Part VII - Summary

Request for Authorization of genetically modified male sterile and herbicide tolerant

MS11 *Brassica napus*

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

EFSA-GMO-BE-2016-XXX

Version CC1

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PART VII – SUMMARY

EFSA-GMO-BE-2016-XXX (MS11 *BRASSICA NAPUS*)

1. GENERAL INFORMATION

1.1. Details of application

(a) Member State of application

Belgium

(b) Application number

EFSA-GMO-BE-2016-XXX

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

MS11 *Brassica napus*

(d) Date of acknowledgement of valid application

Not applicable at the time of submission

1.2. Applicant

(a) Name of applicant

Bayer CropScience LP

(b) Address of applicant

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Represented by:
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Belgium

(c) Name and address of the representative of the applicant established in the Union (if the applicant is not established in the Union)

Bayer CropScience SA-NV is the contact for this submission and all correspondence should be directed to:

Crop Science Division
Bayer CropScience SA-NV
Regulatory Affairs
Square de Meeûs 40
1000 Brussel,
Belgium

1.3. Scope of the application

(a) Genetically modified food

☑ Food containing or consisting of genetically modified plants
☑ Food produced from genetically modified plants or containing ingredients produced from genetically modified plants

(b) Genetically modified feed

☑ Feed containing or consisting of genetically modified plants
☑ Feed produced from genetically modified plants

(c) Genetically modified plants for food or feed uses

☑ Products other than food and feed containing or consisting of genetically modified plants with the exception of cultivation
☐ Seeds and plant propagating material for cultivation in the Union

1.4. Is the product or the uses of the associated plant protection product(s) already authorised or subject to another authorisation within the Union?

No ☑

Yes ☐ (in that case, specify)

Has the genetically modified plant been notified under Part B of Directive 2001/18/EC?

Yes ☐

No ☑ (in that case, provide risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC)

This application requests authorization for food and feed uses, and import and processing and does not include cultivation in the EU. Risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC is provided in the application.

1.5. Has the genetically modified plant or derived products been previously notified for marketing in the Community under Part C of Directive 2001/18/EC?

No ☑

Yes ☐ (in that case, specify)

1.6. Has the product been subject to an application and/or authorised in a third country either previously or simultaneously to this application?

No ☐

Yes ☑ in that case, specify the third country, the date of application and, where available, a copy of the risk assessment conclusions, the date of the authorisation and the scope of the application

The request for authorization of MS11 *B. napus* for import has been submitted in Korea (MFDS 8/9/2016) and Taiwan (TFDA 3/10/2016). The request for authorization of MS11

B. napus for cultivation has been submitted in USA (USDA 16/8/2016 and FDA 26/8/2016).

1.7. General description of the product

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

MS11 *Brassica napus* (*B. napus*) (male sterile line) was produced by means of *Agrobacterium* mediated transformation using the vector pTCO113. MS11 *B. napus* 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. Expression of Barnase in the tapetum cells of MS11 *B. napus* results in lack of viable pollen and male sterility. MS11 *B. napus* contains the *barstar* gene (origin *Bacillus amyloliquefaciens*) coding for the Barstar protein, which is an inhibitor of the Barnase protein. This prophylactic *barstar* gene, driven by the Pnos promoter, is included to enhance transformation frequency. MS11 *B. napus* also contains the *bar* gene (origin *Streptomyces hygroscopicus*) coding for phosphinothricin acetyltransferase (PAT/*bar*) conferring tolerance to glufosinate-ammonium. The *bar* gene is driven by the PssuAt plant promoter that is active in all green tissues of the plant.

(b) Types of products planned to be placed on the market according to the authorisation applied for and any specific form in which the product must not be placed on the market (such as seeds, cut-flowers, vegetative parts) as a proposed condition of the authorisation applied for.

The scope of the current application is for authorisation of MS11 *B. napus* for import, processing and all uses as any other oilseed rape in the EU, according to Art 3(1) and 15(1) of Regulation (EC) No 1829/2003, with the exception of cultivation. The range of uses of this oilseed rape will be identical to the full range of equivalent uses of conventional oilseed rape.

(c) Intended use of the product and types of users.

MS11 *B. napus* will be traded and used in the EU in the same manner as current conventional commercial oilseed rape and by the same operators currently involved in the trade and use of oilseed rape.

(d) Any specific instructions and recommendations for use, storage and handling, including mandatory restrictions proposed as a condition of the authorisation applied for.

With the exception of the male sterile and herbicide tolerance traits, which only have agronomic relevance, the characteristics of MS11 *B. napus* oilseed rape and products derived from it are comparable to those of its conventional counterpart and the commercial reference varieties with a history of safe use. Therefore, MS11 *B. napus* and its derived products will be stored, packaged, transported, handled and used in the same manner as current commercial oilseed rape products. No specific instructions and/or recommendations are warranted or required for the placing on the market of MS11 *B. napus* for import, processing and all uses, excluding cultivation, in the EU.

(e) If applicable, geographical areas within the EU to which the product is intended to be confined under the terms of the authorisation applied for.

MS11 *B. napus* is suitable for use throughout the EU as any other oilseed rape. The scope of this application covers the import, processing and all uses of MS11 *B. napus*, excluding cultivation.

(f) Any type of environment to which the product is unsuited.

MS11 *B. napus* is suitable for use throughout the EU as any other oilseed rape. The scope of this application covers the import, processing and all uses of MS11 *B. napus*, excluding cultivation.

(g) Any proposed packaging requirements.

With the exception of the male sterile and herbicide tolerance traits, which only have agronomic relevance, the characteristics of MS11 *B. napus* are not different from those of its conventional counterpart. Therefore, MS11 *B. napus* and derived products will be used in the same manner as other oilseed rape and no specific packaging is required.

(h) Any proposed labelling requirements in addition to those required by other applicable EU legislation then (EC) No 1829/2003 and when necessary a proposal for specific labelling in accordance with Article 13(2) and (3), Article 25(2)(c) and (d) and Article 25(3) of Regulation (EC) No 1829/2003. In the case of products other than food and feed containing or consisting of genetically modified plants, a proposal for labelling which complies with the requirements of point A(8) of Annex IV to Directive 2001/18/EC must be included.

In accordance with Regulations (EC) No 1829/2003 and 1830/2003, a labelling threshold of 0.9% is applied for the placing on the market of MS11 *B. napus* and derived products.

Operators shall be required to label products containing or consisting of MS11 *B. napus* with the words “genetically modified oilseed rape” or “contains genetically modified oilseed rape” and shall be required to declare the unique identifier in the list of GMOs that have been used to constitute the mixture that contains or consists of this GMO.

Operators shall be required to label foods and feeds derived from MS11 *B. napus* with the words “produced from genetically modified oilseed rape”. In the case of products for which no list of ingredients exists, operators shall ensure that an indication that the food or feed product is produced from GMOs is transmitted in writing to the operator receiving the product.

Operators handling or using MS11 *B. napus* and derived foods and feeds in the EU shall be required to be aware of the legal obligations regarding traceability and labelling of these products. Given that explicit requirements for the traceability and labelling of GMOs and derived foods and feeds are laid down in Regulations (EC) No 1829/2003 and 1830/2003 and that authorised foods and feeds shall be entered in the EU Register for genetically modified food and feed, operators in the food/feed chain will be fully aware of the traceability and labelling requirements for MS11 *B. napus*. Therefore, no further specific measures are to be taken by the applicant.

(i) Estimated potential demand

(i) In the EU

There are no anticipated changes to the demand as a result of the introduction of MS11 *B. napus* into the oilseed rape as the changes have only an agronomic benefit. It is anticipated that the introduction of MS11 *B. napus* oilseed rape will replace some of the oilseed rape in existing food and feed products.

(ii) In EU export markets

There are no anticipated changes to the extent of oilseed rape production in export markets as a result of the introduction of MS11 *B. napus* oilseed rape. It is anticipated that the introduction of MS11 *B. napus* oilseed rape will replace some of the oilseed rape products.

(j) Unique identifier in accordance with Regulation (EC) No 65/2004

The OECD unique identifier for MS11 *B. napus* is BCS-BNØ12-7.

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

Because this application is for consent to import, process and all uses of MS11 *B. napus* as any other oilseed rape, not including the cultivation of varieties of MS11 *B. napus* in the EU, the only potential means of environmental release would be more likely to occur during import, storage and processing of MS11 *B. napus*. However, modern methods of oilseed rape handling minimize losses of seed, so there is little chance of germination of spilled oilseed rape resulting in the development of mature MS11 *B. napus* plants in the EU. Moreover, in the event of incidental spillage, the establishment of volunteer plants would be unlikely, since MS11 *B. napus*, like any other oilseed rape, is unlikely to effectively compete with perennial vegetation outside agricultural fields. The likelihood for spilled seed to survive and establish is negligible. Oilseed rape plants outside agricultural fields can produce seed but this is often prevented because most plants do not survive to reach maturity. This is due to competition from other vegetation, management operations such as roadside mowing, the use of broadleaf herbicides, animal predation, diseases and environmental conditions.

MS11 *B. napus* is not different in composition, nutritional and agronomic characteristics relative to conventional oilseed rape, except for the introduced male sterility and tolerance to glufosinate, and therefore, it is unlikely to pose any threat to the EU environment or to require special measures for its containment. Furthermore, oilseed rape volunteers can be easily controlled using currently available selective herbicides (other than glufosinate) or by mechanical means. Therefore, no special measures are considered to be required in case of misuse or unintended release.

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

2.1. Complete name

(a) Family name
Cruciferae

(b) Genus
Brassica

(c) Species
napus

(d) Subspecies
oleifera

(e) Cultivar/breeding line
various

(f) Common name
oilseed rape (known as canola in Canada)

2.2. Geographical distribution and cultivation of the plant, including the distribution within the Union

Brassica napus is thought to have originated in the Mediterranean. It was cultivated by ancient civilizations in Asia and the Mediterranean and its oil was used for lighting. It was reportedly grown in Europe for lamp oil and lubrication in the 13th century and in Asia for cooking oil for thousands of years. Oilseed rape became widespread as a source of food and animal feed only after 1960 when Canadian scientists created the first double-low (low-erucic acid and low glucosinolate) variety.

In Europe the main producers of *B. napus* are France, Germany, Ukraine, Poland and United Kingdom. Besides Europe, it is currently grown in Canada, China, India, Pakistan, Australia and the USA.

2.3. Information concerning reproduction (for environmental safety aspects)

(a) Mode(s) of reproduction

Under natural conditions, oilseed rape reproduction is through seeds. Oilseed rape flowers are bisexual and contain six stamens, a pistil of two carpels and a superior ovary. Oilseed rape has the capability of both self- and cross- pollination via both insect and wind. However, the majority of fertilization occurs by self-pollination as the large amounts of pollen produced from each flower out competes the pollen from adjacent flowers. Oilseed rape produces a large amount of pollen which can remain viable for four to five days under field conditions.

(b) Specific factors affecting reproduction

The optimum temperature for vegetative growth of oilseed rape is about 20°C. Reproduction of spring oilseed rape is favoured by dry weather conditions, which favours the activity of insect pollinators, and shorter growing seasons. Winter varieties take advantage of longer growing seasons. Water availability is also of importance, particularly during the period of seed ripening.

(c) 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.

2.4. Sexual compatibility with other cultivated or wild plant species (for environmental safety aspects)

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. Given the male sterility of MS11 *B. napus*, the frequency of gene flow from oilseed rape to wild relatives under natural conditions is considered very low. Finally, the fitness of the interspecific hybrids is generally reduced compared to the parents and the stable introgression of a new trait in the weed species genome is confirmed to be extremely difficult.

2.5. Survivability (for environmental safety aspects)

(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 (*e.g.* -0.2 MPa water pressure) and exposure to light. Consequently, the greatest proportion of oilseed rape plants that germinates after harvest ('volunteers') emerges in response to tillage. As most of the oilseed rape seeds that fall on the ground after harvesting will still germinate before the winter season, these seedlings will be destroyed by winter conditions. Seeds that get buried deeper can be lost from the seed bank by predation and decay.

2.6. Dissemination (for environmental safety aspects)

(a) Ways and extent of dissemination

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

(b) Specific factors affecting dissemination

There is no specific factor affecting seed dissemination (oilseed rape seeds have no special adaptations to encourage transport). The seeds are small and birds and small mammals usually eat them on the spot rather than carrying them away

2.7. Geographical distribution within the Union of the sexually compatible species (for environmental safety aspects)

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.

2.8. In the case of plant species not normally grown in the Union, description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts (for environmental safety aspects)

Not relevant as oilseed rape is normally cultivated as a crop in the EU.

2.9. Other potential interactions, relevant to the genetically modified 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 (for environmental safety aspects)

The scope of this application does not include cultivation of MS11 *B. napus* seeds in the EU and therefore no potential interactions with organisms in the ecosystem in the EU are expected. However (and in regions where MS11 *B. napus* seed products will be cultivated) (e.g. North America), numerous insects, fungi, mycoplasmas and viruses are pathogenic to *Brassica napus* and attack the crop during the growing season.

3. MOLECULAR CHARACTERISATION

3.1. Information relating to the genetic modification

(a) Description of the methods used for the genetic modification

The event was developed through *Agrobacterium tumefaciens* mediated transformation of conventional oilseed rape hypocotyls.

(b) Nature and source of the vector used

MS11 *Brassica napus* (*B. napus*) (male sterile line) was produced by means of *Agrobacterium* mediated transformation using the vector pTCO113.

(c) Source of donor nucleic acid(s) used for the transformation, size and intended function of each constituent fragment of the region intended for insertion

The individual components, location, source and function of the inherited DNA sequence are reported in Table 1 below.

Table 1. Description of the genetic elements of pTCO113

Nt Positions	Orientation	Origin
1 - 25		**RB:** right border region of the T-DNA of *Agrobacterium tumefaciens* (Zambryski, 1988 M-234499-01-2)
26 - 97		Polylinker sequences: sequence used in cloning
98 - 309	Counter clockwise	**3'g7:** 3´ untranslated region of the TL-DNA gene 7 of the *Agrobacterium tumefaciens* octopine Ti plasmid (Dhaese et al., 1983 M-180190-01-1)
310 - 331		Polylinker sequences: sequence used in cloning

Nt Positions	Orientation	Origin
332 - 883	Counter clockwise	***bar:*** coding sequence of the phosphinothricin acetyltransferase gene of *Streptomyces hygroscopicus* (Thompson et al., 1987 M-122742-01-1).
884 - 2613	Counter clockwise	**PssuAt:** promoter region of the ribulose-1,5-biphosphate carboxylase small subunit gene of *Arabidopsis thaliana* (Krebbers et al., 1988 M-180191-01-1)
2614 - 2658		Polylinker sequences: sequence used in cloning
2659 - 2919	Counter clockwise	**3'nos:** 3' untranslated region of the nopaline synthase gene from the T-DNA of pTiT37 (Depicker et al., 1982 M-131630-01-2)
2920 - 2935		Polylinker sequences: sequence used in cloning
2936 - 3033	Counter clockwise	**3'barnase:** 3´ untranslated region of the barnase gene from *Bacillus amyloliquefaciens* (Hartley, 1988 M-180195-01-1)
3034 - 3369	Counter clockwise	***barnase:*** coding sequence of the barnase gene of *Bacillus amyloliquefaciens* (Hartley, 1988 M-180195-01-1)
3370 - 3371		Polylinker sequences: sequence used in cloning
3372 - 4879	Counter clockwise	**Pta29:** promoter of the anther-specific gene TA29 of *Nicotiana tabacum* (tobacco) (Seurinck et al., 1990 M-180196-01-1)
4880 - 4920		Polylinker sequences: sequence used in cloning
4921 - 5214	Clockwise	**Pnos:** promoter region of the nopaline synthase gene of *Agrobacterium tumefaciens* (Depicker et al., 1982 M-131630-01-2)
5215 - 5216		Polylinker sequences: sequence used in cloning
5217 - 5489	Clockwise	***barstar:*** coding sequence of the barstar gene of *Bacillus amyloliquefaciens* (Hartley, 1988 M-180195-01-1)
5490 - 5554		Polylinker sequences: sequence used in cloning
5555 - 5766	Clockwise	**3'g7:** 3´ untranslated region of the TL-DNA gene 7 of the *Agrobacterium tumefaciens* octopine Ti plasmid (Dhaese et al., 1983 M-180190-01-1)
5767 - 5840		Polylinker sequences: sequence used in cloning
5841 - 5865		**LB:** left border region of the T-DNA of *Agrobacterium tumefaciens* (Zambryski, 1988 M-234499-01-2)
5866 - 7745	Counter clockwise	***aadA*:** fragment including the aminoglycoside adenyltransferase gene of *Escherichia coli* (Fling et al., 1985 M-231609-01-1)
7746 - 8181	Counter clockwise	***barstar:*** fragment including the barstar gene of *Bacillus amyloliquefaciens* (Hartley, 1988 M-180195-01-1)

Nt Positions	Orientation	Origin
8182 - 8405	Counter clockwise	***aadA*:** fragment including the residual upstream sequences of the aminoglycoside adenyltransferase gene of *Escherichia coli* (Fling et al., 1985 M-231609-01-1)
8406 - 12177		**ORI pVS1:** fragment including the origin of replication of the plasmid pVS1 of *Pseudomonas aeruginosa* (Heeb et al., 2000 M-453202-01-1)
12178 - 13540		**ORI ColE1:** fragment including the origin of replication from the plasmid pBR322 for replication in *Escherichia coli* (Bolivar et al., 1977 M-147993-01-1).

3.2. Information relating to the genetically modified plant

MS11 *Brassica napus* (*B. napus*) (male sterile line) was produced by means of *Agrobacterium* mediated transformation using the vector pTCO113. MS11 *B. napus* 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. Expression of Barnase in the tapetum cells of MS11 *B. napus* results in lack of viable pollen and male sterility. MS11 *B. napus* contains the *barstar* gene (origin *Bacillus amyloliquefaciens*) coding for the Barstar protein, which is an inhibitor of the Barnase protein. This prophylactic *barstar* gene, driven by the Pnos promoter, is included to enhance transformation frequency. MS11 *B. napus* also contains the *bar* gene (origin *Streptomyces hygroscopicus*) coding for phosphinothricin acetyltransferase (PAT/*bar*) conferring tolerance to glufosinate-ammonium. The *bar* gene is driven by the PssuAt plant promoter that is active in all green tissues of the plant.

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

The *barnase* and *barstar* gene and male sterility

MS11 *Brassica napus* (*B. napus*) (male sterile line) was produced by means of *Agrobacterium* mediated transformation using the vector pTCO113. MS11 *B. napus* 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. Expression of Barnase in the tapetum cells of MS11 *B. napus* results in lack of viable pollen and male sterility. MS11 *B. napus* contains the *barstar* gene (origin *Bacillus amyloliquefaciens*) coding for the Barstar protein, which is an inhibitor of the Barnase protein. This prophylactic *barstar* gene, driven by the Pnos promoter, is included to enhance transformation frequency.

The *bar* gene and tolerance to glufosinate-ammonium

MS11 *B. napus* also contains the *bar* gene (origin *Streptomyces hygroscopicus*) coding for phosphinothricin acetyltransferase (PAT/*bar*) conferring tolerance to glufosinate-ammonium. The *bar* gene is driven by the PssuAt plant promoter that is active in all green tissues of the plant. The *bar* gene has been isolated from *Streptomyces hygroscopicus*, a microorganism that produces bialaphos. Bialaphos or its synthetically produced component glufosinate-ammonium is classified as herbicide with phosphinothricin as the active ingredient. Phosphinothricin acts by the inhibition of a

specific amino acid biosynthesis pathway in plants. It is a potent inhibitor of glutamine synthetase (GS), an enzyme that 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.

3.2.2. Information on the nucleic acid(s) sequences actually inserted or deleted

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

The transgenic locus of MS11 *B. napus* was characterized by means of Southern blot analysis and verified the presence of one complete T-DNA insert containing the *bar*, the *barnase* and the *barstar* gene cassettes in MS11 *B. napus*.

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

The corresponding MS11 insertion locus contains a target site deletion (TSD) of 40 bp.

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

The MS11 insert is integrated at the chromosome level as demonstrated by flanking sequence analysis and the Mendelian inheritance of a single gene locus.

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

The Southern blot and PCR results demonstrated the absence of vector backbone sequences in MS11 *B. napus*.

(e) In case of modifications other than insertion or deletion, describe function of the modified genetic material before and after the modification, as well as direct changes in expression of genes as a result of the modification

Not applicable

3.2.3. Information on the expression of the insert

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

The expression of the Barnase, Barstar and PAT/*bar* proteins were analysed in different tissues of MS11 *B. napus* collected at different developmental stages. As expected, the level of Barnase expression was <LLOQ in all MS11 matrices treated with the conventional and the intended herbicides. The expression levels of Barnase, Barstar and PAT/*bar* in all matrices were similar between MS11 *B. napus* treated with the conventional and the intended herbicides.

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

The *barnase* gene is driven by the Pta29 promoter that restricts gene expression to the tapetum cells during anther development. As such, the Barnase protein is not quantifiable in seed tissue. The prophylactic *barstar* gene is driven by the Pnos promoter. The *bar* gene is driven by the PssuAt plant promoter that is active in all green tissues of the plant.

3.2.4. Genetic stability of the insert and phenotypic stability of the genetically modified plant

The genetic stability of the MS11 *B. napus* transgenic locus was demonstrated by assessing individual MS11 *B. napus* plants from five generations by means of Southern blot analysis.

3.2.5. Information (for environmental safety aspects) on how the genetically modified plant differs from the recipient plant in

(a) Mode(s) and /or rate of reproduction

Phenotypic and agronomic data were collected from trials conducted with MS11 *B. napus* at ten sites in Canada and the USA during 2014 growing season. These ten field sites provided a range of environmental and agronomic conditions representative of commercial oilseed rape production. The experiments were arranged as a randomized complete block design with four replicates at each field site. In each of these assessments, MS11 *B. napus* was compared to an appropriate conventional oilseed rape control, N90-740, with the same genetic background as MS11 *B. napus*. In addition, conventional commercial reference varieties were included to provide a range of comparative values that are representative of existing commercial oilseed rape varieties for each measured phenotypic and agronomic characteristic.

Results of these field trials showed that there are no unexpected biologically relevant changes in the agronomic and phenotypic characteristics of MS11 *B. napus* compared to the conventional counterpart, taking into account natural variation. On the basis of these studies, it is possible to conclude that no differences in the mode or rate of reproduction, dissemination, survivability or other agronomic, phenotypic or ecological characteristics are expected in MS11 *B. napus* and that MS11 *B. napus* is not different in its phenotypic and agronomic behaviour relative to conventional oilseed rape, except for the introduced traits.

(b) Dissemination

No differences in the dissemination compared to the conventional counterpart have been observed in agronomic and phenotypic assessments conducted with MS11 *B. napus*.

(c) Survivability

No differences in the survivability compared to the conventional counterpart have been observed in agronomic assessments conducted with MS11 *B. napus*.

(d) Other differences

Except for the introduced traits that are of agronomic interest, the agronomic assessments in the field did not reveal any biologically relevant differences between MS11 *B. napus* and its conventional counterpart.

3.2.6. Any change to the ability of the genetically modified plant to transfer genetic material to other organisms (for environmental safety aspects)

(a) Plant to bacteria gene transfer

None of the genetic elements in MS11 *B. napus* have a genetic transfer function. Therefore, no changes are expected in the ability of MS11 *B. napus* to transfer genetic material to bacteria.

(b) Plant to plant gene transfer

Based on the observation that reproductive morphology in MS11 *B. napus* is unchanged compared to conventional oilseed rape, the out-crossing frequency to other oilseed rape varieties or to wild relatives would be unlikely to be different for MS11 *B. napus*, when compared to conventional oilseed rape varieties. Furthermore, the scope of the current application does not include the cultivation of MS11 *B. napus* varieties in the EU.

4. COMPARATIVE ANALYSIS

4.1. Choice of the conventional counterpart and additional comparators

The non-GM conventional counterpart, N90-740, was included for comparative purposes, because it was the original genetic background selected for transformation of the MS11 event and is appropriate to be grown in the *B. napus* growing regions in Canada and USA. The MS11 *B. napus* and its conventional counterpart have the same genetic background, *B. napus* N90-740.

Six non-GM commercial *B. napus* reference varieties were included to provide reference ranges for the comparative assessment of the agronomic and composition data. The selected *B. napus* varieties cover several germplasm pools.

4.2. Experimental design and statistical analysis of data from field trials for comparative analysis

The *B. napus* plants were grown in 2014 at sites representative of commercial *B. napus* production areas in Canada and the USA.

An analysis of variance (ANOVA) was conducted in a combined-site analysis in which the data was pooled across all sites. ANOVA models were used to perform difference and equivalence tests according to the 2010 EFSA Scientific opinion on statistical considerations for the safety evaluation of GMOs.

4.3. Selection of material and compounds for analysis

The key nutrients and other nutritionally important components that were selected for analysis of MS11 *B. napus* in the compositional study were chosen on the basis of internationally accepted guidance provided by the OECD consensus document on compositional considerations for new varieties of oilseed rape.

4.4. Comparative analysis of agronomic and phenotypic characteristics

An assessment of the phenotypic and agronomic characteristics of MS11 *B. napus* compared to conventional oilseed rape has been performed in the field. Results of this field study showed that there are no unexpected and biologically relevant changes in the agronomic or phenotypic characteristics of MS11 *B. napus* compared to the oilseed conventional counterpart, taking into account natural variation.

4.5. Effect of processing

Composition Analysis of the grain and processed fraction samples and the analysis of protein content in processed fractions demonstrated that the processing of MS11 *B. napus* has no expected differences from that of conventional oilseed rape.

5. TOXICOLOGY

(a) Toxicological testing of the newly expressed proteins

The available information for the assessment of the newly expressed proteins present in MS11 *B. napus* indicates that no adverse effects on human or animal health are expected. The outcome of heat stability studies and data concerning stability to proteolytic enzymes demonstrate that the Barnase, Barstar and PAT/*bar* proteins are quickly degraded under heat treatment, have extremely short structural and functional stabilities under simulated gastric and intestinal conditions. The results of studies with Barnase/Barstar complex suggest that the Barnase/Barstar protein complex is degrading and forms oligomers upon heating; therefore, the native form of the Barnase/Barstar protein complex is not stable upon heating. In addition, the Barnase/Barstar complex has extremely short structural and functional stability under simulated gastric and intestinal conditions. These results indicate a minimal likelihood that the protein could survive and be absorbed through the gastrointestinal system and consequently that the newly expressed Barnase, Barstar and PAT/*bar* is unlikely to be toxic.

(b) Testing of new constituents other than proteins

Not applicable as the genetic modification in MS11 *B. napus* does not give rise to the expression of any new constituents other than the Barnase, Barstar and PAT/*bar* proteins.

(c) Information on natural food and feed constituents

No new constituents other than the Barnase, Barstar and PAT/*bar* proteins are expressed in MS11 *B. napus*. The comparative assessment of MS11 *B. napus* showed no biologically relevant differences between MS11 *B. napus* and its conventional counterpart, taking into account natural variation. Therefore, there is no need for further assessment.

(d) Testing of the whole genetically modified food and feed

There are no indications of possible toxicity of MS11 *B. napus* and whole food and/or feed testing with MS11 *B. napus* is not deemed necessary. From the results of the 90-day feeding study in rats it was concluded that the MS11 *B. napus* meal incorporated up to 15% (w/w) in the diet had no adverse effects on the growth or health of Sprague Dawley rats.

6. ALLERGENICITY

(a) Assessment of allergenicity of the newly expressed protein

The bioinformatics analysis demonstrated that there are no biologically relevant sequence similarities to allergens when Barnase, Barstar and PAT/*bar* protein sequences were used as query sequences for a FASTA search against the allergen database.

Based on the weight of evidence approach it can be concluded that the newly expressed Barnase, Barstar and PAT/*bar* are unlikely to be allergenic.

(b) Assessment of allergenicity of the whole genetically modified plant

There is no evidence to suggest that the food derived from MS11 *B. napus* is likely to be more allergenic than the food derived from the conventional *B. napus* varieties.

7. NUTRITIONAL ASSESSMENT

(a) Nutritional assessment of the genetically modified food

The newly expressed proteins in MS11 *B. napus* have been assessed and confirmed safe for humans. In addition the newly expressed proteins were not detectable in oil (the main food product derived from oilseed rape is the oilseed rape oil) produced from MS11 *B. napus*. Therefore no nutritional impact is expected and the risk to European consumers from MS11 *B. napus* is considered negligible.

(b) Nutritional assessment of the genetically modified feed

Chronic dietary exposure estimates were low, due to the minor protein expression levels in MS11 *B. napus* seeds and whole plants. In addition, MS11 *B. napus* seed will not be commercialized. Therefore, the food and feed derived from MS11 *B. napus* is assumed to be nutritionally equivalent to food and feed derived from conventional *B. napus* varieties.

EXPOSURE ASSESSMENT – ANTICIPATED INTAKE/EXTENT OF USE

The chronic dietary exposure estimates for livestock were based on a worst-case scenario as it was assumed that 100% of rape seeds or whole plant material would have been harvested from the MS11 *B. napus* plants, that no degradation and/or loss of functionality of the proteins would have occurred during the processing of the oilseed rape to the animal feed (*e.g.* toasting of canola meal), and that maximum percentages of both oilseed rape commodities would be used to prepare animal feed. However, the chronic dietary exposure estimates were low, due to the minor protein expression levels in MS11 *B. napus* seeds and whole plants. As mentioned before, MS11 *B. napus* seed will not be commercialized.

8. RISK CHARACTERISATION

A comprehensive risk characterization of MS11 *B. napus* has been carried out by considering all available evidence from the analyses discussed through this application. The following conclusions from molecular characterization, phenotypic and agronomic analyses, compositional analyses, toxicology assessment, allergenicity assessment and exposure assessment have been considered:

- The *bar*, *barnase* and *barstar* genes were introduced into the *B. napus* genome in a single gene construct via direct-gene transfer. The regulatory sequences used in this construct are derived from common plants or plant microorganism that are routinely used in plant biotechnology and have a history of safe use.

In the molecular characterisation of the MS11 *B. napus* transgenic locus, bioinformatics analysis of the full DNA sequence revealed no evidence supporting cryptic gene expression or unintended effects resulting from the genetic modification.

The source organism for the Barnase and Barstar proteins, *Bacillus amyloliquefaciens,* is ubiquitous in nature and found throughout the world as common soil bacteria. None of the newly expressed proteins have amino acid sequence homology to known toxins or allergens.

The expression levels of Barnase, Barstar and PAT/*bar* in all matrices were similar between MS11 *B. napus* treated with trait-specific herbicide and untreated MS11 *B. napus*. The genetic stability of MS11 *B. napus* in five generations has been demonstrated by means of Southern blot analysis. The phenotype for the expressed MS11 *B. napus* trait has been shown to be stable over multiple generations. Segregation ratios determined for five generations of MS11 *B. napus* confirmed that the MS11 *B. napus* insert is inherited in a predictable manner and as expected for a single insertion. These data are consistent with Mendelian principles and support the conclusion that MS11 *B. napus* consists of a single insert integrated at a single chromosomal locus within the *B. napus* nuclear genome.

Altogether, the data presented for the molecular characterization show no evidence that the genetic modification of MS11 *B. napus* can trigger unintended changes or raises any safety concerns.

- The comparative assessment of the MS11 *B. napus* showed no differences that would require further assessment of the agronomic and phenotypic endpoints or the *B. napus* grain composition parameters with respect to their possible impact on food and feed safety and nutritional properties.

The field trials were conducted in representative commercial *B. napus* production areas in Canada and the USA and sufficiently represented the environment where the GM crop will be cultivated (environmental heterogeneity sufficiently captured). In addition, considering the comparative assessment study design (with comparators inside each field site), no impact of other growing conditions not tested in the field trials is expected in the outcome of the comparative assessment.

The comparative analysis showed that in all cases continuous agronomic and phenotypic characteristics of MS11 *B. napus* from plants not treated with the intended herbicide (Test CHM), which were identified as different from the characteristics of its conventional counterpart, were equivalent (or more likely equivalent than not) to those of the reference varieties. In most cases continuous agronomic and phenotypic characteristics of MS11 *B. napus* from plants treated with the intended herbicide (Test TIH), which were identified as different from the characteristics of its conventional counterpart, were equivalent (or more likely equivalent than not) to those of the reference varieties.

All mean values of MS11 *B. napus* and the conventional counterpart are within the ranges from the ILSI database and either within or only slightly higher or lower than the ranges reported by OECD. In addition, for composition parameters showing differences and/or lack of equivalence and significant genotype per site interaction, the by site analysis resulted in either significant differences at only few sites, no trend for the difference was observed, or the type and magnitude of the mean differences has no relevance from a

food and feed safety and nutrition point of view. Hence, the identified differences were not considered biologically and nutritionally relevant.

Based on the results outcome of the comparative analysis of the composition as well as agronomic and phenotypic characteristics conducted, there are no unexpected or unintended effects and no impact on either the agronomic performance of the plants or the nutritional value of the grain from plants as a result of the genetic modification of the *B. napus* plants. No biologically relevant differences and/or lack of equivalence were identified between MS11 *B. napus* and its conventional counterpart, except for the introduced traits, taking into account natural variation.

- The available information for the assessment of the newly expressed proteins present in MS11 *B. napus* indicates that no adverse effects on human or animal health are expected. The outcome of heat stability studies and data concerning stability to proteolytic enzymes demonstrate that the Barnase, Barstar and PAT/*bar* proteins are quickly degraded under heat treatment, have extremely short structural and functional stabilities under simulated gastric and intestinal conditions. The results of studies with Barnase/Barstar complex suggest that the Barnase/Barstar protein complex is degrading and forms oligomers upon heating; therefore, the native form of the Barnase/Barstar protein complex is not stable upon heating. In addition, the Barnase/Barstar complex has extremely short structural and functional stability under simulated gastric and intestinal conditions. These results indicate a minimal likelihood that the protein could survive and be absorbed through the gastrointestinal system and consequently that the newly expressed Barnase, Barstar and PAT/*bar* is unlikely to be toxic.

The results of the comparative assessment conducted on MS11 *B. napus* supports a conclusion that no biologically relevant differences, except for the introduced traits, were identified in the composition data obtained from MS11 *B. napus* or in its agronomics and phenotypic characteristics that would require further assessment with respect to their possible impact on food and feed safety and nutritional properties. Therefore there are no indications of any potential adverse effect that could arise from natural constituents' changes.

The results of the animal studies conducted with the whole food and feed derived from MS11 *B. napus* identified no toxicologically relevant effects.

Overall, the results of the toxicological assessment indicate that consumption of MS11 *B. napus* food and feed products will be as safe as consumption of equivalent products from conventional oilseed rape, regardless of the anticipated intake level.

- The bioinformatics analysis demonstrated that there are no biologically relevant sequence similarities to allergens when Barnase, Barstar and PAT/*bar* protein sequences were used as query sequences for a FASTA search against the allergen database.

Based on the weight of evidence approach it can be concluded that the newly expressed Barnase, Barstar and PAT/*bar* are unlikely to be allergenic.

There is no evidence to suggest that the food derived from MS11 *B. napus* is likely to be more allergenic than the food derived from the conventional *B. napus* varieties.

- The expression levels of the Barnase and Barstar proteins in MS11 *B. napus* seed were <LLOQ. The dietary exposure to the PAT/*bar* protein via consumption of food grade oilseed rape oil was considered to be negligible. The European consumers will not be exposed to the PAT/*bar* protein via the consumption of refined oilseed rape oil derived from MS11 *B. napus* seeds.

The chronic dietary exposure estimates for livestock were also based on a worst-case scenario as it was assumed that 100% of rape seeds or whole plant material would

have been harvested from the MS11 *B. napus* plants, that no degradation and/or loss of functionality of the proteins would have occurred during the processing of the oilseed rape to the animal feed (*e.g.* toasting of canola meal), and that maximum percentages of both oilseed rape commodities would be used to prepare animal feed. However, the chronic dietary exposure estimates were low, due to the minor protein expression levels in MS11 *B. napus* seeds and whole plants.

The evidences presented throughout this application and summarized above demonstrate that:

- The food and feed derived from MS11 *B. napus* has no adverse effects on human and animal health;
- The food derived from MS11 *B. napus* does not differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer compared to conventionally produced food;
- The food derived from MS11 *B. napus* does not mislead the consumer;
- The feed derived from MS11 *B. napus* not differ from the feed which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for animals or humans compared to conventionally produced feed;
- The feed derived from MS11 *B. napus* does not harm or mislead the consumer by impairing distinctive features of the animal products compared to conventionally produced feed.

The assumptions made during the risk assessment are very conservative and include the following:

- All *B. napus* grain consumed in the EU would be from MS11 *B. napus* plants
- No loss or degradation of protein would occur during processing and food preparation of *B. napus* seed products.

The labelling requirements specified in Articles 5(3)(f) and 17(3)(f) of Regulation (EC) No 1829/2003 are not applicable because the characteristics of the food and feed products from MS11 *B. napus* are not different from the characteristics of its conventional counterpart taking into account natural variation.

9. POST-MARKET MONITORING ON GENETICALLY MODIFIED FOOD/FEED

The risk characterization of MS11 *B. napus* has shown that the risk for potential adverse effects on human and animal health is negligible in the context of the intended uses of MS11 *B. napus*. It is therefore considered that there is no need for post marketing monitoring of food and feed derived from MS11 *B. napus*.

10. ENVIRONMENTAL ASSESSMENT

10.1. Mechanism of interaction between the genetically modified plant and target organisms

In this area of assessment, the main environmental concern, according to the EFSA ERA Guidance, is that target organisms develop resistance to the insect or pathogen tolerance traits expressed by the GM plant.

MS11 *B. napus* has been developed to confer male sterility and tolerance to glufosinate-ammonium, no target organisms are associated with this product, and therefore an assessment of the potential resistance development in target organisms resulting from the import, processing and food and feed use MS11 *B. napus* is not relevant.

10.2. Potential changes in the interactions of the genetically modified plant with the biotic environment resulting from the genetic modification

The scope of the application is for food and feed uses, import and processing and excludes cultivation. The environmental exposure is limited to accidental release of MS11 *B. napus* during transportation and processing for food and feed.

(a) Persistence and invasiveness

MS11 *B. napus* is not a stand-alone product and will not be commercialized as a single event. MS11 *B. napus* is only used for the production of the MS11 x RF3 *B. napus* hybrid seed. The scope of this application is for food and feed uses, import and processing. It does not include cultivation of MS11 *B. napus* in the EU. As a consequence, exposure to the environment will be limited to unintended release of MS11 *B. napus* as a result of segregation from the harvest of MS11 x RF3, which could occur for example via accidental losses (or spillage) during transportation, loading and/ or unloading of the imported viable commodity including MS11 *B. napus* destined for processing into animal feed or human food products. However, in the cases that the accidental spillage of viable plant material from MS11 *B. napus* would occur – MS11 would require a restorer-of-fertility line (RF3) for viable hybrid seed production. If by some chance these hybrids germinated successfully, they could be controlled using authorized herbicides for controlling oilseed rape (except glufosinate-ammonium). General volunteer management practices are already in place: http://www.europabio.org/sites/default/files/products/information/management_of_oilseed_rape_volunteers_-_july_2013_0.pdf. In conclusion, although MS11 *B. napus* can grow under the EU conditions, the scale of the environmental exposure through accidental spillage implies the exposure would be ultimately low.

Given the low levels of environmental exposure that will result from the import, processing and food and feed use of MS11 *B. napus* in the EU as well as male sterility of the event, it is highly unlikely that out-crossing with wild relatives would occur. Therefore, it can be concluded that the persistence and invasiveness potential of MS11 *B. napus* is no different from the conventional crop.

In summary, taking a conservative approach where a worst case scenario that considers that accidental spillage of viable plant material from MS11 *B. napus* during import, transportation, storage, handling or processing in the EU will occur, the likelihood that this could result in environmental harm is highly unlikely and the consequences would be marginal. The risk is therefore negligible.

Given the low levels of exposure that could arise from accidental spillage of MS11 *B. napus* imported into the EU, the lack of wild relatives that could take up the traits and the nature of the traits, which is unlikely to confer selective advantage, the uncertainty associated with this risk characterization can be considered very low. The probability of long-term environmental adverse effects is negligible.

(b) Selective advantage or disadvantage

It was previously demonstrated that the inherited genetic sequence in MS11 *B. napus* did not lead to any biologically meaningful alterations of the phenotypic characteristics, such as plant growth and development, morphology, agronomic performance, composition, nutritional value or safety characteristics, when compared to the conventional oilseed rape, except for the male sterility and the inherited herbicide tolerance trait. Therefore, it was concluded that MS11 *B. napus* is not meaningfully different from conventional oilseed rape, with the exception of the intentionally introduced agronomically beneficial traits.

Compared with conventional oilseed rape, the introduced male sterility and the herbicide tolerance trait in MS11 *B. napus* confer a selective advantage only under specific conditions (i.e. following treatment with trait-specific herbicide). The advantage is of purely agronomic interest and presents negligible risk to the non-agricultural environments. Given that MS11 *B. napus* is not a stand-alone product and will not be commercialized as a single event and the scope of this application, the likelihood is negligible for the inherited traits in MS11 *B. napus* to confer any meaningful competitive advantage or disadvantage of relevance to the environment.

(c) Potential for gene transfer

The scope of this application covers the import, processing and all uses of MS11 *B. napus* as any other oilseed rape in the EU, excluding cultivation. Therefore, no deliberate release of viable plant material in the EU environment is expected and interactions of MS11 *B. napus* with the biotic environment will be limited. Given the low likelihood of occurrence of horizontal gene transfer and lack of adverse consequences if it were to occur, the import, processing, and food and feed use of MS11 *B. napus* in the EU is not likely to pose any risk to human and animal health or the environmental.

Considering the low exposure and lack of hazard from horizontal gene transfer of the *barnase*, *barstar* and *bar* genes from MS11 *B. napus* to micro-organisms resulting from the import, processing and all uses of MS11 *B. napus*, the risk that this would result in adverse effects on human or animal health or the environment is negligible.

(d) Interactions between the genetically modified plant and target organisms

MS11 *B. napus* has been developed to confer male sterility and tolerance to glufosinate-ammonium, no target organisms are associated with this product, and therefore an assessment of the potential resistance development in target organisms resulting from the import, processing and food and feed use of MS11 *B. napus* is not relevant for this application.

(e) Interactions of the genetically modified plant with non-target organisms

Given male sterility of MS11 *B. napus*, it is highly unlikely that accidental spillage of viable plant material would result in feral populations in the EU. Therefore an assessment of potential direct effects of MS11 *B. napus* on NTO populations is not relevant for this application. However, the assessment considers potential indirect adverse effects on NTO populations due to exposure through faeces of animals fed with MS11 *B. napus*.

MS11 *B. napus* has been developed to confer male sterility and tolerance to glufosinate-ammonium; therefore, the traits are not intended for control of a particular target organism and there are not known adverse effects on any organisms. Therefore, even if protected organisms were exposed through manure and faeces, the likelihood that adverse effects could occur would be highly unlikely.

(f) Effects on human health

This application is for the import, processing and all uses as any other oilseed rape, but excludes the cultivation of MS11 *B. napus* in the EU. Therefore, no deliberate release of viable plant material in the EU environment is expected and interactions of MS11 *B. napus* with human health will be limited to the occupational hazards associated with the storage, handling and processing of MS11 *B. napus*. Given the low levels of environmental exposure combined with the negligible hazard occurring from the contact with MS11 *B. napus* seed, the likelihood for any adverse effects, occurring in humans as a result of their contact with this seed, is no different from conventional oilseed rape. MS11 *B. napus* seed contains the Barstar and PAT proteins, which have negligible potential to cause any toxic or allergenic effects in humans. Therefore, the risk of changes in the occupational health aspects of this oilseed rape is negligible.

(g) Effects on animal health

This application is for the import, processing and all uses as any other oilseed rape, but excludes the cultivation of MS11 *B. napus* in the EU. Therefore, no deliberate release of viable plant material in the EU environment is expected and interactions of MS11 *B. napus* with animal health will be limited to the occupational hazards associated with the storage, handling and processing of MS11 *B. napus*. Given the low levels of environmental exposure combined with the negligible hazard occurring from the contact with MS11 *B. napus* seed, the likelihood for any adverse effects, occurring in animals as a result of their contact with this seed, is no different from conventional oilseed rape. MS11 *B. napus* seed contains the Barstar and PAT proteins, which have negligible potential to cause any toxic or allergenic effects in animals. Therefore, the risk of changes in the occupational health aspects of this oilseed rape is negligible.

(h) Effects on biogeochemical processes

Cultivation of MS11 *B. napus* in the EU is not included in the scope of this application. An assessment of the impacts of MS11 *B. napus* on biogeochemical processes resulting from specific cultivation, management and harvesting techniques is not relevant given the scope of this application.

(i) Impacts of the specific cultivation, management and harvesting techniques

Cultivation of MS11 *B. napus* in the EU is not included in the scope of this application. An assessment of the impacts of specific cultivation, management and harvesting techniques of MS11 *B. napus* is therefore not relevant given the scope of this application.

10.3. Potential interactions with the abiotic environment

Overall results of the comparative analysis of MS11 *B. napus* with respect to its conventional counterpart indicate that observed differences in composition and agronomic and phenotypic characteristics fell within the range of natural variability for oilseed rape with a history of safe use. Therefore, there is no evidence that this oilseed rape would be any different from conventional oilseed rape with regard to its baseline interactions with the abiotic environment.

In addition, because this application is for import, processing and all uses as any other oilseed rape in the EU, but excluding cultivation, interactions of MS11 *B. napus* with the environment will be limited. Moreover, MS11 *B. napus* will never be commercialized as a stand-alone product and therefore no negative impact on the abiotic environment may be expected to result from the import, processing and all uses as any other oilseed rape in the EU.

10.4. Risk characterisation

Results from the environmental risk assessment which takes into consideration the risk characterization and includes results described above addressing risk hypotheses for the specific areas of assessment laid down in 2010 EFSA guidance, support a conclusion that the import, processing and all uses of MS11 *B. napus* (excluding cultivation) as any other oilseed rape, in the EU represents negligible risk to human and animal health and the environment and poses no greater risk than the import and processing of conventional oilseed rape.

11. ENVIRONMENTAL MONITORING PLAN

(a) General (risk assessment, background information)

As required by Article 5(5)(b) and 17(5)(b) of Regulation (EC) No 1829/2003 the proposed Post-Market Environmental Monitoring (PMEM) plan for MS11 *Brassica napus* (*B. napus*) 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 PMEM also takes into account the Scientific Opinion on guidance on the Post-Market Environmental Monitoring of genetically modified plants

(b) Interplay between environmental risk assessment and monitoring

An environmental risk assessment (e.r.a.) was carried out for MS11 *B. napus* 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 MS11 *B. napus* 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 MS11 *B. napus*.

(c) Case-specific genetically modified plant monitoring (approach, strategy, method and analysis)

The scientific evaluation of the characteristics of MS11 *B. napus* in the ERA 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 MS11 *B. napus*. It is therefore considered that there is no need for case-specific monitoring.

(d) General surveillance of the impact of the genetically modified 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 Genetically Modified Organism (GMO) or its use for human and animal health or the environment that were not predicted in the ERA.

The scope of this application is the authorisation of MS11 *B. napus* for food and feed uses, import and processing. The scope of the application does not include authorisation for the cultivation of MS11 *B. napus* seed products. Therefore, exposure to the environment will be limited to unintended release of MS11 *B. napus*, which could occur for example via substantial losses during loading/unloading of the viable commodity including MS11 *B. napus* (as a result of segregation from the harvest of MS11 x RF3) destined for processing into animal feed or human food products. Exposure can be 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 herbicide).

However and in order to safeguard against any adverse effects on human and animal health or the environment that were not anticipated in the ERA, general surveillance on MS11 *B. napus* 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 MS11 *B. napus* 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 holder and operators handling and using viable MS11 *B. napus*. The operators will be provided with guidance to facilitate reporting of any unanticipated adverse effect from handling and use of viable MS11 *B. napus*.

(e) Reporting the results of monitoring

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

If information that confirms an adverse effect of MS11 *B. napus* and that alters the existing risk assessment becomes available, the authorisation holder will immediately investigate and inform the European Commission. The authorisation holder, 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 confirmed effect.

The authorisation holder 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 unanticipated adverse effects, if any, that have arisen from handling and use of viable MS11 *B. napus*.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of MS11 *B. napus* 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 of Regulation (EC) No 1829/2003. Confidential parts of such report shall be submitted in separate documents.

12. DETECTION AND IDENTIFICATION TECHNIQUES FOR THE GENETICALLY MODIFIED PLANT

The detection method for MS11 *B. napus* was sent to the Community Reference Laboratory (CRL) of the Joint Research Centre of the European Commission (EC-JRC) for the purposes of experimental testing and validation in the frame of the food and feed application of MS11 *B. napus*. Appropriate control samples were also made available to the JRC-CRL.

13. INFORMATION RELATING TO PREVIOUS RELEASES OF THE GENETICALLY MODIFIED PLANT (FOR ENVIRONMENTAL SAFETY ASPECTS)

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

(a) Notification number

There is no history of field release of MS11 *B. napus* in the EU.

(b) Conclusions of post-release monitoring

Not applicable.

(c) Results of the release in respect to any risk to human health and the environment, submitted to the Competent Authority in accordance with Article 10 of Directive 2001/18/EC)

Not applicable.

13.2. History of previous releases of the genetically modified plant carried out outside the Union by the same notifier

(a) Release country

MS11 *B. napus* has been tested in Canada and the USA (and Chile in a contra season program).

(b) Authority overseeing the release

Canada: Canadian Food Inspection Agency; U.S.: U.S. Department of Agriculture; Chile: SAG

(c) Release site

Canada and U.S.: multiple major canola-growing provinces, states and regions respectively; northern Chile.

(d) Aim of the release

Regulatory trials, testing of efficacy, yield and product development, and contra season program in Chile

(e) Duration of the release

MS11 has been tested in Canada for 9 years.

(f) Aim of post-releases monitoring

Volunteer assessment.

(g) Duration of post-releases monitoring

The CFIA confined permits require 3 years of post-trial monitoring.

(h) Conclusions of post-release monitoring

Oilseed rape volunteers are sometimes observed since oilseed rape has secondary dormancy. If volunteers occur, the practice is to eliminate them manually or chemically to prevent occurrence in subsequent crops.

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

Field-testing provided no evidence that MS11 *B. napus* would be the cause of any adverse effects to human health or to the environment.