS-BNØØ5-8 RF3: ACS-BNØØ3-6 MS8xRF3: ACS-BNØØ5-8xACS-BNØØ3-6
d) Date of acknowledgement of valid application: Not available at the date of application

2. Applicant

a) Name of applicant: This is an application submitted by Bayer CropScience AG.
b) Address of applicant: Bayer CropScience AG represented by Bayer BioScience NV Alfred-Nobel-Strasse 50 Technologiepark 38 D - 40789 Monheim am Rhein B-9052 Gent Germany Belgium
c) Name and address of the person established in the Community who is responsible for the placing on the market, whether it be the manufacturer, the importer or the distributor, if different from the applicant (Commission Decision 2004/204/EC Art 3(a)(ii)): MS8/RF3 oilseed rape will be imported and processed in the EU by the same groups who currently import,

[1] The designation "MS8/RF3" is used to refer to "MS8, RF3 and MS8xRF3".

process and distribute commodity oilseed rape.

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 (with the exception of processed oil)

☐ 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)

The scope of this application has been selected in order to complement existing scopes for MS8/RF3 oilseed rape that have already been notified and authorized in the EU (see Point A.6.).

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: 1. Notification C/BE/96/01 for placing on the market of MS8, RF3 and MS8xRF3 oilseed rape has been authorized in the EU by Commission Decision 2007/232/EC and, in accordance with the provisions of Article 18(2) of Directive 2001/18/EC, the import approval decision of the Belgian Lead Member State on 25 May 2007. The authorization for MS8, RF3 and MS8xRF3 oilseed rape in line with Commission Decision 2007/232/EC was based on a positive final opinion adopted by the EFSA GMO Panel in September 2005. Commission Decision 2007/232/EC authorizes the import and processing of MS8, RF3 and MS8xRF3 oilseed rape as any other oilseed rape, with the exception of cultivation and uses as or in food.	

2. Food (processed oil) and feed produced from MS8, RF3 and MS8xRF3 oilseed rape were notified to the European Commission as existing food and feed, respectively, falling within the scope of Articles 8(1)(a) and 20(1)(b) of Regulation (EC) N° 1829/2003 on 5 September 2004. On 17 April 2007, Bayer CropScience submitted a request for renewal in line with Articles 11 and 23 of Regulation (EC) N° 1829/2003 of the authorisation for existing food (processed oil) and feed from MS8, RF3 and MS8xRF3 oilseed rape that were lawfully placed on the market. Renewal application EFSA-GMO-RX-MS8-RF3 was considered valid by the EFSA on 28 March 2008 and a positive final opinion was adopted by the EFSA GMO Panel in September 2009. As a consequence and in line with Articles 11(4) and 23(4) of Regulation (EC) N° 1829/2003, food (processed oil) and feed produced from MS8, RF3 and MS8xRF3 oilseed rape are authorized in the EU.

3. The EFSA GMO Panel has reviewed the available scientific information relating to the safety of MS8/RF3 oilseed rape at four different occasions and concluded that MS8, RF3 and MS8xRF3 oilseed rape is unlikely to have an adverse effect on human and animal health or, in the context of its proposed uses, on the environment (EFSA Opinion, 2005, EFSA Opinion, 2009a, EFSA Opinion, 2009b and EFSA Opinion 2010).

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

Yes ☒	No ☐

If *yes*, specify:

MS8/RF3 Global Approvals

Country		Registration Type	Date
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
		Environment	22-Sep-06
	RF3	Food	
		Feed	27-Mar-03
		Environment	24-Apr-07
	MS8xRF3	Food	31-Mar-01
		Feed	27-Mar-03
		Environment	23-Aug-07
EU		Food (processed oil)	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:

MS8/RF3 oilseed rape were obtained by genetic modification of *Brassica napus*.

MS8 oilseed rape (male sterile line) contains the *barnase* gene (origin *Bacillus amyloliquefaciens*) coding for a ribonuclease, Barnase. The *barnase* gene is driven by the Pta29 promoter that restricts gene expression to the tapetum cells during anther development. Therefore, the Barnase protein is not expressed in any tissue of MS8 oilseed rape, except the tapetum cells during anther development. Expression of the Barnase in the tapetum cells of MS8 oilseed rape results in lack of viable pollen and male sterility. MS8 oilseed rape also contains the *bar* gene (origin *Streptomyces hygroscopicus*) coding for a phosphinothricin acetyl transferase (PAT) confering tolerance to herbicides containing glufosinate-ammonium. The *bar* gene is driven by the PssuAt plant promoter that is active in all green tissues of the plant.

RF3 oilseed rape (fertility restorer line) contains the *barstar* gene (origin *Bacillus amyloliquefaciens*), coding for the Barstar protein, which is an inhibitor of the Barnase protein. The *barstar* gene is driven by the Pta29 promoter that restricts gene expression to the tapetum cells during anther development. Therefore, the Barstar protein is not expressed in any tissue of RF3 oilseed rape, except the tapetum cells during anther development. Expression of the Barstar protein in the tapetum cells leads to

restoration of fertility after crossing to the MS8 oilseed rape. RF3 oilseed rape also contains the *bar* gene (origin *Streptomyces hygroscopicus*) coding for a phosphinothricin acetyl transferase (PAT) confering tolerance to herbicides containing glufosinate-ammonium. The *bar* gene is driven by the PssuAt plant promoter that is active in all green tissues of the plant.

The male sterile MS8 oilseed rape and the fertility restorer RF3 oilseed rape form the basis of a hybridization system in oilseed rape. F1 hybrids of oilseed rape varieties yield 20-25% more than the best open-pollinated oilseed rape varieties and the uniformity of the hybrid plants is an advantage in commercial fields facilitating harvesting and marketing. The incorporation of the *bar* gene provides a weed management tool to oilseed rape growers.

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

No change in the use patterns for oilseed rape is anticipated in the frame of this application. The human food products derived from MS8/RF3 oilseed rape are only expected to replace part of the oilseed rape products in existing human food products.

With regard to derived products for human consumption, the principal product derived from oilseed rape grains for human consumption is vegetable oil. The raw agricultural commodity, *i.e.* whole oilseed rape grains, are not anticipated to be directly consumed as part of the human diet and any such use would be unintentional and any such exposure negligible.

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

The products, covered by this authorization, will be used as any other commercial oilseed rape, with the exception of cultivation.

With regard to derived products for human consumption, the principal product derived from oilseed rape grains for human consumption is vegetable oil. The raw agricultural commodity, *i.e.* whole oilseed rape grains, are not anticipated to be directly consumed as part of the human diet and any such use would be unintentional and any such exposure negligible.

MS8/RF3 oilseed rape grain will be handled in the same way as any other commercial oilseed rape by the same operators currently involved in the trade and use of commercial oilseed rape.

d) Specific instructions and/or recommendations for use, storage and handling, including mandatory restrictions proposed as a condition of the authorisation applied for:

No mandatory restrictions for use, storage and handling are proposed as a condition of the authorisation. All standard practices applicable to oilseed rape today remain adequate for the handling of MS8/RF3 oilseed rape.

When MS8/RF3 oilseed rape is placed on the EU market, the labelling and traceability requirements according to Regulation (EC) N° 1829/2003 and Regulation (EC) N° 1830/2003 will apply.

e) Any proposed packaging requirements:

No specific packaging requirements are 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 oilseed rape does not harbour characteristics that require specific labelling. Hence, no additional labelling is proposed other than the GM labelling requirements under Regulations (EC) 1829/2003 and 1830/2003.

g) Unique identifier for the GM plant (Regulation (EC) 65/2004; does not apply to applications concerning only food and feed produced from GM plants, or containing ingredients produced from GM plants): MS8: ACS-BNØØ5-8 RF3: ACS-BNØØ3-6 MS8xRF3: ACS-BNØØ5-8xACS-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.

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

The case of accidental spillage of non-processed MS8/RF3 oilseed rape, in transit or at the processing facility, has been assessed in the environmental risk assessment under notification C/BE/96/01 and is addressed in the post market monitoring plan for MS8/RF3 oilseed rape (see Commission Decision 2007/232/EC).

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

1. Complete name

a) Family name:	*Brassicaceae* (or *Cruciferae)*
b) Genus:	*Brassica*
c) Species:	*napus*
d) Subspecies:	*oleifera*
e) Cultivar/breeding line or strain:	MS8 and RF3 oilseed rape
f) Common name:	oilseed rape, colza

2 a. Information concerning reproduction

(i) Mode(s) of reproduction Reproduction is by seeds. The fruiting bodies produced by the *Brassicaceae* family are siliques, commonly called pods, 5 to 10 cm in length. Between 15 and 25 seeds are produced per pod. Each oilseed rape plant produces hundreds of small, spherical, light brown to black seeds. Each seed is generally 1 to 2 mm in diameter. There are generally 250.000 to 300.000 seeds per kilogram of seed.

(ii) Specific factors affecting reproduction

Pollination is affected by temperature (insect visits), humidity (pollen viability) and wind (pollen dispersal).

The spring-type *B. napus* is not very drought tolerant. Air and soil temperatures influence plant growth and productivity. The optimum temperature for maximal growth and development of spring-type oilseed rape is just over 20°C, and it is best grown between 12°C and 30°C. After emergence, seedlings prefer relatively cool temperatures up to flowering; high temperatures at flowering will hasten the plant's development, reducing the time from flowering to maturity.

(iii) Generation time

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

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

The sexual compatibility between *Brassica* species has been studied in detail. While many interspecific and intergeneric crosses have been made between *Brassica napus* and its relatives, many have necessitated specific tissue culture intervention in the form of ovary culture, ovule culture, embryo rescue and protoplast fusion.

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 four species: *Brassica rapa* (synonym *Brassica campestris*), *Brassica juncea*, *Hirschfeldia incana*, *Raphanus raphanistrum*.

3. Survivability

a) Ability to form structures for survival or dormancy

Oilseed rape is an annual plant that survives through seed formation. If seeds are buried due to e.g. cultivation, they may persist for periods of up to ten years under ideal conditions

b) Specific factors affecting survivability

Optimal germination conditions for oilseed rape are 20°C, high water availability and exposure to light. Consequently, the greatest proportion of oilseed rape plants that germinate after harvest emerge in response to tillage.

4. Dissemination

a) Ways and extent of dissemination

Relevant for dissemination are pollen and seeds.

b) Specific factors affecting dissemination

Pollinating insects, in particular honeybees (*Apis mellifera*) and bumblebees (*Bombus* spp.) play a major role in *Brassica napus* pollination. There is no specific factor affecting seed dissemination (oilseed rape seeds have no special adaptations to encourage transport).

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

Since the late 1940's, oilseed rape 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 three species of *Brassica* (*B. napus, B. rapa* and *B. juncea*) have commercialized 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 can be subdivided into winter and spring forms. The winter annual is grown in regions where winter conditions do not result in very low temperatures. In North America and northern Europe, the spring biotype of *B. napus* is grown that requires no vernalisation prior to flowering.

The main four compatible species of *B. napus* (*Brassica rapa*, *Brassica juncea*, *Hirschfeldia incana*, *Raphanus raphanistrum*) are found throughout Europe, with *Hirschfeldia incana* primarily found in Southern Europe. However, the frequency of gene flow from oilseed rape to these wild relatives under natural conditions is considered very low and the fitness of the interspecific hybrids is generally reduced compared to the parents. Therefore, stable introgression of a new trait in the weed species genome is confirmed to be extremely difficult.

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 relevant as oilseed rape is normally cultivated as a crop in the EU.

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

The scope of this application does not include cultivation of MS8/RF3 oilseed rape seeds in the EU and therefore no potential interactions with organisms in the ecosystem in the EU are expected.

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

MS8 and RF3 oilseed rape were produced by *Agrobacterium tumefaciens* mediated transformation

with the plasmids pTHW107 and pTHW118, respectively.

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

The genetic elements to be transferred into the plant are described in Tables 1 and 2.

Table 1. Genetic elements of the T-DNA region of plasmid pTHW107 (MS8 oilseed rape)

Genetic element	Description	Source	Size (bp[1])	Intended function
RB[2]	T-DNA right border sequence	*A. tumefaciens*	25	T-DNA integration
3'g7	3' untranslated region of the TL-DNA gene 7	*A. tumefaciens*	306	Stop signal for gene transcription
bar	Coding sequence of the phosphinotricin acetyltransferase (PAT) protein	*S. hygroscopicus*	552	The PAT protein detoxifies phosphinotricin resulting in tolerance to glufosinate-ammonium herbicides
PssuAt	Promoter region of the ribulose-1,5-biphosphate carboxylase small subunit gene	*A. thaliana*	1775	Constitutive promoter targeting gene expression mainly to green tissue
3'nos	3' untranslated region of the nopaline synthase gene	*A. tumefaciens*	261	Stop signal for gene transcription
3'barnase	3' untranslated region of the *barnase* gene	*B. amyloliquefaciens*	114	Stop signal for gene transcription
barnase	Coding sequence of the *barnase* gene	*B. amyloliquefaciens*	336	The Barnase protein is a ribonuclease that, when expressed in the tapetum cells during anther development, results in lack of viable pollen and male sterility.
Pta29	Promoter of the anther-specific TA29 gene	*N. tabacum*	1553	Promotor targeting gene expression only in anthers.
LB[3]	T-DNA left border sequence	*A. tumefaciens*	25	T-DNA integration

[1] bp: base pair
[2] RB: right border
[3] LB: left border

Table 2. Genetic elements of the T-DNA region of plasmid pTHW118 (RF3 oilseed rape)

Genetic element	Description	Source	Size (bp[1])	Intended function
RB[2]	T-DNA right border sequence	*A. tumefaciens*	25	T-DNA integration
3'g7	3' untranslated region of the TL-DNA gene 7	*A. tumefaciens*	305	Stop signal for gene transcription
bar	Coding sequence of the phosphinotricin acetyltransferase gene	*S. hygroscopicus*	552	The PAT protein detoxifies phosphinotricin resulting in tolerance to glufosinate-ammonium herbicides
PssuAt	Promoter region of the ribulose-1,5-biphosphate carboxylase small subunit gene	*A. thaliana*	1775	Constitutive promoter targeting gene expression mainly to green tissue
3'nos	3' untranslated region of the nopaline synthase gene	*A. tumefaciens*	323	Stop signal for gene transcription
barstar	Coding sequence of the *barstar* gene	*B. amyloliquefaciens*	273	The Barstar protein, when expressed in the tapetum cells during anther development, inhibits activity of the Barnase protein and therefore restores fertility.
Pta29	Promoter of the anther-specific TA29 gene	*N. tabacum*	1554	Promotor targeting gene expression only in anthers.
LB[3]	T-DNA left border sequence	*A. tumefaciens*	25	T-DNA integration

[1] bp: base pair
[2] RB: right border
[3] LB: left border

D. INFORMATION RELATING TO THE GM PLANT

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

The male sterile MS8 oilseed rape contains the *bar* and *barnase* genes. The fertility restorer RF3 oilseed rape contains the *bar* and *barstar* genes.

The *barnase* and *barstar* gene as the basis of a hybridization system in oilseed rape

The *barnase* and *barstar* genes have both been isolated from the bacterium *Bacillus amyloliquefaciens*. They code for two small single-chain proteins, designated as Barnase and Barstar, respectively. Barnase is the common name of the specific extracellular ribonuclease secreted by the bacterium. Ribonucleases are naturally occurring enzymes that are very commonly found in all kind of organisms and in nature: some are extracellularly released by bacteria, but some are also expressed in eukaryotic organisms. They are capable of degrading and digesting RNA. Barstar is the name for the specific inhibitor of the Barnase enzyme. The function of the Barstar enzyme is to protect the *Bacillus amyloliquefaciens* organism from the effects of the Barnase activity. The inhibition of Barnase by Barstar is highly specific. Both Barnase and Barstar have been the subject of intensive studies for many years. Under the control of a specific plant promoter, that exclusively expresses these genes in the tapetal cell-layer during anther development, the *barnase* and *barstar* genes are the basis of a well-characterised hybridization system in oilseed rape.

The *bar* gene and tolerance to glufosinate-ammonium herbicides

The *bar* gene, coding for the enzyme phosphinothricin acetyl transferase (PAT), has been isolated from *Streptomyces hygroscopicus*, a microorganism that produces bialaphos. Bialaphos or its synthetically produced component glufosinate-ammonium is a registered herbicide with phosphinothricin the active ingredient. Phosphinothricin is a potent inhibitor of glutamine synthetase which plays a central role in the assimilation of ammonia and in the regulation of the nitrogen metabolism in the plant. Phosphinothricin based herbicides are highly effective against plants, but are safe to humans and animals and are rapidly biodegraded in the environment. The *bar* gene product, PAT, metabolizes phosphinothricin to an inactive, acetylated derivative.

2. Information on the sequences actually inserted or deleted

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

MS8 oilseed rape contains a single copy of the pTHW107 T-DNA inserted at a single genomic locus and no vector backbone sequences were detected in MS8 oilseed rape.

RF3 oilseed rape contains a single genomic locus that is composed of one partial copy of the pTHW118 T-DNA, flanked by another partial copy of the pTHW118 T-DNA in an inverted orientation. No vector backbone sequences were detected in RF3 oilseed rape.

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 MS8 and RF3 inserts are located in the nuclear genome of oilseed rape.

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

See D.2 a).

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 tissues 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.

b) Parts of the plant where the insert is expressed

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

The agronomic performance, including potential differences in reproduction, for MS8/RF3 oilseed rape has been evaluated in the frame of application C/BE/96/01 under Directive 2001/18/EC that was granted consent by Commission Decision 2007/232/EC. The authorization for MS8, RF3 and MS8xRF3 oilseed rape in line with Commission Decision 2007/232/EC was based on a positive final opinion adopted by the EFSA GMO Panel in September 2005. Commission Decision 2007/232/EC authorizes the import and processing of MS8, RF3 and MS8xRF3 oilseed rape as any other oilseed rape, with the exception of cultivation and uses as or in food.

b) Dissemination

The agronomic performance, including potential differences in dissemination, for MS8/RF3 oilseed rape has been evaluated in the frame of application C/BE/96/01 under Directive 2001/18/EC that was granted consent by Commission Decision 2007/232/EC. The authorization for MS8, RF3 and MS8xRF3 oilseed rape in line with Commission Decision 2007/232/EC was based on a positive final opinion adopted by the EFSA GMO Panel in September 2005. Commission Decision 2007/232/EC authorizes the import and processing of MS8, RF3 and MS8xRF3 oilseed rape as any other oilseed rape, with the exception of cultivation and uses as or in food.

c) Survivability

The agronomic performance, including potential differences in survivability, for MS8/RF3 oilseed rape has been evaluated in the frame of application C/BE/96/01 under Directive 2001/18/EC that was granted consent by Commission Decision 2007/232/EC. The authorization for MS8, RF3 and MS8xRF3 oilseed rape in line with Commission Decision 2007/232/EC was based on a positive final opinion adopted by the EFSA GMO Panel in September 2005. Commission Decision 2007/232/EC authorizes the import and processing of MS8, RF3 and MS8xRF3 oilseed

rape, with the exception of cultivation and uses as or in food.

d) Other differences

The agronomic performance for MS8/RF3 oilseed rape has been evaluated in the frame of application C/BE/96/01 under Directive 2001/18/EC that was granted consent by Commission Decision 2007/232/EC. The authorization for MS8, RF3 and MS8xRF3 oilseed rape in line with Commission Decision 2007/232/EC was based on a positive final opinion adopted by the EFSA GMO Panel in September 2005. Commission Decision 2007/232/EC authorizes the import and processing of MS8, RF3 and MS8xRF3 oilseed rape as any other oilseed rape, with the exception of cultivation and uses as or in food.

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 inherited in MS8/RF3 oilseed rape 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

Detailed analysis of the inserted sequences in MS8/RF3 oilseed rape confirms that the possibility of transfer of genetic material to bacteria is highly unlikely.

b) Plant to plant gene transfer

The scope of this application does not include authorization for cultivation of MS8/RF3 oilseed rape seeds in the EU. As a consequence, exposure to the environment will be limited to unintended release of MS8/RF3 oilseed rape, which could occur for example via substantial losses during loading/unloading of the viable commodity including MS8/RF3 oilseed rape.

In any case, MS8/RF3 oilseed rape was found to be unchanged compared to commercially available oilseed rape, thereby confirming that the potential for gene transfer from MS8/RF3 oilseed rape to other oilseed rape and/or wild relatives is the same as with any commercially available oilseed rape.

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

7.1 Comparative assessment

A comparative assessment for compositional and nutritional equivalence was performed on MS8xRF3 oilseed rape grain. The comparative assessment was conducted to determine if MS8xRF3 oilseed rape grain is compositionally and nutritionally equivalent to grain from the parent Drakkar variety.

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 during the growing 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

MS8/RF3 oilseed rape is as safe as and as nutritious as commercially available oilseed rape and therefore, the specification of food from MS8/RF3 oilseed rape is equivalent to that of food from commercially available oilseed rape.

7.6 Effect of processing

The same production processes applied to traditional oilseed rape grain will be used for MS8/RF3 oilseed rape grain. MS8/RF3 oilseed rape will be grown using the agronomic practices of the region of production and the grain will be harvested, transported, stored and processed using the same processes as used for any other oilseed rape currently in commerce.

7.7 Anticipated intake/extent of use

No change in the use patterns for oilseed rape is anticipated in the frame of this application. The human food products derived from MS8/RF3 oilseed rape are only expected to replace part of the

oilseed rape products in existing human food products.

With regard to derived products for human consumption, the principal product derived from oilseed rape grains for human consumption is vegetable oil. In the course of processing the oilseed rape grains to refined oil and food grade quality oil, all protein compounds of the oilseed rape grain are degraded. As a consequence, there is no anticipated human food intake for the PAT, Barstar/Barnase proteins via food grade oilseed rape oil derived from MS8/RF3 oilseed rape or human food products containing this oil. The raw agricultural commodity, *i.e.* whole oilseed rape grains, are not anticipated to be directly consumed as part of the human diet and any such use would be unintentional and any such exposure negligible.

In conclusion, no potential dietary and nutritional impacts have been identified for MS8/RF3 oilseed rape in the context of the current application.

7.8 Toxicology

7.8.1 Safety assessment of newly expressed proteins

The safety of MS8/RF3 oilseed rape, including the newly expressed proteins, has been assessed. The proteins encoded by the introduced genes are not toxic to mammals and present no risk to human health. The PAT protein is the only newly-expressed protein present in MS8/RF3 seed. Barnase and Barstar proteins are only expressed in the tapetum cells of the flower buds and therefore will not occur in food containining or derived from MS8/RF3 grain.

With regard to derived products for human consumption, the principal product derived from oilseed rape grains for human consumption is vegetable oil. In the course of processing the oilseed rape grains to refined oil and food grade quality oil, all protein compounds of the oilseed rape grain are degraded. As a consequence, there is no anticipated human food intake for the PAT, Barstar/Barnase proteins via food grade oilseed rape oil derived from MS8/RF3 oilseed rape or human food products containing this oil. The raw agricultural commodity, *i.e.* whole oilseed rape grains, are not anticipated to be directly consumed as part of the human diet and any use would be unintentional and any such exposure negligible.

7.8.2 Testing of new constituents other than proteins

Not applicable since no new constituents other than proteins are present in MS8/RF3 oilseed rape.

7.8.3 Information on natural food and feed constituents

Natural constituents of oilseed rape have not been changed in MS8/RF3 oilseed rape.

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 safety of MS8/RF3 oilseed rape, including the newly expressed proteins, has been assessed. The proteins encoded by the introduced genes are not allergenic to mammals and present no risk to human health. The PAT protein is the only newly-expressed protein present in MS8/RF3 seed. Barnase and Barstar proteins are only expressed in the tapetum cells of the flower buds and therefore will not occur in food containining or derived from MS8/RF3 grain.

With regard to derived products for human consumption, the principal product derived from oilseed rape grains for human consumption is vegetable oil. In the course of processing the oilseed rape grains to refined oil and food grade quality oil, all protein compounds of the oilseed rape grain are degraded. As a consequence, there is no anticipated human food intake for the PAT, Barstar/Barnase proteins via food grade oilseed rape oil derived from MS8/RF3 oilseed rape or human food products containing this oil. The raw agricultural commodity, *i.e.* whole oilseed rape grains, are not anticipated to be directly consumed as part of the human diet and any use would be unintentional and any such exposure negligible.

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, oilseed rape does not contain common food toxins or antinutritional components of concern for human health, because either the product only has minor amounts of these active compounds or their levels decrease (or they even disappear) during processing.

With regard to derived products for human consumption, the principal product derived from oilseed rape grains for human consumption is vegetable oil. In the course of processing the oilseed rape grains to refined oil and food grade quality oil, all protein compounds of the oilseed rape grain are degraded. As a consequence, there is no anticipated human food intake for the PAT, Barstar/Barnase proteins via food grade oilseed rape oil derived from MS8/RF3 oilseed rape or human food products containing this oil. The raw agricultural commodity, *i.e.* whole oilseed rape grains, are not anticipated to be directly consumed as part of the human diet and any use would be unintentional and any such exposure negligible.

In conclusion, there is no indication of increased allergenicity in the case of MS8/RF3 oilseed rape and all available data confirm that MS8/RF3 oilseed rape is as safe as and as nutritious as any other commercially available oilseed rape for human food use.

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

Not applicable since the scope of this application does not include GM feed.

7.11 Post-market monitoring of GM food/feed

No post-market monitoring plan is required for GM food containing or produced from MS8/RF3 oilseed rape.

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

Not applicable since there are no target organisms in the case of MS8/RF3 oilseed rape.

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

9.1 Persistence and invasiveness

Persistence and invasiveness for MS8/RF3 oilseed rape has been assessed in the environmental risk assessment in the frame of notification C/BE/96/01 under Directive 2001/18/EC that was granted consent by Commission Decision 2007/232/EC. The authorization for MS8, RF3 and MS8xRF3 oilseed rape in line with Commission Decision 2007/232/EC was based on a positive final opinion adopted by the EFSA GMO Panel in September 2005. Commission Decision 2007/232/EC authorizes the import and processing of MS8, RF3 and MS8xRF3 oilseed rape as any other oilseed rape, with the exception of cultivation and uses as or in food.

9.2 Selective advantage or disadvantage

Selective advantage or disadvantage for MS8/RF3 oilseed rape has been assessed in the environmental risk assessment in the frame of notification C/BE/96/01 under Directive 2001/18/EC that was granted consent by Commission Decision 2007/232/EC. The authorization for MS8, RF3 and MS8xRF3 oilseed rape in line with Commission Decision 2007/232/EC was based on a positive final opinion adopted by the EFSA GMO Panel in September 2005. Commission Decision 2007/232/EC authorizes the import and processing of MS8, RF3 and MS8xRF3 oilseed rape as any other oilseed rape, with the exception of cultivation and uses as or in food.

9.3 Potential for gene transfer

Potential for gene transfer for MS8/RF3 oilseed rape has been assessed in the environmental risk assessment in the frame of notification C/BE/96/01 under Directive 2001/18/EC that was granted consent by Commission Decision 2007/232/EC. The authorization for MS8, RF3 and MS8xRF3 oilseed rape in line with Commission Decision 2007/232/EC was based on a positive final opinion adopted by the EFSA GMO Panel in September 2005. Commission Decision 2007/232/EC authorizes the import and processing of MS8, RF3 and MS8xRF3 oilseed rape as any other oilseed rape, with the exception of cultivation and uses as or in food.

9.4 Interactions between the GM plant and target organisms

Not applicable since there are no target organisms in the case of MS8/RF3 oilseed rape.

9.5 Interactions of the GM plant with non-target organisms

Interaction of the GM plant with non-target organisms for MS8/RF3 oilseed rape has been assessed in the environmental risk assessment in the frame of notification C/BE/96/01 under Directive 2001/18/EC that was granted consent by Commission Decision 2007/232/EC. The authorization for MS8, RF3 and MS8xRF3 oilseed rape in line with Commission Decision 2007/232/EC was based on a positive final opinion adopted by the EFSA GMO Panel in September 2005. Commission Decision 2007/232/EC authorizes the import and processing of MS8, RF3 and MS8xRF3 oilseed rape as any other oilseed rape, with the exception of cultivation and uses as or in food.

9.6 Effects on human health

Persistence and invasiveness for MS8/RF3 oilseed rape has been assessed in the environmental risk assessment in the frame of notification C/BE/96/01 under Directive 2001/18/EC that was granted consent by Commission Decision 2007/232/EC. The authorization for MS8, RF3 and MS8xRF3 oilseed rape in line with Commission Decision 2007/232/EC was based on a positive final opinion adopted by the EFSA GMO Panel in September 2005. Commission Decision 2007/232/EC authorizes the import and processing of MS8, RF3 and MS8xRF3 oilseed rape as any other oilseed rape, with the exception of cultivation and uses as or in food.

9.7 Effects on animal health

Effects on animal health for MS8/RF3 oilseed rape has been assessed in the environmental risk assessment in the frame of notification C/BE/96/01 under Directive 2001/18/EC that was granted consent by Commission Decision 2007/232/EC. The authorization for MS8, RF3 and MS8xRF3 oilseed rape in line with Commission Decision 2007/232/EC was based on a positive final opinion adopted by the EFSA GMO Panel in September 2005. Commission Decision 2007/232/EC authorizes the import and processing of MS8, RF3 and MS8xRF3 oilseed rape as any other oilseed rape, with the exception of cultivation and uses as or in food.

9.8 Effects on biogeochemical processes

Effects on biogeochemical processes for MS8/RF3 oilseed rape has been assessed in the environmental risk assessment in the frame of notification C/BE/96/01 under Directive 2001/18/EC that was granted consent by Commission Decision 2007/232/EC. The authorization for MS8, RF3 and MS8xRF3 oilseed rape in line with Commission Decision 2007/232/EC was based on a positive final opinion adopted by the EFSA GMO Panel in September 2005. Commission Decision 2007/232/EC authorizes the import and processing of MS8, RF3 and MS8xRF3 oilseed rape as any other oilseed rape, with the exception of cultivation and uses as or in food.

9.9 Impacts of the specific cultivation, management and harvesting techniques

Not applicable since the scope of this application does not include cultivation of MS8/RF3 oilseed rape seed products in the EU.

10. Potential interactions with the abiotic environment

Potential interactions with the abiotic environment for MS8/RF3 oilseed rape has been assessed in the environmental risk assessment in the frame of notification C/BE/96/01 under Directive 2001/18/EC that was granted consent by Commission Decision 2007/232/EC. The authorization for MS8, RF3 and MS8xRF3 oilseed rape in line with Commission Decision 2007/232/EC was based on a positive final opinion adopted by the EFSA GMO Panel in September 2005. Commission Decision 2007/232/EC authorizes the import and processing of MS8, RF3 and MS8xRF3 oilseed rape as any other oilseed rape, with the exception of cultivation and uses as or in food.

11. Environmental monitoring plan

11.1 General (risk assessment, background information)

An environmental monitoring plan for MS8/RF3 is part of the authorisation conditions for MS8/RF3 oilseed rape according to Commission Decision 2007/232/EC.

11.2 Interplay between environmental risk assessment and monitoring

See Point 11.1

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

See Point 11.1

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

See Point 11.1

11.5 Reporting the results of monitoring

See Point 11.1

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

Validated detection methods are available for MS8/RF3 oilseed rape (http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm).

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. Reference is made to notification C/BE/96/01 for placing on the market of MS8, RF3 and MS8xRF3 oilseed rape which has been authorized in the EU by Commission Decision 2007/232/EC. The authorization for MS8, RF3 and MS8xRF3 oilseed rape in line with Commission Decision 2007/232/EC was based on a positive final opinion adopted by the EFSA GMO Panel in September 2005. Commission Decision 2007/232/EC authorizes the import and processing of MS8, RF3 and MS8xRF3 oilseed rape as any other oilseed rape, with the exception of cultivation and uses as or in food.

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

a) Release country :

Not applicable. Reference is made to notification C/BE/96/01 for placing on the market of MS8, RF3 and MS8xRF3 oilseed rape which has been authorized in the EU by Commission Decision 2007/232/EC. The authorization for MS8, RF3 and MS8xRF3 oilseed rape in line with Commission Decision 2007/232/EC was based on a positive final opinion adopted by the EFSA GMO Panel in September 2005. Commission Decision 2007/232/EC authorizes the import and processing of MS8, RF3 and MS8xRF3 oilseed rape as any other oilseed rape, with the exception of cultivation and uses as or in food.

b) Authority overseeing the release

Not applicable. Reference is made to notification C/BE/96/01 for placing on the market of MS8, RF3 and MS8xRF3 oilseed rape which has been authorized in the EU by Commission Decision 2007/232/EC. The authorization for MS8, RF3 and MS8xRF3 oilseed rape in line with Commission Decision 2007/232/EC was based on a positive final opinion adopted by the EFSA GMO Panel in September 2005. Commission Decision 2007/232/EC authorizes the import and processing of MS8, RF3 and MS8xRF3 oilseed rape as any other oilseed rape, with the exception of cultivation and uses as or in food.

c) Release site

Not applicable. Reference is made to notification C/BE/96/01 for placing on the market of MS8, RF3 and MS8xRF3 oilseed rape which has been authorized in the EU by Commission Decision 2007/232/EC. The authorization for MS8, RF3 and MS8xRF3 oilseed rape in line with Commission Decision 2007/232/EC was based on a positive final opinion adopted by the EFSA GMO Panel in September 2005. Commission Decision 2007/232/EC authorizes the import and processing of MS8, RF3 and MS8xRF3 oilseed rape as any other oilseed rape, with the exception of cultivation and uses as or in food.

d) Aim of the release

Not applicable. Reference is made to notification C/BE/96/01 for placing on the market of MS8, RF3 and MS8xRF3 oilseed rape which has been authorized in the EU by Commission Decision 2007/232/EC. The authorization for MS8, RF3 and MS8xRF3 oilseed rape in line with Commission Decision 2007/232/EC was based on a positive final opinion adopted by the EFSA GMO Panel in September 2005. Commission Decision 2007/232/EC authorizes the import and processing of MS8, RF3 and MS8xRF3 oilseed rape as any other oilseed rape, with the exception of cultivation and uses as or in food.

e) Duration of the release

Not applicable. Reference is made to notification C/BE/96/01 for placing on the market of MS8, RF3 and MS8xRF3 oilseed rape which has been authorized in the EU by Commission Decision 2007/232/EC. The authorization for MS8, RF3 and MS8xRF3 oilseed rape in line with Commission Decision 2007/232/EC was based on a positive final opinion adopted by the EFSA GMO Panel in September 2005. Commission Decision 2007/232/EC authorizes the import and processing of MS8, RF3 and MS8xRF3 oilseed rape as any other oilseed rape, with the exception of cultivation and uses as or in food.

f) Aim of post-releases monitoring

Not applicable. Reference is made to notification C/BE/96/01 for placing on the market of MS8, RF3 and MS8xRF3 oilseed rape which has been authorized in the EU by Commission Decision 2007/232/EC. The authorization for MS8, RF3 and MS8xRF3 oilseed rape in line with Commission Decision 2007/232/EC was based on a positive final opinion adopted by the EFSA GMO Panel in September 2005. Commission Decision 2007/232/EC authorizes the import and processing of MS8, RF3 and MS8xRF3 oilseed rape as any other oilseed rape, with the exception of cultivation and uses as or in food.

g) Duration of post-releases monitoring

Not applicable. Reference is made to notification C/BE/96/01 for placing on the market of MS8, RF3 and MS8xRF3 oilseed rape which has been authorized in the EU by Commission Decision 2007/232/EC. The authorization for MS8, RF3 and MS8xRF3 oilseed rape in line with Commission Decision 2007/232/EC was based on a positive final opinion adopted by the EFSA GMO Panel in September 2005. Commission Decision 2007/232/EC authorizes the import and processing of MS8,

RF3 and MS8xRF3 oilseed rape as any other oilseed rape, with the exception of cultivation and uses as or in food.

h) Conclusions of post-release monitoring

Not applicable. Reference is made to notification C/BE/96/01 for placing on the market of MS8, RF3 and MS8xRF3 oilseed rape which has been authorized in the EU by Commission Decision 2007/232/EC. The authorization for MS8, RF3 and MS8xRF3 oilseed rape in line with Commission Decision 2007/232/EC was based on a positive final opinion adopted by the EFSA GMO Panel in September 2005. Commission Decision 2007/232/EC authorizes the import and processing of MS8, RF3 and MS8xRF3 oilseed rape as any other oilseed rape, with the exception of cultivation and uses as or in food.

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

Not applicable. Reference is made to notification C/BE/96/01 for placing on the market of MS8, RF3 and MS8xRF3 oilseed rape which has been authorized in the EU by Commission Decision 2007/232/EC. The authorization for MS8, RF3 and MS8xRF3 oilseed rape in line with Commission Decision 2007/232/EC was based on a positive final opinion adopted by the EFSA GMO Panel in September 2005. Commission Decision 2007/232/EC authorizes the import and processing of MS8, RF3 and MS8xRF3 oilseed rape as any other oilseed rape, with the exception of cultivation and uses as or in food.

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 status and process of approval is available at:

http://www.efsa.europa.eu/EFSA/ScientificPanels/gmo/efsa_locale-1178620753812_GMOApplications.htm

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

1. Notification C/BE/96/01 for placing on the market of MS8, RF3 and MS8xRF3 oilseed rape has been authorized in the EU by Commission Decision 2007/232/EC and, in accordance with the provisions of Article 18(2) of Directive 2001/18/EC, the import approval decision of the Belgian Lead Member State on 25 May 2007. The authorization for MS8, RF3 and MS8xRF3 oilseed rape in line with Commission Decision 2007/232/EC was based on a positive final opinion adopted by the EFSA GMO Panel in September 2005. Commission Decision 2007/232/EC authorizes the import and processing of MS8, RF3 and MS8xRF3 oilseed rape as any other oilseed rape, with the exception of cultivation and uses as or in food.

2. Food (processed oil) and feed produced from MS8, RF3 and MS8xRF3 oilseed rape were notified to the European Commission as existing food and feed, respectively, falling within the scope of Articles 8(1)(a) and 20(1)(b) of Regulation (EC) N° 1829/2003 on 5 September 2004. On 17 April 2007, Bayer CropScience submitted a request for renewal in line with Articles 11 and 23 of Regulation (EC) N° 1829/2003 of the authorisation for existing food (processed oil) and feed from MS8, RF3 and MS8xRF3 oilseed rape that were lawfully placed on the market. Renewal application EFSA-GMO-RX-MS8-RF3 was considered valid by the EFSA on 28 March 2008 and a positive final opinion was adopted by the EFSA GMO Panel in September 2009. As a consequence and in line with Articles 11(4) and 23(4) of Regulation (EC) N° 1829/2003, food (processed oil) and feed produced from MS8, RF3 and MS8xRF3 oilseed rape are authorized in the EU.

3. The EFSA GMO Panel has reviewed the available scientific information relating to the safety of

MS8/RF3 oilseed rape at four different occasions and concluded that MS8, RF3 and MS8xRF3 oilseed rape is unlikely to have an adverse effect on human and animal health or, in the context of its proposed uses, on the environment (EFSA Opinion, 2005, EFSA Opinion, 2009a, EFSA Opinion, 2009b and EFSA Opinion 2010).

c) EFSA opinion

The EFSA GMO Panel has reviewed the available scientific information relating to the safety of MS8/RF3 oilseed rape at four different occasions and concluded that MS8, RF3 and MS8xRF3 oilseed rape is unlikely to have an adverse effect on human and animal health or, in the context of its proposed uses, on the environment (EFSA Opinion, 2005, EFSA Opinion, 2009a, EFSA Opinion, 2009b and EFSA Opinion 2010). However, an EFSA opinion on this specific application is not yet available.

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

Not yet available.

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

Information on detection protocols is posted at http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm

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

http://bch.biodiv.org/

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

Reference is made to notification C/BE/96/01 for placing on the market of MS8, RF3 and MS8xRF3 oilseed rape which has been authorized in the EU by Commission Decision 2007/232/EC. The authorization for MS8, RF3 and MS8xRF3 oilseed rape in line with Commission Decision 2007/232/EC was based on a positive final opinion adopted by the EFSA GMO Panel in September 2005. Commission Decision 2007/232/EC authorizes the import and processing of MS8, RF3 and MS8xRF3 oilseed rape as any other oilseed rape, with the exception of cultivation and uses as or in food.