PART II

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

MS8xRF3xGT73

for food and feed uses, and import and processing, in accordance with articles 5 and 17 of Regulation (EC) N° 1829/2003 GM Food and GM Feed

A. GENERAL INFORMATION

1. Details of application

a) Member State of application: The Netherlands
b) Application number: Not available at the date of application
c) Name of the product (commercial and other names): MS8xRF3xGT73 oilseed rape has been obtained by conventional crossing between three genetically modified oilseed rape events: MS8, RF3 and GT73. No new genetic modification was used for the development of MS8xRF3xGT73 oilseed rape. The unique identifier assigned to MS8xRF3xGT73 oilseed rape is ACS-BNØØ5-8xACS-BNØØ3-6xMON-ØØØ73-7.
d) Date of acknowledgement of valid application: Not available at the date of application

2. Applicant

a) Name of applicant: This is a joint application submitted by Bayer CropScience AG and Monsanto Company.
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 Monsanto Company represented by Monsanto Europe S.A. 800 N. Lindbergh Boulevard Avenue de Tervuren 270-272 St Louis, Missouri, 63167 B-1150 Brussels United States 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)): MS8xRF3xGT73 oilseed rape will be imported and processed in the EU by the same groups who currently import, 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

☐ GM plants for feed use

☒ Feed containing or consisting of GM plants

☒ Feed produced from GM plants

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

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

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

Yes ☐	No ☒
If *yes*, specify	

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

Yes ☐	No ☒
If *no*, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC An environmental risk assessment for MS8xRF3xGT73 oilseed rape has been carried out in accordance with Annex II to Directive 2001/18/EC and Commission Decision 2002/623/EC and is described in Point D.9 below.	

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

Yes ☐	No ☒
If *yes*, specify:	

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

Yes ☐	No ☒
If *yes*, specify:	

8. General description of the product

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

MS8xRF3xGT73 oilseed rape has been obtained by means of conventional crossing between three genetically modified oilseed rape events: MS8, RF3 and GT73 oilseed rape. No new genetic modification was used for the development of MS8xRF3xGT73 oilseed rape. MS8xRF3xGT73 oilseed rape combines a hybridization system in oilseed rape with tolerance to glufosinate ammonium and glyphosate herbicides.

As described above, the parental plants for MS8xRF3xGT73 oilseed rape are MS8, RF3 and GT73 oilseed rape. MS8, RF3 and GT73 were obtained by genetic modification of *Brassica napus*.

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

In the EU, the only oilseed rape product for human consumption is the oil. By-products of processing, such as hulls and meal, are included in animal diet. Rapeseed meal is used exclusively as a high protein feed supplement for livestock, poultry and fish.

MS8xRF3xGT73 oilseed rape grain will be imported in the EU from the major oilseed rape growing areas as commodity and will be used for downstream purposes as human food, animal feed and industrial products in the same way as commercially available oilseed rape.

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.

MS8xRF3xGT73 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 MS8xRF3xGT73 oilseed rape.

When MS8xRF3xGT73 oilseed rape is placed on the EU market, the labelling and traceability requirements according to Regulation (EC) N° 1829/2003 and Regulation (EC) N° 1830/2003will 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:

MS8xRF3xGT73 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):

ACS-BNØØ5-8xACS-BNØØ3-6xMON-ØØØ73-7

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

No restrictions are necessary.

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 MS8xRF3xGT73 oilseed rape, in transit or at the processing facility, has been assessed in the risk assessment and foreseen in the post market monitoring plan (see paragraph 11.4).

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

1. Complete name

a) Family name:	*Brassicaceae* (or *Cruciferae)*
b) Genus:	*Brassica*
c) Species:	*napus*
d) Subspecies:	*oleifera*
e) Cultivar/breeding line or strain:	MS8, RF3 and GT73 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 MS8xRF3xGT73 oilseed rape seeds in the EU and therefore no potential interactions with organisms in the ecosystem in the EU are expected. However and in regions where MS8xRF3xGT73 oilseed rape seed products will be cultivated (eg. North America), numerous insects, fungi, mycoplasmas and viruses are pathogenic to *Brassica napus* and attack the crop during the growing season.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification

MS8xRF3xGT73 oilseed rape has been obtained by conventional crossing between three genetically modified oilseed rape events: MS8, RF3 and GT73 oilseed rape. No new genetic modification was used for the development of MS8xRF3xGT73 oilseed rape.

MS8, RF3 and GT73 oilseed rape were produced by *Agrobacterium tumefaciens* mediated transformation.

2. Nature and source of the vector used

MS8xRF3xGT73 oilseed rape has been obtained by conventional crossing between three genetically modified oilseed rape events: MS8, RF3 and GT73 oilseed rape.

MS8 and RF3 oilseed rape were produced by *Agrobacterium tumefaciens* mediated transformation with the plasmids pTHW107 and pTHW118, respectively. The ~11.5kb PV-BNGT04 vector was used for the transformation of oilseed rape to produce GT73.

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, 2 and 3.

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

Table 3. Genetic elements of the T-DNA region of plasmid PV-BNGT04 (GT73 oilseed rape)

Genetic element	Description	Source	Size (bp[1])	Intended function
B-Right Border	T-DNA right border sequence	*A. tumefaciens*	356	Involved in T-DNA transfer
P-*FMV*	35S promoter	Figwort Mosaic Virus	563	Used to drive expression of the *gox 247* expression cassette
TS-*CTP1*	Chloroplast transit peptide sequence	*A. thaliana*	263	Facilitates import of the newly translated proteins into the chloroplast
CS-*gox247*	Coding sequence of a variant of the glyphosate oxidoreductase gene	*O. anthropi* sp. strain LBAA	1295	Expresses the GOX protein that catalyses the breakdown of glyphosate into aminomethylphosphonic acid (AMPA) and glyoxylate
T-E9	3' nontranslated region of the pea ribulose-1,5-bisphosphate carboxylase, small subunit E9 gene	*P. sativum*	642	Directs transcriptional termination and polyadenylation of the mRNA
P-*FMV*	35S promoter	Figwort Mosaic Virus	679	Used to drive expression of the *gox 247* expression cassette
TS-*CTP2*	Chloroplast transit peptide sequence	*A. thaliana*	227	Facilitates import of the newly translated proteins into the chloroplast
CS-*cp4 epsps*	Coding sequence for the synthetic 5-enolpyruvylshikimate-3-phosphate synthase (*cp4 epsps*)	*Agrobacterium* sp. strain CP4	1367	Expresses the CP4 EPSPS protein which displays reduced affinity for glyphosate relative to endogenous plant EPSPSs
T-E9	3' nontranslated region of the pea ribulose-1,5-bisphosphate carboxylase, small subunit E9 gene	*P. sativum*	642	Directs transcriptional termination and polyadenylation of the mRNA
B-Left Border	T-DNA left border sequence	*A. tumefaciens*	441	Involved in T-DNA transfer

[1] bp: base pair

D. INFORMATION RELATING TO THE GM PLANT

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

MS8xRF3xGT73 oilseed rape combines a hybridization system in oilseed rape with tolerance to glufosinate-ammonium and glyphosate herbicides, obtained by the conventional crossing of MS8, RF3 and GT73 oilseed rape.

The male sterile MS8 oilseed rape contains the *bar* and *barnase* genes. The fertility restorer RF3 oilseed rape contains the *bar* and *barstar* genes. GT73 oilseed rape contains the *goxv247* and *cp4 epsps* 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.

The *goxv247* and *cp4 epsps* genes and tolerance to glyphosate herbicides

The *gox* gene encodes the glyphosate oxidoreductase (GOX) protein. GOX imparts glyphosate tolerance by degrading glyphosate *in plant* . GOX and GOXv247, a variant of GOX, are more than 99% identical, differing by only 3 amino acids out of 431. The substitution of the histidine residue at position 334 with arginine determines a ten-fold lowering of the apparent K_m[1] ($appK_m$) for glyphosate in GOXv247 and thus enhances the efficiency of glyphosate degradation. GOX was isolated from *Ochrobactrum anthropi* (formerly *Achromobacter*) sp. strain LBAA, and catalyses the breakdown of glyphosate into aminomethylphosphonic acid (AMPA) and glyoxylate. The GOXv247 protein produced by GT73 effectively inactivates the herbicide and enables growth when GT73 plants are treated with glyphosate.

[1] The Michaelis-Menten constant, K_m, is equal to that concentration of substrate, which in this case is glyphosate, expressed in moles per litre that gives half the numerical initial maximal velocity of the reaction. The K_m is a measure of the affinity of a particular substrate for an enzyme. The lower the K_m, the higher the affinity for the enzyme.

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

2. Information on the sequences actually inserted or deleted

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

MS8xRF3xGT73 oilseed rape has been obtained by means of conventional crossing between three genetically modified oilseed rape events: MS8, RF3 and GT73 oilseed rape.

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.

Southern blot analysis of GT73 oilseed rape demonstrated the presence of one intact copy of the insert containing the *goxv247* and *cp4 epsps* expression cassettes at a single integration site. No additional elements from the transformation vector PV-BNGT04, linked or unlinked to the T-DNA, were detected in the genome of GT73.

To confirm the intactness and stability of the inserts present in MS8xRF3xGT73 oilseed rape compared to the inserts in the individual parental events MS8, RF3 and GT73 oilseed rape, a complete and detailed analysis was performed by means of Southern blot. Identical Southern hybridization patterns were observed for MS8xRF3xGT73 oilseed rape compared to MS8, RF3 and GT73 oilseed rape, thereby confirming the intactness and stability of the MS8, RF3 and GT73 inserted sequences and their flanking regions in MS8xRF3xGT73 oilseed rape

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

MS8xRF3xGT73 oilseed rape has been obtained by conventional crossing between MS8, RF3 and GT73 oilseed rape and therefore the MS8, RF3 and GT73 inserts are located in the nuclear genome of MS8xRF3xGT73 oilseed rape.

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

As discussed in Point D.2 a), Southern blot analysis confirmed the intactness and stability of the MS8, RF3 and GT73 inserted sequences, including their flanking regions, in MS8xRF3xGT73 oilseed rape. Therefore, the organization of the inserted genetic material in MS8xRF3xGT73 oilseed rape is the same as in the single parental events MS8, RF3 and GT73 oilseed rape, respectively.

3. Information on the expression of the insert

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

As described in detail in Section D.3 (b) below, the results of the protein expression analysis for MS8xRF3xGT73 oilseed rape show that with regard to PAT, CP4 EPSPS and GOX protein expression levels, there is no interaction between MS8, RF3 and GT73 oilseed rape when combined by conventional crossing.

b) Parts of the plant where the insert is expressed

The PAT, CP4 EPSPS and GOX protein expression levels have been determined in leaf and seed tissue of MS8xRF3xGT73 oilseed rape and the single parental events MS8, RF3 and GT73 oilseed rape. PAT protein expression was detected in leaf and seed tissue of MS8xRF3xGT73, MS8 and RF3 oilseed rape. CP4EPSPS and GOX protein expression was detected in leaf and seed tissue of MS8xRF3xGT73 and GT73 oilseed rape.

In addition, protein expression analysis has demonstrated that the PAT, CP4 EPSPS and GOX protein levels measured in seed and leaf tissue of MS8xRF3xGT73 oilseed rape are consistent with the expression levels of the PAT, CP4 EPSPS and GOX proteins in MS8, RF3 and GT73 oilseed rape, respectively, thereby confirming that the combination of MS8, RF3 and GT73 oilseed rape by conventional crossing did not have an impact on the PAT, CP4 EPSPS and GOX protein expression levels.

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

a) Reproduction

The agronomic performance of MS8xRF3xGT73 oilseed rape has been evaluated at a field trial in Canada during the 2008 growing season. No differences regarding reproduction characteristics have been observed during that field trial.

b) Dissemination

The agronomic performance of MS8xRF3xGT73 oilseed rape has been evaluated at a field trial in Canada during the 2008 growing season. No differences regarding dissemination characteristics have been observed during that field trial.

c) Survivability

The agronomic performance of MS8xRF3xGT73 oilseed rape has been evaluated at a field trial in Canada during the 2008 growing season. No differences regarding survivability characteristics have been observed during that field trial.

d) Other differences

The agronomic performance of MS8xRF3xGT73 oilseed rape has been evaluated at a field trial in Canada during the 2008 growing season. In conclusion, the agronomic performance of MS8xRF3xGT73 oilseed rape is comparable to the agronomic performance of commercially available oilseed rape, with the exception of tolerance to glufosinate-ammonium and glyphosate herbicides.

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

As described in Section D.2. a), Southern blot analysis confirmed the intactness and stability of the MS8, RF3 and GT73 inserted sequences, including their flanking regions, in MS8xRF3xGT73 oilseed rape. As described in Section D.3.a), protein expression analysis demonstrated that PAT, CP4 EPSPS and GOX protein levels in seed and leaf tissue of MS8xRF3xGT73 oilseed rape are as expected based on the PAT, CP4 EPSPS and GOX protein expression in MS8, RF3 and GT73 oilseed rape. The combination of MS8, RF3 and GT73 oilseed rape by means of conventional crossing did not have an impact on the PAT, CP4 EPSPS and GOX protein expression levels. As described in Section D.7.4, detailed phenotypic analysis performed throughout a field trial in Canada during the 2008 growing season demonstrated that the agronomic performance of MS8xRF3xGT73 oilseed rape is comparable to the agronomic performance of commercially available oilseed rape.

In conclusion, this demonstrates that the MS8, RF3 and GT73 oilseed rape inserts have been stably inherited in MS8xRF3xGT73 oilseed rape and that MS8xRF3xGT73 oilseed rape is genetically and phenotypically stable.

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 and GT73 oilseed rape confirms that the possibility of transfer of genetic material to bacteria is highly unlikely. Since no new genetic modification was introduced in MS8xRF3xGT73 oilseed rape, the possibility of transfer of genetic material from MS8xRF3xGT73 oilseed rape to bacteria is equally unlikely as for MS8, RF3 and GT73 oilseed rape.

b) Plant to plant gene transfer

The scope of this application is for authorization of MS8xRF3xGT73 oilseed rape for food and feed uses, and import and processing and does not include authorization for cultivation of MS8xRF3xGT73 oilseed rape seeds in the EU. As a consequence, exposure to the environment will be limited to unintended release of MS8xRF3xGT73 oilseed rape, which could occur for example via substantial losses during loading/unloading of the viable commodity including MS8xRF3xGT73 oilseed rape destined for processing into animal feed or human food products.

In any case and as discussed in detail in Section D.7.4. of this application, the basic parameters relating to reproductive fitness of MS8xRF3xGT73 oilseed rape were analyzed at a field trial in Canada during the 2008 growing season. For all parameters evaluated, MS8xRF3xGT73 oilseed rape was found to be unchanged compared to commercially available oilseed rape, thereby confirming that the potential for gene transfer from MS8xRF3xGT73 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 MS8xRF3xGT73 oilseed rape grain collected from a field trial carried out at five locations in Canada during the 2008 growing season. The comparative assessment was conducted to determine if MS8xRF3xGT73 oilseed rape grain is compositionally and nutritionally equivalent to grain from commercially available MS8xRF3 oilseed rape with the same genetic background. In addition, a set of four commercially available oilseed rape hybrids (one commercially available MS8xRF3 oilseed rape hybrid and three commercially available GT73 oilseed rape hybrids) were included in the field trial to develop reference ranges for comparison. Also ranges available from the literature, and including data from non-GM oilseed rape varieties, have been used in the comparison with MS8xRF3xGT73 oilseed rape.

The results of this compositional analysis of MS8xRF3xGT73 oilseed rape grain from a field trial in Canada during the 2008 growing season demonstrates that grain from MS8xRF3xGT73 oilseed rape is compositionally and nutritionally equivalent to grain from commercially available oilseed rape grain, and spraying with glufosinate-ammonium and glyphosate, does not have an effect on the nutrient composition of MS8xRF3xGT73 oilseed rape grain.

7.2 Production of material for comparative assessment

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

A comparative assessment for compositional and nutritional equivalence was performed on MS8xRF3xGT73 oilseed rape grain collected from a field trial carried out at five locations in Canada during the 2008 growing season. The five locations were situated in the typical oilseed rape growing regions of Canada. The field trial design was a Randomized Block Design with four repetitions. The plants were cultivated under typical agronomic practices for growing oilseed rape in Canada, including the use of herbicides, insecticides and fungicides as necessary.

b) The baseline used for consideration of natural variations

A comparative assessment between MS8xRF3xGT73 oilseed rape and commercially available MS8xRF3 oilseed rape with the same genetic background has been carried out. In addition, composition data derived from a set of commercially available MS8xRF3 and GT73 oilseed rape hybrids, grown in the same field trial as MS8xRF3xGT73 oilseed rape, as well as publicly available literature references, including data from non-GM oilseed rape varieties, have been used as the baseline in the comparison with MS8xRF3xGT73 oilseed rape.

7.3 Selection of material and compounds for analysis

The compounds which were selected for compositional and nutritional analyses of MS8xRF3xGT73 oilseed rape grain comprise the important basic nutrients of oilseed rape as defined by the OECD. These are proximate and fibre compounds, micro-nutrients such as minerals and tocopherols, the anti-nutrients glucosinolates, phytic acid and erucic acid, fatty acids and amino acids.

7.4 Agronomic traits

The agronomic performance evaluation of MS8xRF3xGT73 oilseed rape was carried out during a field trial at five locations in Canada during the 2008 growing season. The five locations were situated in the typical oilseed rape growing regions of Canada. The agronomic evaluations included: assessment of agronomic performance, insect and disease infestation susceptibility and tolerance to abiotic heat stress. Overall this study demonstrates that the agronomic characteristics of MS8xRF3xGT73 oilseed rape are comparable to commercially available oilseed rape.

7.5 Product specification

MS8xRF3xGT73 oilseed rape has been obtained by means of conventional crossing between three genetically modified oilseed rape events: MS8, RF3 and GT73 oilseed rape. No new genetic modification was used for the development of MS8xRF3xGT73 oilseed rape.

As discussed in detail in this application, MS8xRF3xGT73 oilseed rape is as safe as and as nutritious as commercially available oilseed rape and therefore, the specification of food and animal feed from MS8xRF3xGT73 oilseed rape is equivalent to that of food and animal feed from commercially available oilseed rape.

7.6 Effect of processing

The same production processes applied to traditional oilseed rape grain will be used for MS8xRF3xGT73 oilseed rape grain. MS8xRF3xGT73 oilseed rape will be grown using the agronomic practices of the region of production and the grain will 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

As discussed in Section D.7.1., compositional analysis of MS8xRF3xGT73 oilseed rape grain demonstrates that grain from MS8xRF3xGT73 oilseed rape is compositionally and nutritionally equivalent to grain from commercially available oilseed rape grain. In addition, no change in the use patterns for oilseed rape is anticipated. The human food and animal feed products derived from MS8xRF3xGT73 oilseed rape are only expected to replace part of the oilseed rape products in existing human food and animal feed products.

In conclusion, no potential dietary and nutritional impacts have been identified for oilseed rape products derived from MS8xRF3xGT73 oilseed rape.

7.8 Toxicology

7.8.1 Safety assessment of newly expressed proteins

MS8xRF3xGT73 oilseed rape has been obtained by means of conventional crossing between three genetically modified oilseed rape events: MS8, RF3 and GT73 oilseed rape. No new genetic modification was used for the development of MS8xRF3xGT73 oilseed rape and therefore, there are no newly expressed proteins in MS8xRF3xGT73 oilseed rape other than the ones already assessed as safe in the case of MS8, RF3 and GT73 oilseed rape.

7.8.2 Testing of new constituents other than proteins

Not applicable since no new constituents other than proteins are present in MS8xRF3xGT73 oilseed rape.

7.8.3 Information on natural food and feed constituents

As described in detail in Section D.7.1., natural constituents of oilseed rape have not been changed in MS8xRF3xGT73 oilseed rape.

7.8.4 Testing of the whole GM food/feed

MS8xRF3xGT73 oilseed rape has been obtained by means of conventional crossing between three genetically modified oilseed rape events: MS8, RF3 and GT73 oilseed rape. No new genetic modification was used for the development of MS8xRF3xGT73 oilseed rape.

The single parental events MS8, RF3 and GT73 oilseed rape have been previously assessed as safe and this was confirmed by the EFSA GMO Panel.

In addition and as described in Section D.3., the PAT, CP4 EPSPS and GOX protein expression levels in seed and leaf tissues of MS8xRF3xGT73 oilseed rape are as expected based on the PAT, CP4 EPSPS and GOX protein expression in MS8, RF3 and GT73 oilseed rape, thereby confirming that the combination of the MS8, RF3 and GT73 oilseed rape in MS8xRF3xGT73 oilseed rape did not have an impact on the PAT, CP4 EPSPS and GOX protein expression levels.

Furthermore and as described in Section D.7.1, compositional analysis has confirmed that grain from MS8xRF3xGT73 oilseed rape is compositionally and nutritionally equivalent to grain from commercially available oilseed rape grain.

In conclusion, MS8xRF3xGT73 oilseed rape is as safe as and as nutritious as any other commercially available oilseed rape for human food and animal feed use and no further testing of the whole GM food/feed is considered necessary.

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

MS8xRF3xGT73 oilseed rape has been obtained by means of conventional crossing between three genetically modified oilseed rape events: MS8, RF3 and GT73 oilseed rape. No new genetic modification was used for the development of MS8xRF3xGT73 oilseed rape and therefore, there are no newly expressed proteins in MS8xRF3xGT73 oilseed rape other than the ones already assessed as safe in the case of MS8, RF3 and GT73 oilseed rape.

7.9.2 Assessment of allergenicity of the whole GM plant or crop

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

MS8xRF3xGT73 oilseed rape has been obtained by conventional crossing between three genetically modified oilseed rape events: MS8, RF3 and GT73 oilseed rape. No new genetic modification was used for the development of MS8xRF3xGT73 oilseed rape.

The potential allergenicity of the single parental events MS8, RF3 and GT73 oilseed rape has been previously assessed. With regard to MS8, RF3 and GT73 oilseed rape, it was concluded that MS8, RF3 and GT73 oilseed rape are as safe as conventional oilseed rape for humans and animals and that there is no indication of increased allergenicity in the case of MS8, RF3 and GT73 oilseed rape.

As discussed in Section D.2 a), Southern blot analysis confirmed the intactness and stability of the MS8, RF3 and GT73 inserted sequences, including their flanking regions, in MS8xRF3xGT73 oilseed rape. Furthermore, up-to-date bioinformatic analyses of the MS8, RF3 and GT73 oilseed rape inserts did not indicate the creation of putative ORF amino acid sequences with biologically significant sequence similarities with known toxins and known allergens.

In addition and as described in Section D.7.1 of this application, comparative analysis has confirmed that MS8xRF3xGT73 oilseed rape is substantially equivalent to commercially available oilseed rape. Also, no change in the use patterns for oilseed rape is anticipated. The human food and animal feed products derived from MS8xRF3xGT73 oilseed rape are only expected to replace part of the oilseed rape products in the existing human food and animal feed diet, with the total consumption of oilseed rape products remaining unchanged.

In conclusion, there is no indication of increased allergenicity in the case of MS8xRF3xGT73 oilseed rape and all available data confirm that MS8xRF3xGT73 oilseed rape is as safe as and as nutritious as any other commercially available oilseed rape for human food and animal feed use.

7.10 Nutritional assessment of GM food/feed

7.10.1 Nutritional assessment of GM food

As discussed in Section D.7.1., a comparative compositional analysis was carried out for proximate and fibre compounds, micro-nutrients such as minerals and tocopherols, the anti-nutrients glucosinolates, phytic acid and erucic acid, fatty acids and amino acids between MS8xRF3xGT73 oilseed rape grain and grain from commercially available oilseed rape. This comparative compositional analysis confirmed that grain from MS8xRF3xGT73 oilseed rape is compositionally and nutritionally equivalent to grain from commercially available oilseed rape grain.

The main product derived from oilseed rape grains for human consumption is vegetable oil. The raw agricultural commodity, *i.e.* whole oilseed rape grains, are not directly consumed as part of the human diet (GEMS/Food regional diets, FAO/WHO, 2003). 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 by high temperature and pressure applied to the grain during screw pressing, or separated by extraction with a non-polar solvent and destroyed by the temperature of the solvent recovery. Minute traces of protein in the crude oil are further removed during the alkali treatment and deodorization steps of the oil refining. As a consequence, there is no anticipated human food intake for the PAT, CP4 EPSPS and GOX proteins via food grade oilseed rape oil derived from MS8xRF3xGT73 oilseed rape or human food products containing this oil.

In conclusion, vegetable oil derived from MS8xRF3xGT73 oilseed rape grain will be nutritionally equivalent to vegetable oil derived from commercially available oilseed rape grain and there is no nutritional impact expected from the human food use of MS8xRF3xGT73 oilseed rape and derived food products.

7.10.2 Nutritional assessment of GM feed

As discussed in Section D.7.1., a comparative compositional analysis was carried out for proximate and fibre compounds, micro-nutrients such as minerals and tocopherols, the anti-nutrients glucosinolates, phytic acid and erucic acid, fatty acids and amino acids between MS8xRF3xGT73 oilseed rape grain and grain from commercially available oilseed rape. This comparative compositional analysis confirmed that grain from MS8xRF3xGT73 oilseed rape is compositionally and nutritionally equivalent to grain from commercially available oilseed rape grain.

Meal and hulls, which are by-products of oilseed rape processing, can be used in animal feed. Oilseed rape contains some antinutritional factors, some of which are concentrated in the meal fraction. Glucosinolates are toxins that in modern oilseed rape varieties are below international standards. As discussed in Section D.7.3, total glucosinolates content for MS8xRF3xGT73 oilseed rape grain is below the safety threshold of 30µmol/g. After oil extraction with hexane the remaining meal is desolvented by heating. This process further reduces the content of glucosinolates. Rapeseed meal is typically subjected to a moist heat treatment to facilitate oil removal. This treatment denatures proteins and detoxifies antinutrional factors.

In conclusion, oilseed rape meal and hulls derived from MS8xRF3xGT73 oilseed rape grain will be nutritionally equivalent to oilseed rape meal and hulls derived from commercially available oilseed rape grain and there is no nutritional impact expected from the animal feed use of MS8xRF3xGT73 oilseed rape and derived products.

7.11 Post-market monitoring of GM food/feed

No post-market monitoring plan is required for GM food/feed produced from MS8xRF3xGT73 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 MS8xRF3xGT73 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

A review of the reproductive and vegetative fitness finds that MS8xRF3xGT73 oilseed rape compares to commercially available oilseed rape in all aspects except for the tolerance to herbicide products containing glufosinate-ammonium and glyphosate.

In addition, the scope of this application is for authorization of MS8xRF3xGT73 oilseed rape for food and feed uses, and import and processing and does not include authorization for cultivation of MS8xRF3xGT73 oilseed rape seeds in the EU

In conclusion, there is negligible likelihood for MS8xRF3xGT73 oilseed rape to become environmentally persistent or invasive giving rise to any weediness within the context of this application.

9.2 Selective advantage or disadvantage

A review of the reproductive and vegetative fitness finds that MS8xRF3xGT73 oilseed rape compares to commercially available oilseed rape in all aspects except for the tolerance to herbicide products containing glufosinate-ammonium and glyphosate.

In addition, the scope of this application is for authorization of MS8xRF3xGT73 oilseed rape for food and feed uses, and import and processing and does not include authorization for cultivation of MS8xRF3xGT73 oilseed rape seeds in the EU

In conclusion, there is negligible likelihood for increased survival of MS8xRF3xGT73 oilseed rape within the context of this application.

9.3 Potential for gene transfer

The scope of this application is for authorization of MS8xRF3xGT73 oilseed rape for food and feed uses, and import and processing and does not include authorization for cultivation of MS8xRF3xGT73 oilseed rape seeds in the EU. As a consequence, exposure to the environment will be limited to unintended release of MS8xRF3xGT73 oilseed rape, which could occur for example via substantial losses during loading/unloading of the viable commodity including MS8xRF3xGT73 oilseed rape destined for processing into animal feed or human food products.

In any case and as discussed in detail in Section D.7.4. of this application, the basic parameters relating to reproductive fitness of MS8xRF3xGT73 oilseed rape were analyzed at a field trial in Canada during the 2008 growing season. For all parameters evaluated, MS8xRF3xGT73 oilseed rape was found to be unchanged compared to commercially available oilseed rape, thereby confirming that the potential for gene transfer from MS8xRF3xGT73 oilseed rape to other oilseed rape and/or wild relatives is the same as with any commercially available oilseed rape.

Detailed analysis of the inserted sequences in MS8, RF3 and GT73 oilseed rape confirms that the possibility of transfer of genetic material to bacteria is highly unlikely. Since no new genetic modification was introduced in MS8xRF3xGT73 oilseed rape, the possibility of transfer of genetic material from MS8xRF3xGT73 oilseed rape to bacteria is equally unlikely as for MS8, RF3 and GT73 oilseed rape.

9.4 Interactions between the GM plant and target organisms

Not applicable since there are no target organisms in the case of MS8xRF3xGT73 oilseed rape.

9.5 Interactions of the GM plant with non-target organisms

MS8xRF3xGT73 oilseed rape combines a hybridization system in oilseed rape with tolerance to glufosinate-ammonium and glyphosate herbicides. As a consequence, there are no non-target organisms in the case of MS8xRF3xGT73 oilseed rape.

9.6 Effects on human health

MS8xRF3xGT73 oilseed rape has been obtained by conventional crossing between three genetically modified oilseed rape events: MS8, RF3 and GT73 oilseed rape. No new genetic modification was used for the development of MS8xRF3xGT73 oilseed rape.

All three GM parents have already been notified, risk assessed and authorized in the EU, thereby confirming that MS8, RF3 and GT73 oilseed rape are as safe as and as nutritious as commercial oilseed rape. In the current application, it has been demonstrated that there are no interactions between MS8, RF3 and GT73 oilseed rape when combined by conventional crossing in MS8xRF3xGT73 oilseed rape. In conclusion, this confirms that MS8xRF3xGT73 oilseed rape is as safe as and as nutritious as any commercial oilseed rape.

9.7 Effects on animal health

MS8xRF3xGT73 oilseed rape has been obtained by conventional crossing between three genetically modified oilseed rape events: MS8, RF3 and GT73 oilseed rape. No new genetic modification was used for the development of MS8xRF3xGT73 oilseed rape.

All three GM parents have already been notified, risk assessed and authorized in the EU, thereby confirming that MS8, RF3 and GT73 oilseed rape are as safe as and as nutritious as commercial oilseed rape. In the current application, it has been demonstrated that there are no interactions between MS8, RF3 and GT73 oilseed rape when combined by conventional crossing in MS8xRF3xGT73 oilseed rape. In conclusion, this confirms that MS8xRF3xGT73 oilseed rape is as safe as and as nutritious as any commercial oilseed rape.

9.8 Effects on biogeochemical processes

As discussed in detail in Section D.7.4., the agronomic performance of MS8xRF3xGT73 oilseed rape has been demonstrated to be unchanged compared to commercially available oilseed rape. Furthermore, the scope of this application is for authorization of MS8xRF3xGT73 oilseed rape for food and feed uses, and import and processing and does not include authorization for cultivation of MS8xRF3xGT73 oilseed rape seeds in the EU.

In conclusion, negligible effects are expected on the biogeochemical processes occurring in the soil within the context of the current application.

9.9 Impacts of the specific cultivation, management and harvesting techniques

Not applicable since the scope of this application is for authorization of MS8xRF3xGT73 oilseed rape for food and feed uses, and import and processing and does not include authorization for cultivation of MS8xRF3xGT73 oilseed rape seeds in the EU.

10. Potential interactions with the abiotic environment

No interaction with the abiotic environment is foreseen that would differ from any other commercially available oilseed rape.

Furthermore, the scope of this application is for authorization of MS8xRF3xGT73 oilseed rape for food and feed uses, and import and processing and does not include authorization for cultivation of MS8xRF3xGT73 oilseed rape seeds in the EU.

In conclusion, negligible effects are expected with regard to potential interactions with the abiotic environment within the context of the current application.

11. Environmental monitoring plan

11.1 General (risk assessment, background information)

As required by Article 5(5)(b) and 17(5)(b) of Regulation (EC) No. 1829/2003 the proposed monitoring plan for MS8xRF3xGT73 oilseed rape has been developed according to the principles and objectives outlined in Annex VII of Directive 2001/18/EC and Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC. The structure of the monitoring plan also takes into account the guidance on presentation of applications provided in the Guidance Document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed (The EFSA Journal (2006) 99, pp. 1-100).

11.2 Interplay between environmental risk assessment and monitoring

The scope of this application is the authorisation of MS8xRF3xGT73 oilseed rape for import, processing, food and feed use in the European Union (EU) under Regulation (EC) No. 1829/2003. The scope of the application does not include authorisation for the cultivation of MS8xRF3xGT73 oilseed rape seed products in the EU.

An environmental risk assessment (e.r.a.) was carried out for MS8xRF3xGT73 oilseed rape according to the principles laid down in Annex II to Directive 2001/18/EC and Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC. The scientific evaluation of the characteristics of MS8xRF3xGT73 oilseed rape in the e.r.a. has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses of MS8xRF3xGT73 oilseed rape relative to:

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

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

As discussed in Section D.11.2., the scientific evaluation of the characteristics of MS8xRF3xGT73 oilseed rape in the e.r.a. has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses of MS8xRF3xGT73 oilseed rape. It is therefore considered that there is no need for case-specific monitoring.

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

In accordance with Council Decision 2002/811/EC, general surveillance is not based on a particular hypothesis and it should be used to identify the occurrence of unanticipated adverse effects of the viable GMO or its use for human and animal health or the environment that were not predicted in the e.r.a.

Exposure to the environment will be limited to unintended release of MS8xRF3xGT73 oilseed rape, which could occur for example via substantial losses during loading/unloading of the viable commodity including MS8xRF3xGT73 oilseed rape destined for processing into animal feed or human food products. However, such exposure is highly unlikely to give rise to an adverse effect and can be easily controlled by clean up measures and the application of current practices used for the control of any adventitious oilseed rape plants, such as manual or mechanical removal and the application of herbicides (with the exception of glufosinate-ammonium and glyphosate herbicides). Furthermore, unintended environmental effects due to the unintended release of MS8xRF3xGT73 oilseed rape will be no different than that of other commercial oilseed rape.

However and in order to safeguard against any adverse effects on human and animal health or the environment that were not anticipated in the e.r.a., general surveillance on MS8xRF3xGT73 oilseed rape will be undertaken for the duration of the authorisation. The general surveillance will take into consideration, and be proportionate to, the extent of imports of MS8xRF3xGT73 oilseed rape and use thereof in the Member States.

In order to increase the possibility of detecting any unanticipated adverse effects, a monitoring system will be used, which involves the authorisation holders and operators handling and using viable MS8xRF3xGT73 oilseed rape. The operators will be provided with guidance to facilitate reporting of any unanticipated adverse effect from handling and use of viable MS8xRF3xGT73 oilseed rape.

11.5 Reporting the results of monitoring

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

If information that confirms an adverse effect of MS8xRF3xGT73 oilseed rape and that alters the existing risk assessment becomes available, the authorisation holders will immediately investigate and inform the European Commission. The authorisation holders, in collaboration with the European Commission and based on a scientific evaluation of the potential consequences of the observed adverse effect, will define and implement management measures to protect human and animal health or the environment, as necessary. It is important that the remedial action is proportionate to the significance of the observed effect.

The authorisation holders will submit an annual monitoring report including results of the general surveillance in accordance with the conditions of the authorisation. The report will contain information on any unanticipated adverse effects that have arisen from handling and use of viable MS8xRF3xGT73 oilseed rape.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of MS8xRF3xGT73 oilseed rape and, as appropriate, the measures that were taken to ensure the safety of human and animal health or the environment.

The report will also clearly state which parts of the provided information are considered to be confidential, together with a verifiable justification for confidentiality in accordance with Article 30.

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

The detection method for MS8xRF3xGT73 oilseed rape is based on the validated detection methods that are available for MS8, RF3 and GT73 oilseed rape (http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm).

The detection method for MS8xRF3xGT73 oilseed rape has been sent to the Community Reference Laboratory (CRL) of the Joint Research Centre of the European Commission (EC-JRC) for the purpose of experimental testing and validation. Appropriate control samples have also been made available to the JRC-CRL.

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

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

No field trials have been carried out with MS8xRF3xGT73 oilseed rape in the EU.

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

a) Release country :

MS8xRF3xGT73 oilseed rape has been released outside the Community in Canada and Australia. MS8xRF3xGT73 oilseed rape is approved for unconfined release in Canada.

b) Authority overseeing the release

Australia: Office of Gene Technology Regulator (OGTR)

c) Release site

Australia

States: Victoria and South Australia

Local government areas:

Vic: Horsham Rural City, Heywood, North Grampians, Glenelg

SA: Naracoorte/Lucindale

d) Aim of the release

Australia: Seed production and evaluation of agronomic traits including herbicide tolerance, germination efficiency and flowering dates.

e) Duration of the release

Australia: April 2007 to May 2010

f) Aim of post-releases monitoring Australia: Post harvest inspections of release sites are conducted on a regular basis for the identification of any volunteer plants, and destruction of these plants prior to flowering.
g) Duration of post-releases monitoring Australia: Post harvest monitoring continues for a period of at least 24 months, with a minmum volunteer-free period of 12 months.
h) Conclusions of post-release monitoring No adverse effects as a result of these releases.
i) Results of the release in respect to any risk to human health and the environment No adverse effects as a result of these releases.

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) No notification for MS8xRF3xGT73 oilseed rape has been submitted according to Directive 2001/18/EC.
c) EFSA opinion Not available at the time of submission of this application.
d) Commission Register (Commission Decision 2004/204/EC) Not yet available.
e) Molecular Register of the Community Reference Laboratory/Joint Research Centre Information on detection protocols will be 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) No notification for MS8xRF3xGT73 oilseed rape has been submitted according to Directive 2001/18/EC.