Application for authorization to place on the market MON 88302 oilseed rape in the European Union, according to Regulation (EC) No 1829/2003 on genetically modified food and feed

Part VII

Summary

Version Completeness Check #3 (March 2012)

1. GENERAL INFORMATION

1.1. Details of application

(a) Member State of application

Belgium

(b) Application number

EFSA-GMO-BE-2011-101

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

The Monsanto development code for this genetically modified oilseed rape is MON 88302. Currently, no commercial name has been attributed to this product.

(d) Date of acknowledgement of valid application

Not available

1.2. Applicant

(a) Name of applicant

Monsanto Company, represented by Monsanto Europe S.A.

(b) Address of applicant

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

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

See above

1.3. Scope of the application

(a) GM food

- ☑ Food containing or consisting of GM plants
- ☑ Food produced from GM plants or containing ingredients produced from GM plants

(b) GM feed

- ☑ Feed containing or consisting of GM plants
- ☑ Feed produced from GM plants

(c) GM plants for food or feed use

- ☑ Products other than food and feed containing of consisting of GM plants with the exception of cultivation
- ☐ Seeds and plant propagating material for cultivation in the EU

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

No ☑

Yes ☐ (in that case, specify)

1.5. Has the GM 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)

The protein expression, composition, safety and agronomic and phenotypic characteristics of MON 88302 have been studied at multiple locations in North America and Chile that cover a range of environmental conditions. The data collected from these field releases have been used in the risk assessment presented in the MON 88302 application. A summary of the conclusions of the risk analysis that demonstrate the safety of MON 88302 to humans, animals and to the environment, has been presented in the respective sections throughout this summary.

1.6. Has the GM plant or derived products been previously notified for marketing in the Union under Part C of Directive 2001/18/EC?

No ☑

Yes ☐ (in that case, specify)

1.7. Has the product been notified/authorised in a third country either previously or simultaneously?

No ☐

Yes ☑ (in that case, specify the third country and provide a copy of the risk assessment conclusions, the date of the authorisation and the scope)

Regulatory submissions have been made to the United States Department of Agriculture Animal and Plant Health Inspection Service (USDA-APHIS), the United States Food and Drug Administration (US FDA), the Canadian Food Inspection Agency and Health Canada. Additionally, submissions have been made in Japan, Korea, Singapore and the Philippines. Approvals from these agencies have not yet been obtained.

Regulatory submissions will also be made to countries that import significant quantities of oilseed rape or food and feed products derived from oilseed rape and have functional regulatory review processes in place. These will include submissions to countries such as China, New Zealand, Australia, Indonesia, Mexico and Colombia. Also, as appropriate, notifications will be made to countries that import significant quantities of oilseed rape and oilseed rape products and do not have a formal regulatory review process for biotechnology derived crops.

1.8. General description of the product

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

Monsanto Company has developed a second-generation glyphosate-tolerant oilseed rape product, MON 88302, designed to provide growers with improved weed control through tolerance to higher rates of glyphosate and greater flexibility for glyphosate herbicide application. MON 88302 produces the 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) protein, via the incorporation of a *cp4 epsps* coding sequence. The CP4 EPSPS protein confers

tolerance to the herbicide glyphosate, the active ingredient in the family of Roundup®[1] agricultural herbicides.

MON 88302 utilizes a *FMV/Tsf1* chimeric promoter sequence to drive CP4 EPSPS expression in different plant tissues. By virtue of CP4 EPSPS expression in pollen, MON 88302 provides tolerance to glyphosate during the sensitive reproductive stages of growth, and enables the application of glyphosate at higher rates up to first flower with no detectable impact to male fertility.

(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 (seeds, cut-flowers, vegetative parts, etc.) as a proposed condition of the authorisation applied for

This application is for authorization of MON 88302 for import, processing and all uses as any other oilseed rape in the EU, according to Articles 5 and 17 of Regulation (EC) No. 1829/2003 on genetically modified food and feed. The range of uses of this oilseed rape will be identical to the full range of equivalent uses of conventional oilseed rape. The scope of this application does not include the cultivation of MON 88302 varieties in the EU.

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

MON 88302 oilseed rape will be used and traded in the EU in the same manner as current commercial oilseed rape and by the same operators currently involved in the trade and use of oilseed rape.

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

No specific conditions or instructions are considered necessary for placing on the market MON 88302 for import, processing and all uses in the EU, as specified in Section 1.8(b) of this document. It has been demonstrated that, with the exception of the glyphosate-tolerance trait, MON 88302 is not different in composition, nutritional and agronomic characteristics relative to conventional counterpart and is equivalent to the conventional commercial reference varieties with a history of safe usage. Therefore, MON 88302 and its derived products will be stored, packaged, transported, used and handled in the same manner as current commercial oilseed rape. No specific conditions or instructions are warranted or required for the placing on the market of MON 88302 for import, processing and all uses specified in Section 1.8(b) of this document.

(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.

MON 88302 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 MON 88302, excluding cultivation.

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

MON 88302 is suitable for use throughout the EU as any other oilseed rape.

[1] [1] Roundup® and Roundup Ready® are registred trademarks of Monsanto Technology LLC.

(g) Any proposed packaging requirements

With the exception of the glyphosate-tolerance trait, MON 88302 is not different in composition, nutritional and agronomic characteristics relative to conventional counterpart and is equivalent to the conventional commercial reference varieties with a history of safe usage. Therefore, MON 88302 and derived products will be used in the same manner as other oilseed rape and no specific packaging is required. For labelling, *see* Section 1.8(h) of this document.

(h) Any proposed labelling requirements in addition to those required by law and when necessary a proposal for specific labelling in accordance with Articles 13(2), (3) and 25(2)(c), (d) and 25(3) of Regulation (EC) No 1829/2003. In the case of GMO plants, food and/or feed containing or consisting of GMO plants, a proposal for labelling has to be included complying with the requirements of Annex IV, A(8) of Directive 2001/18/EC.

In accordance with Regulations (EC) No. 1829/2003 and 1830/2003, the current labelling threshold of 0.9% will continue to be applied for the marketing of MON 88302 and derived products.

Operators shall be required to label products containing or consisting of MON 88302 with the words "genetically modified oilseed rape" or "contains genetically modified oilseed rape" and shall continue to declare the unique identifier MON-883Ø2-9 in the list of GMOs that have been used to constitute a mixture that contains or consists of this GMO.

Operators shall be required to label foods and feeds derived from MON 88302 with the words "produced from genetically modified oilseed rape". In the case of products for which no list of ingredients exists, operators shall continue to ensure that an indication that the food or feed product is produced from GMOs is transmitted in writing to the operator receiving the product.

Operators handling or using MON 88302 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 authorized foods and feeds shall be entered in the Community Register, operators in the food/feed chain will be fully aware of the traceability and labelling requirements for MON 88302. Therefore, no further specific measures are to be taken by the applicant.

(i) Estimated potential demand

(i) In the Union

The EU is a big producer of oilseed rape. In 2009/2010, the EU-27 produced about 21.6 MMT of oilseed rape seed[2] and planted approximately 6.5 Mha. The largest oilseed rape producers in the EU are France, Germany, Poland and United Kingdom. The EU also imports oilseed rape from markets such as Ukraine and other Eastern European countries, Australia and Canada.

[2] http://www.fas.usda.gov/psdonline -Accessed on 6 February 2012

(ii) In export markets for EU supplies

The EU is not an exporter of oilseed rape.

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

The unique identifier for this genetically modified oilseed rape is MON-883Ø2-9.

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

Because this application is for consent to import, process and all uses of MON 88302 as any other oilseed rape, not including the cultivation of varieties of MON 88302 in the EU, the only potential means of environmental release would be more likely to occur during import, storage and processing of MON 88302. However, modern methods of oilseed rape handling minimize losses of seed, so there is little chance of germination of spilt oilseed rapes resulting in the development of mature MON 88302 plants in the EU. Moreover, in the event of incidental spillage, the establishment of volunteer plants would be unlikely, since MON 88302, like any other oilseed rape, is unlikely to effectively compete with perennial vegetation outside agricultural fields. The likelihood for spilt 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.

MON 88302 is not different in composition, nutritional and agronomic characteristics relative to the conventional counterpart, except for the introduced tolerance to glyphosate, 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 glyphosate) 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

Brassicaceae (previously known as Crucifereae)

(b) Genus

Brassica

(c) Species

napus

(d) Subspecies

oleifera

(e) Cultivar/breeding line or strain

Ebony

(f) Common name

Oilseed rape

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 made two important genetic modifications to oilseed rape which lead to 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 in the US.

2.3. Information concerning reproduction (for environmental safety aspects)

(a) Mode(s) of reproduction

Brassica napus, an amphidiploid (chromosome n=19, AA and CC genomes), is thought to be derived from a cross between two diploid *Brassica* species, *B. rapa* (chromosome n=10, AA genome) and *B. oleracea* (chromosome n=9, CC genome).

Under natural conditions, oilseed rape reproduction is through seeds. The seeds have no special or specific adaptations to facilitate widespread dispersal and therefore any shattered seed will remain in close proximity to the site of production. Further dissemination may occur by means of fauna or machinery. Oilseed rape 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. 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

Temperature, moisture, light, nutrition and variety influence the length of each growth stage. 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 particular importance during the period of seed ripening.

(c) Generation time

Oilseed rape is an annual crop. Winter oilseed rape is planted in the fall, overwinters and is harvested the following summer. There are two types of winter oilseed rape: one that requires vernalization (winter-chilling) to produce flowers and one that does not require vernalization. Spring oilseed rape which is planted in the early spring, requires no vernalization to flower, and is harvested in late summer.

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

The minimum soil temperature for oilseed rape to germinate is 3.3 °C. For optimum seed germination, seeding should be delayed until soil temperatures exceed 9°C. The length of time needed for emergence is dependent on soil temperature. Oilseed rape will emerge in 17 to 21 days from planting when the average soil temperature is in the low 4 °C. When the soil temperature averages 10 °C, oilseed rape will emerge in approximately 10 days. Seeding into cooler soil temperatures will cause slow and uneven germination, thin or uneven stands and fosters weed competition.

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

Potential for cross-pollination with cultivated oilseed rape varieties

Brassica napus is predominantly self-pollinating although interplant outcrossing rates (among plants touching one another) range from 12% to 55% with a mean of 30%. Pollen of *B. napus* is heavy and sticky and pollen movement is primarily by insects, such as honey bees although wind is also responsible for some pollen movement. Most (98.8%) pollen travels less than twelve meters from its source although dispersal due to pollinators may occur over greater distances at low frequency. In general, the percentage of pollen flow and potential for outcrossing diminishes with increasing distance from the source.

Potential for cross-pollination and introgression with other *Brassica* species

There are reports of hybridization under field conditions with *B. napus* as the pollen donor with other *Brassica* species including *B. rapa, B. juncea* and *B. oleracea.* In general, in all cases the resulting hybrids had decreased environmental fitness

evidenced by a variety of characteristics including decreased pollen viability, seed production, seedling survival, etc. when compared to parental varieties.

Potential for cross-pollination and introgression with related species in the family Brassicaceae

Other species in the family Brassicaceae with which *B. napus* is sexually compatible under field conditions includes *Hirschfeldia incana, Raphanus raphanistrum* and *Sinapsis arvensis.* The potential for hybridization under field conditions is, however, low, and, if it were to occur, the hybrids would have reduced survival and limited reproductive success.

2.5. Survivability (for environmental safety aspects)

(a) Ability to form structures for survival or dormancy

Cultivated oilseed rape plants are annuals and they reproduce solely by means of seeds.

Although *B. napus* has some characteristics typical of weedy species such as a high reproductive capacity, rapid growth and multiple pollination mechanisms (self, wind, insect), it also has many characteristics typical of domesticated species including low genetic diversity, lack of long-distance seed dispersal mechanisms, limited population persistence, lack of primary seed dormancy and an inability to compete well with perennial species. Oilseed rape has been documented to be present in disturbed areas such as roadsides and railways used for transportation of seed and the margins of fields where it has been previously grown. However, populations of oilseed rape outside agricultural fields do not effectively compete with perennial vegetation, and usually persist only for a few years in the absence of ongoing seed introductions into areas from spillage during handling and transport or processing. 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.

The viability of the large majority of oilseed rape seeds in soil declines over time. However, oilseed rape seed can persist in the soil for several years becoming secondarily dormant, and then germinate as volunteers. Oilseed rape that has germinated and emerged unintentionally in a subsequent crop, also known as volunteer oilseed rape, may compete with the succeeding rotational crop. However, controlling volunteer oilseed rape is not problematic. Any volunteer, including volunteers with GM traits, can be managed with pre-plant or selective post-emergent herbicide applications or by mechanical means.

(b) Specific factors affecting survivability

See Section 2.5(a) of this document.

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

2.6. Dissemination (for environmental safety aspects)

(a) Ways and extent of dissemination

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

Pollen may also be considered as a means for dissemination and therefore cross-pollination. *Brassica napus* is predominantly self-pollinating although interplant cross-pollination can also occur at rates ranging from 12% to 55%. Pollen dispersal may be enhanced by wind and by weather conditions favouring pollinator (insects, mainly bees) activity. An overview of the cross-pollination has been provided in Section 2.4 of this document.

(b) Specific factors affecting dissemination

See Section 2.6(a) of this document.

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

The sexually compatible species in the EU, as mentioned in Section 2.4 of this document, can be found across the EU, in areas where natural conditions would allow the growth and reproduction of oilseed rape plants.

2.8. 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 (for environmental safety aspects)

Not applicable, as oilseed rape is grown in the EU.

2.9. 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 (for environmental safety aspects)

Oilseed rape is known to interact with other organisms in the environment. It is sensitive to a number of economically important insect pests infestations and diseases (backleg and *Sclerotinia* stem rot are the most serious diseases in spring and winter oilseed rape) and it is also susceptible to competition from surrounding weeds.

Historically, the presence of the naturally occurring toxicants, erucic acid in the oil fraction and glucosinolates in the meal has made rapeseed oil and meal derived from *B. napus* unattractive for human consumption and as an animal feed, respectively, particularly in western countries. However, in the 1960s intensive breeding programs resulted in the development and introduction of low erucic acid varieties of oilseed rape or 'canola' (Canadian oil, low acid). Further breeding efforts lowered glucosinolates in oilseed rape varieties to acceptable levels and oilseed rape is now grown both for its high quality vegetable oil and its high quality animal feed.

Today, rapeseed oil is high quality oil that is used in a variety of foods including frying and baking oils, salad oils, margarines and shortenings, and is the most

valuable component of oilseed rape seed. The seed is also processed into oilseed rape meal which is used as high protein animal feed.

3. MOLECULAR CHARACTERISATION

3.1. Information relating to the genetic modification

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

MON 88302 was developed through *Agrobacterium* mediated transformation of conventional oilseed rape hypocotyls using plasmid vector PV-BNHT2672.

(b) Nature and source of the vector used

Plasmid vector PV-BNHT2672 is approximately 9.7 kb and contains one T-DNA that is delineated by Left Border and Right Border regions. The T-DNA contains the *cp4 epsps* coding sequence under the control of the *FMV/Tsf1* chimeric promoter, the *Tsf1* leader and intron sequences, and the *E9* 3′ untranslated region. The chloroplast transit peptide, CTP2 directs transport of the CP4 EPSPS protein to the chloroplast and is derived from CTP2 target sequence of the *Arabidopsis thaliana shkG* gene.

The backbone region of PV-BNHT2672, located outside of the T-DNA, contains two origins of replication for maintenance of plasmid vector in bacteria (*ori V* and *ori pBR322*), a bacterial selectable marker gene (*aadA*), and a coding sequence for repressor of primer protein (*rop*) for maintenance of plasmid vector copy number in *Escherichia coli* (*E. coli*).

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

The genetic elements of PV-BNHT2672 intended for insertion into the oilseed rape genome comprised between the T-DNA border regions are, from the Right border region to the Left border region: the P-FMV/Tsf1 chimeric promoter derived from enhancer sequences of *35S* promoter of the figwort mosaic virus and the promoter from the *Tsf1* gene of *Arabidopsis thaliana*; the leader and intron sequences from the *Tsf1* gene of *Arabidopsis thaliana*; the EPSPS chloroplast transit peptide (CTP) coding sequence from the *shkG* gene of *Arabidopsis thaliana*; the codon optimized coding sequence of *cp4 epsps* from *Agrobacterium* sp. strain CP4; and the polyadenylation sequence derived from the 3' untranslated region of the pea (*Pisum sativum*) ribulose 1,5 bisphosphate carboxylase small subunit (*rbcS2*) *E9* gene. Each individual components and the function of the DNA sequences in MON 88302 are given in Table 1.

Table 1. Summary of genetic elements intended for insertion in MON 88302

Genetic Element [1]	Location in plasmid	Function and source
B-Right Border Region	1-357	DNA region from *Agrobacterium tumefaciens* containing the Right Border sequence used for transfer of the T-DNA.
P-FMV/Tsf1	428-1467	Chimeric promoter consisting of the promoter of the *Tsf1* gene from the *Arabidopsis thaliana* encoding elongation factor EF 1α and enhancer sequences from the *35S* promoter from the figwort mosaic virus.
L-Tsf1	1468-1513	5' untranslated leader (exon 1) from the *Arabidopsis thaliana Tsf1* gene encoding elongation factor EF-1α.
I-Tsf1	1514-2135	Intron from the Arabidopsis thaliana Tsf1 gene encoding elongation factor EF 1α
TS-CTP2	2145-2372	Targeting sequence from the *shkG* gene encoding the chloroplast transit peptide region of *Arabidopsis thaliana* EPSPS that directs transport of the CP4 EPSPS protein to the chloroplast.
CS-*cp4 epsps*	2373-3740	Codon optimized coding sequence of the *aroA* gene from the *Agrobacterium* sp. strain CP4 encoding the CP4 EPSPS protein.
T-E9	3783-4425	3' untranslated sequence from the *rbcS2* gene of *Pisum sativum* (pea) encoding the Rubisco small subunit.
B-Left Border Region	4469 4910	DNA region from *Agrobacterium tumefaciens* containing the Left Border sequence used for transfer of the T-DNA.

[1]B – border, P – promoter, L – leader, TS - targeting sequence, CS - coding sequence, T - 3' non-translated transcriptional termination sequence and polyadenylation signal sequences.

3.2. Information relating to the GM plant

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

MON 88302 was produced by incorporation of the *cp4 epsps* coding sequence from the common soil bacterium *Agrobacterium* sp. strain CP4. The *cp4 epsps* coding sequence directs the production of the 5-enolpyruvylshikimate-3-phosphate synthase (termed CP4 EPSPS) that is less sensitive to inhibition by glyphosate compared to the endogenous plant EPSPS. Hence, the CP4 EPSPS renders MON 88302 tolerance to glyphosate, the active ingredient in the Roundup® family of agricultural herbicides.

MON 88302 utilizes a *FMV/Tsf1* chimeric promoter sequence to drive CP4 EPSPS expression in different plant tissues. By virtue of CP4 EPSPS expression in pollen, MON 88302 provides tolerance to glyphosate during the sensitive reproductive stages of growth, and enables the application of glyphosate at higher rates up to first flower with no detectable impact to male fertility.

In conclusion, MON 88302 was designed to provide growers with improved weed control through greater flexibility for glyphosate herbicide application. Weed competition can be a major limiting factor in oilseed rape production leading to significant yield reductions. Certain perennial weeds, such as Canada thistle, dandelion, common lambsquarters, kochia, smartweed and wild buckwheat are known to be particularly important to control in oilseed rape production. Glyphosate is highly effective against the majority of annual and perennial grasses and broad-leaf weeds.

3.2.2. *Information on the sequences actually inserted or deleted*

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

The molecular analysis shows that MON 88302 contains one single copy of the of the *cp4 epsps* expression cassette, *i.e.*, the T-DNA that is stably integrated at a single locus of the oilseed rape genome and is inherited according to Mendelian principles over multiple generations.

No additional elements from the transformation vector PV-BNHT2672, linked or unlinked to the expression cassette, were detected in the genome of MON 88302. Additionally, no element of the PV-BNHT2672 backbone sequence was detected in MON 88302.

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

No deletion was intended, however there was a 29 bp unintended deletion of DNA sequence at the site of cassette insertion in MON 88302.

Minor deletions and/or insertions of DNA due to double-strand break repair mechanisms in the plant during *Agrobacterium*-mediated transformation process are not uncommon. Further analyses revealed that there is no known function associated with this deleted region.

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

The presence of the MON 88302 insert in the oilseed rape nuclear genome is best shown by the Chi square (χ^2) analysis of the segregation data. The results of

the χ^2 analysis indicate that a single insert is integrated in the plant nuclear genome and is stably inherited as a single locus, following a Mendelian one-locus model.

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

Molecular analysis was conducted to characterize the insert in MON 88302. Genomic DNA was analyzed using Southern blot to determine the insert number (number of insertions of the integrated DNA within the oilseed rape genome), the copy number (the number of copies of the integrated DNA within one locus), the integrity and organization of the inserted *cp4 epsps* expression cassette and the presence or absence of plasmid backbone sequences. DNA sequence analyses confirmed the sequence identity between the MON 88302 insert and the corresponding insert from the plasmid PV-BNHT2672. The results of PCR and sequence analyses further confirmed the organisation of the genetic elements within the *cp4 epsps* expression cassette of MON 88302, which were identical to that in plasmid PV-BNHT2672.

(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

As described in Section 3.2.2 of this document, the *cp4 epsps* is the only expression cassette inserted in MON 88302. Therefore, CP4 EPSPS is the only newly expressed protein in MON 88302.

CP4 EPSPS protein levels in tissues of MON 88302 relevant to the food/feed safety assessment were determined by a validated enzyme-linked immunosorbent assay (ELISA).

The expression levels of the CP4 EPSPS protein were analysed from tissues of MON 88302 obtained from four replicate plots planted in a randomized complete block field design during the 2009 growing season from three field sites in the US and three field sites in Canada. Both glyphosate treated and glyphosate untreated samples were analyzed.

The mean CP4 EPSPS protein level in seed tissues of MON 88302 across all sites was 27 µg/g dw for samples treated with glyphosate and 31 µg/g dwt for samples untreated with glyphosate. The CP4 EPSPS protein expression levels (µg/g dw) determined from treated tissues of MON 88302 were comparable to those determined from untreated MON 88302 tissues, showing that glyphosate application in MON 88302 does not alter nor have any negative effects on the expression of the CP4 EPSPS protein in the plant.

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

The expression of the CP4 EPSPS proteins occurs throughout the plant. In terms of food and feed safety assessment of MON 88302, seed is the most relevant tissue.

3.2.4. ***Genetic stability of the insert and phenotypic stability of the GM plant***

MON 88302 contains a single copy of the T DNA sequence that was integrated into a single locus of the oilseed rape genome. The inserted DNA is inherited in a Mendelian fashion and is stably maintained through multiple generations of breeding. This has been confirmed by Southern blot analyses.

3.2.5. ***Information (for environmental safety aspects) on how the GM plant differs from the recipient plant in:***

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

Phenotypic and agronomic data were collected from nine field trials planted in 2009 and 2010 with MON 88302 in a randomized complete block design with four replicates at each field site. Two field sites were located in the US, three in Canada and four in Chile. In each of these assessments, MON 88302 was compared to an appropriate conventional counterpart (conventional control Ebony) with genetic background similar to MON 88302, but lacking the introduced trait. In addition, several conventional commercial reference varieties were included (a total of 7 different reference varieties in the US and Canadian trials and a total of 12 different reference varieties in the Chilean trials) to provide a range of comparative values that are representative of existing commercial oilseed rape varieties for each measured phenotypic, agronomic, and environmental interaction characteristic.

Results showed that there are no unexpected changes in the phenotype or ecological interactions indicative of increased pest or weed potential of MON 88302 compared to the conventional counterpart. On the basis of the studies described above, 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 MON 88302 and that MON 88302 is equivalent to the conventional counterpart in its phenotypic and agronomic behaviour, except for the glyphosate-tolerance trait.

(b) Dissemination

See Section 3.2.5(a) above.

(c) Survivability

See Section 3.2.5(a) above.

(d) Other differences

See Section 3.2.5(a) above.

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

(a) Plant to bacteria gene transfer

None of the genetic elements inserted in MON 88302 has a genetic transfer function. Therefore, no changes are expected in the ability of this oilseed rape to transfer genetic material to bacteria.

The scope of this application does not cover the cultivation of MON 88302 in the EU. Therefore the routes of exposure will be low and limited to exposure of micro-organisms to MON 88302 and indirect exposure through manure and

faeces of animals fed MON 88302, accidental seed release during transportation and processing, and consumption of MON 88302 in food and feed. Additionally, in the unlikely case that plant *cp4 epsps* gene transfers to bacteria, there is no potential of hazard since EPSPS proteins are already present in microbial populations and possess no plausible mechanism of toxicity.

(b) Plant to plant gene transfer

Based on the observation that reproductive morphology in MON 88302 is unchanged compared to the conventional counterpart and that pollen production and pollen viability were unaffected by the genetic modification, the out-crossing frequency to other oilseed rape varieties or to wild relatives would be unlikely to be different for MON 88302, when compared to conventional oilseed rape varieties. Futhermore, the scope of the current application does not include the cultivation of MON 88302 varieties in the EU. Therefore there will be limited routes of exposure of other plants to MON 88302. In the unlikely case that hybridization with conventional oilseed rape or any compatible wild relative occurs, the potential hazard from the herbicide tolerance trait is negligible since it does not impart a selective advantage in the absence of the herbicide.

4. COMPARATIVE ANALYSIS

4.1. Choice of the conventional counterpart and additional comparators

The oilseed rape variety Ebony, the conventional counterpart, was used as the recipient for the DNA insertion to create MON 88302. Ebony has the background genetics of MON 88302, but does not contain the *cp4 epsps* expression cassette, thus, the effect of the *cp4 epsps* expression cassette and the expressed CP4 EPSPS protein can be assessed in an unbiased manner.

Ebony was used as the conventional oilseed rape comparator to support the safety assessment of MON 88302.

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

MON 88302 and the conventional counterpart were grown in 2009 in five US and Canada field sites and in 2009-2010 in four Chile field sites. Additionally, several conventional commercial reference varieties were used to provide reference substances representative for their respective growing regions. At each field site, the test, the conventional counterpart and reference seed were planted in a randomized complete block design with four replicates per block. Field locations were acceptable environments for oilseed rape growth and are distributed across a wide geographical area to provide a variety of agronomic practices, soils and climatic factors. All the plants were grown under normal agronomic field conditions for their respective geographic regions. The test MON 88302 was both treated and untreated with glyphosate herbicide.

An analysis of variance (ANOVA) was conducted in a combined-site analysis in which the data was pooled across all sites. ANOVA models were chosen 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 in the compositional studies were chosen on the basis of internationally accepted guidance provided by the OECD on compositional considerations for oilseed rape.

Results from the compositional analysis indicate that seed composition of glyphosate-treated and glyphosate untreated MON 88302 is not different from that of the conventional counterpart and is equivalent to the seed composition of conventional commercial reference varieties with a history of safe usage.

4.4. Comparative analysis of agronomic and phenotypic characteristics

Results from the phenotypic and agronomic assessments indicate that, taking into account the natural variation of oilseed rape plants, the agronomic and phenotypic characteristics of MON 88302 are not different from those of the conventional counterpart and are equivalent to those from the conventional commercial reference varieties (with the exception of the introduced herbicide-tolerant trait).

See also Section 3.2.5 of this document.

4.5. Effect of processing

With the exception of the glyphosate-tolerance trait, MON 88302 is not different relative to the conventional counterpart. Therefore, the processing of MON 88302 is not expected to be any different from that of conventional oilseed rape.

5. TOXICOLOGY

(a) Toxicological testing of newly expressed proteins

The CP4 EPSPS protein has been assessed for its potential toxicity according to the recommendations of Codex. The *cp4 epsps* gene is the only gene expressing a protein in MON 88302. Therefore, the safety assessment of the newly expressed protein is focused on the CP4 EPSPS protein expressed in MON 88302.

The assessment of the potential toxicity of an introduced protein is based on comparing the biochemical characteristics of the introduced protein to characteristics of known toxins, based on the premise that a protein is not likely to have a toxic effect if:

- The protein has a demonstrated history of safe use;
- The protein has no structural similarity to known toxins or other biologically active proteins that could cause adverse effects in humans or animals;
- The protein does not exert any acute toxic effects to mammals;
- If the protein is rapidly digested in mammalian gastrointestinal systems.

The safety of the *cp4 epsps* donor organism (*Agrobacterium*) and the ubiquitous presence of homologous EPSPS enzymes in food crops (*e.g.*, soybean and corn) and common microorganisms (*e.g., Saccharomyces cerevisiae*), established that the EPSPS protein, and its enzyme activity pose no novel risks from a food or feed perspective. The CP4 EPSPS protein showed to

lack structural similarity to known toxins, allergens or biologically active or anti-nutritional proteins known to have adverse effects on mammals. Furhtermore no indications of toxicity were reported in mice administered the CP4 EPSPS protein by oral gavage. Finally, the low concentration of the protein in tissues that are consumed and its rapid digestibility in simulated digestive fluids provide additional assurance of its safety.It is therefore possible to conclude that the CP4 EPSPS protein is safe and poses no concerns for humans, animals and the environment.

(b) Testing of new constituents other than proteins

Oilseed rape has a long history of safe use and consumption around the world. As described in Section 4 of this document, seed composition of MON 88302 has been shown to be compositionally not different to seed composition of conventional oilseed rape. Therefore, no testing of any constituent other than the introduced new protein is required.

(c) Information on natural food and feed constituents

Oilseed rape is known to contain a number of natural anti-nutritional analytes, such as glucosinolates, erucic acid, sinapine and phytic acid. These antinutrients were evaluated in MON 88302 compositional analyses and their levels were demonstrated to be similar to those of the conventional commercial reference varieties and not different to those in the conventional counterpart.

(d) Testing of the whole GM food/feed

The data presented in this application establish that seed composition of MON 88302 is not different from the seed composition of the conventional counterpart. Overall results of the comparison indicate that observed differences fell within the range of natural variability for oilseed rape with a history of safe usage. In addition, the safety for humans and animals of the newly expressed CP4 EPSPS proteins has been demonstrated on the basis of extensive characterization, history of safe use, lack of structural similarities with known protein toxins and allergens, absence of acute toxicity in oral gavage studies in rodents and rapid digestion in simulated gastric fluid. Moreover, the history of safe use of the introduced protein and the familiarity of the host organisms from which the gene is derived has been demonstrated. Taken together there are no evidences of any adverse effects of the CP4 EPSPS protein in MON 88302 on human or animal health.

Based on this weight of evidence, no more data is required to demonstrate that MON 88302 is as safe as conventional oilseed rape from a food and feed perspective.

6. ALLERGENICITY

(a) Assessment of allergenicity of the newly expressed protein

The *cp4 epsps* gene is the only gene inserted in MON 88302. Therefore, the safety assessment of the newly expressed protein is focused on the CP4 EPSPS protein expressed in MON 88302.

Following the guidelines adopted by the Codex Alimentarius Commission an assessment of potential allergenicity of introduced proteins has been

conducted, by comparing the characteristics of the introduced protein to characteristics of known allergens. A protein is not likely to be associated with allergenicity if:

- the protein is from a non-allergenic source;
- the protein does not share structural similarities to known allergens based on the amino acid sequence;
- the protein represents only a very small portion of the total plant protein;
- the protein is rapidly digested in mammalian gastrointestinal systems;
- the protein is not stable to heat treatment.

The CP4 EPSPS protein in MON 88302 has been assessed for its potential allergenicity according to these safety assessment guidelines and has demonstrated not to be allergenic. Additionally, the CP4 EPSPS protein and its donor organism *Agrobacterium* have a long history of safe use. Based on the weight of evidence, it can be concluded that the allergenic potential of the CP4 EPSPS protein is negligible and therefore, this protein does not pose a significant allergenic risk.

(b) Assessment of allergenicity of the whole GM plant

Oilseed rape is not considered a common allergenic food. MON 88302 has been shown to have no meaningful differences compared to conventional oilseed rape, except for the introduced glyphosate tolerance trait conferred by the expression of the CP4 EPSPS protein which has no allergenic properties (see Section 6(a) of this document). Therefore, it is unlikely that MON 88302 could alter the overall allergenicity of the whole plant or the allergy risk for oilseed rape consumers.

7. NUTRITIONAL ASSESSMENT

(a) Nutritional assessment of GM food

The introduced trait in MON 88302 is of agronomic interest, and is not intended to change any nutritional aspect of this oilseed rape. The presence of this trait is not expected to alter patterns or volumes of oilseed rape consumption.

Results of the extensive compositional analyses indicate that observed differences fell within the range of natural variability for oilseed rape with a history of safe usage, and the seed composition of MON 88302 is not different to the seed composition of the conventional counterpart.

Overall, MON 88302 reveals comparable nutritional characteristics to conventional counterpart oilseed rape, as well as to oilseed rape varieties in commerce. Hence this oilseed rape is not expected to be more or less attractive for use as food (or feed), for processing or as a food (or feed) ingredient. Therefore, anticipated dietary intake of oilseed rape-derived foods (and feeds) is not expected to be altered, and no nutritional imbalances are expected as a result of the presence of MON 88302 in the oilseed rape supply.

(b) Nutritional assessment of GM feed

The data presented in this application establish that seed composition of MON 88302 is not different to the seed composition of the conventional counterpart and that it is equivalent to seed composition of the set of conventional commercial reference varieties, except for the expression of the CP4 EPSPS protein.

Based on this weight of evidence, no more data is required to demonstrate that MON 88302 is as safe as conventional oilseed rape from a food and feed perspective.

8. EXPOSURE ASSESSMENT – ANTICIPATED INTAKE/EXTENT OF USE

The exposure assessment in humans and animals indicates that there is minimal, if any, dietary exposure to CP4 EPSPS protein from consumption of foods and feed derived from MON 88302.

There are no anticipated changes in the intake and/or extent of use of oilseed rape or derived products for use as or in food or feed as a result of the addition of MON 88302 to the oilseed rape supply. MON 88302 is expected to replace a portion of current oilseed rape such that its intake or use will represent some fraction of the total products derived from oilseed rape.

9. RISK CHARACTERISATION FOR THE SAFETY ASSESSMENT OF GM FOOD AND FEED

Based on the information provided in this application, we can conclude that MON 88302 is as safe as conventional oilseed rape. The molecular characterization of MON88302 did not raise any safety concern and did not show any evidence of unintended changes in MON 88302. Detailed compositional comparisons of MON 88302, its conventional counterpart and conventional commercial reference varieties demonstrated that MON 88302 is compositionally similar to the conventional oilseed rape comparator and that MON 88302 is not a contributor to compositional variability in oilseed rape. The assessed phenotypic and agronomic characteristics of MON 88302 were within the range expected for oilseed rape and did not show any phenotypic changes indicative of increased plant weed/pest potential of MON 88302 compared to conventional oilseed rape. An extensive characterisation of the CP4 EPSPS protein expressed in MON 88302 confirmed that the protein is safe for human and animal consumption. Additionally, the exposure assessment in humans and animals indicates that there is minimal, if any, dietary exposure to CP4 EPSPS protein from consumption of foods and feed derived from MON 88302.

In summary, there are no signs of adverse or unanticipated effects observed in a number of safety studies and the pre-market risk characterisation for food and feed use of MON 88302. The consumption of food and feed derived from GM plants is as safe as the consumption of its respective comparators. It can be concluded that the food derived from a GM plant is not nutritionally disadvantageous for the consumer compared to the food which is intended to replace. Finally, it can be also concluded that the feed derived from a GM plant does not harm or mislead the

consumer by impairing distinctive features of the animal products compared to conventionally produced feed.

10. POST-MARKET MONITORING ON GM FOOD/FEED

Based on the information provided in this application, it is reasonable to conclude that MON 88302 is as safe as conventional oilseed rape. There are no intrinsic hazards related to MON 88302 indicating that MON 88302 is less safe than its conventional counterpart. The pre-market risk characterisation for food and feed use of MON 88302 demonstrates that the risks of consumption of MON 88302 or its derived products are no different from the risks associated with the consumption of conventional oilseed rape or its derived products. As a consequence, specific risk management measures are not indicated and post-market monitoring of the use of this oilseed rape for food and feed is not considered necessary.

11. ENVIRONMENTAL ASSESSMENT

11.1. Mechanism of interaction between the GM plant and target organisms

According to the EFSA ERA Guidance, the primary focus for the assessment on target organisms is the development of resistance to the insect or pathogen tolerance traits expressed by the GM plant. The scope of this application covers the import, processing and all uses as any other oilseed rape, but excludes the cultivation of MON 88302 in the EU. Hence, no deliberate release of viable plant material in the EU environment is expected and no target organisms are associated with this event. Therefore an assessment of the potential resistance development in target organisms resulting from the import, processing and all uses as any other oilseed rape in the EU is not relevant for this submission. No further risk characterization is necessary.

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

(a) Persistence and invasiveness including plant to plant gene flow

Results from the assessment support a conclusion that the capabilities of MON 88302 or sexually compatible species that receive the trait to persist in agricultural fields or invade non-agricultural habitats are comparable to those of conventional oilseed rape in the EU. Thus, MON 88302 is not more likely to represent an agronomic problem in agricultural fields or become more invasive in natural habitats and no adverse effects on ecological functions within agricultural production fields or on biodiversity are expected as a result of the import, processing and all uses of MON 88302 as any other oilseed rape.

Given the negligible hazard and the low levels of environmental exposure that could arise from the import, processing and all uses of MON 88302 as any other oilseed rape and the fact that any exposure would be limited spatially and temporally, any direct or indirect, immediate or delayed environmental harm through increased persistence or invasiveness is considered as negligible. Thus, no risk management strategies are necessary.

(b) Potential for gene transfer

The scope of this application covers the import, processing, and all uses of MON 88302 as any other oilseed rape in the EU. Therefore, no deliberate

release of viable plant material in the EU environment is expected, and interactions of MON 88302 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 MON 88302 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 *cp4 epsps* gene from MON 88302 to micro-organisms, resulting from the import and processing of MON 88302, the risk that this would result in adverse effects on human or animal health or the environment is negligible. Thus, no risk management strategies are considered necessary.

(c) Interactions between the GM plant and target organisms

The scope of this application covers the import, processing and all uses of MON 88302 as any other oilseed rape, but excludes the cultivation of MON 88302 in the EU. No deliberate release of viable plant material in the EU environment is expected and no target organisms are associated with this event. Therefore an assessment of the potential resistance development in target organisms resulting from the import, processing and all uses as any other oilseed rape of MON 88302 in the EU is not relevant for this submission.

(d) Interactions of the GM plant with non-target organisms

The scope of this application covers the import, processing and all uses of MON 88302 as any other oilseed rape, but excludes the cultivation of MON 88302 in the EU. Therefore, no deliberate release of viable plant material in the EU environment is expected and interactions of MON 88302 with the biotic environment will be very limited. Importantly, CP4 EPSPS is heat inactivated during processing for feed and CP4 EPSPS can also be inactivated in the digestive tract of animals. Given the low levels of environmental exposure combined with low hazard from exposure of MON 88302 to NTOs, the likelihood of adverse effects from the import of MON 88302 to NTO communities that perform in-field ecological functions and NTO communities outside of the field, is negligible.

The conclusion from the risk characterization is that the probability that direct or indirect interactions between MON 88302 and NTOs that could lead to direct or indirect, immediate or delayed environmental harm as a result of import, processing and use of MON 88302 in the EU (excluding cultivation) is negligible. Thus, no risk management strategies are necessary.

(e) Effects on human and animal health

This application is for the import, processing and all uses as any other oilseed rape, but excluding the cultivation of MON 88302 in the EU. Therefore, no deliberate release of viable plant material in the EU environment is expected and interactions of MON 88302 with humans and animal health will be limited to the occupational hazards associated with the cultivation, storage, handling and processing of MON 88302. Given the low levels of environmental exposure combined with the negligible hazard occurring from the contact of workers with MON 88302 seeds, the likelihood of adverse effects on workers handling MON 88302 import and processing in the EU is negligible.

(f) Effects on biogeochemical processes

The scope of this application covers the import, processing and all uses of MON 88302 in the EU as any other oilseed rape (excluding the cultivation of MON 88302). Therefore, no deliberate release of viable plant material in the EU environment is expected, and interactions of MON 88302 with the biotic environment will be very limited. Importantly, CP4 EPSPS protein is heat inactivated during processing for feed, and CP4 EPSPS can also be inactivated in the digestive tract of animals thereby limiting any exposure via faeces of animals fed processed or unprocessed MON 88302 seed. Given the low level of environmental exposure combined with a lack of hazard, the import, processing, and food and feed use of MON 88302 in the EU is not likely to adversely impact soil micro-organisms that perform ecological functions in-field or in non-agricultural habitats, and therefore poses negligible environmental risk.

The conclusion from the risk characterization is that the probability that direct or indirect interactions between MON 88302 and soil micro-organisms that could lead to immediate or delayed harm to human and animal health or the environment as a result of import, processing, or food and feed use in the EU is negligible. Thus, no risk management strategies are considered necessary.

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

Cultivation of MON 88302 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 MON 88302 is therefore not relevant for this application.

11.3. Potential interactions with the abiotic environment

Although the CP4 EPSPS protein is introduced in oilseed rape, it already has a safe history of use and it has no known negative interactions with the abiotic environment.

Overall results of the comparative analysis of MON 88302 with respect ot 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 usage. 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, interactions of MON 88302 with the environment will be limited. Moreover no negative impact of MON 88302 on the abiotic environment is expected to result from the import, processing and all uses as any other oilseed rape in the EU.

11.4. Risk characterisation for the environmental risk assessment

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 lied down in EFSA (2010) guidance, support a conclusion that the import, processing and all uses in the EU (excluding cultivation) of MON 88302, as any other oilseed rape, 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. Because no immediate adverse effects are expected, the probability of long-term adverse effects is also negligible.

12. 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 monitoring plan for MON 88302 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 monitoring plan also takes into account the Scientific Opinion on guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants[3].

(b) Interplay between environmental risk assessment and monitoring

The scope of this application is the authorisation of MON 88302 for import, processing, and the use of food and feed produced from MON 88302 in the European Union (EU) under Regulation (EC) No. 1829/2003. The scope of the application does not include authorisation for the cultivation of MON 88302 seed products in the EU.

An environmental risk assessment (ERA) was carried out for MON 88302 according to the principles laid down in Annex II to Directive 2001/18/EC, the Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC and the Guidance Document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed[4]. The scientific evaluation of the characteristics of MON 88302 in the ERA (*see* Section E of Part II of this application) 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 MON 88302 relative to:

- Persistence and invasiveness including plant to plant gene flow
- Plant to micro-organisms gene transfer
- Interactions between the GM plant and target organisms
- Interactions of the GM plant with non-target organisms
- Impacts of the specific cultivation, management and harvesting techniques
- Effects on biochemical processes
- Effects on human and animal health.

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

As discussed in Section E.4.2 of Part II of this application, the scientific evaluation of the characteristics of MON 88302 in the ERA has shown that the risk for potential adverse effects on human and animal health or the

[3] www.efsa.europa.eu/en/efsajournal/doc/2316.pdf -Accessed on 6 February 2012.
[4] www.efsa.europa.eu/en/scdocs/doc/1879.pdf -Accessed on 6 February 2012

environment is negligible in the context of the intended uses of MON 88302. It is therefore considered that there is no need for case-specific monitoring.

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

Any potential adverse effects of MON 88302 on human health and the environment, which were not anticipated in the ERA, can be addressed under the general surveillance. General surveillance is largely based on routine observation and implies the collection, scientific evaluation and reporting of reliable scientific evidence, in order to be able to identify whether unanticipated, direct or indirect, immediate or delayed adverse effects have been caused by the placing on the market of a genetically modified (GM) crop in its receiving environment.

In order to allow detection of the broadest possible scope of unanticipated adverse effects, general surveillance is performed by either selected, existing networks, or by specific company stewardship programmes, or by a combination of both. The consent holder will ensure that appropriate technical information on MON 88302 and relevant legislation will be available for the relevant networks, in addition to further relevant information from a number of sources, including industry and government websites, official registers and government publications.

Following the approval of this oilseed rape in the EU, the consent holder will approach key stakeholders and key networks of stakeholders of the product (including international grain traders, oilseed rape processors and users of oilseed rape seed for animal feed) and inform them that the product has been authorised. The consent holder will request key stakeholders and networks for their participation in the general surveillance of the placing on the market of this oilseed rape, in accordance with the provisions of Directive 2001/18/EC and the consent. Key stakeholders and networks will be requested to be aware of their use of this oilseed rape and to inform the consent holder in case of potential occurrence of any unanticipated adverse effects to health or the environment, which they might attribute to the import or use of this product. Appropriate technical information on MON 88302 will be provided to them.

Where there is scientifically valid evidence of a potential adverse effect (whether direct or indirect), linked to the genetic modification, then further evaluation of the consequence of that effect should be science-based and compared with available baseline information. Relevant baseline information will reflect prevalent use practices and the associated impact of these practices on the environment. Where scientific evaluation of the observation confirms the possibility of an unanticipated adverse effect, this would be investigated further to establish a correlation, if present, between the use of MON 88302 and the observed effect. The evaluation should consider the consequence of the observed effect and remedial action, if necessary, should be proportionate to the significance of the observed effect.

(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 MON 88302 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 observed 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 any unanticipated adverse effects that have arisen from handling and use of viable MON 88302.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of MON 88302 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.

13. DETECTION AND EVENT-SPECIFIC IDENTIFICATION TECHNIQUES FOR THE GM PLANT

The presence of the *cp4 epsps* gene and the CP4 EPSPS protein in oilseed rape or in oilseed rape derived products can be identified by employing different techniques. Southern blot or PCR techniques can identify the inserted nucleotide sequence, while the CP4 EPSPS protein can be detected in all tissues of MON 88302, by optimised tissue extraction, standardised electrophoretic blotting and immunodetection methodologies.

A MON 88302-specific PCR-based assay allowing the identification and quantification of MON 88302 has been provided to the Joint Research Centre (JRC)[5], acting as the European Union Reference Laboratory for GM Food and Feed (EURL-GMFF).

14. INFORMATION RELATING TO PREVIOUS RELEASES OF THE GM PLANT (FOR ENVIRONMENTAL SAFETY ASPECTS)

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

(a) Notification number

There is no history of release of MON 88302 in the EU.

(b) Conclusions of post-release monitoring

Not applicable

[5] http://gmo-crl.jrc.ec.europa.eu/ Accessed on 6 February 2012

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

Not applicable

14.2. History of previous releases of the GM plant carried out outside the Union by the same notifier

(a) Release country

MON 88302 has been field tested in the US and Canada since 2005 and in Chile since 2007.

(b) Authority overseeing the release

US: United States Department of Agriculture (USDA)

Chile: Agriculture and Livestock Service (SAG)

Canada: Canadian Food Inspection Agency (CFIA)

(c) Release site

US/Canada/Chile: In major oilseed rape growing regions of the respective countries.

(d) Aim of the release

US/Canada/Chile: regulatory trials, efficacy, yield, breeding, product development, and demonstration.

(e) Duration of the release

US/Canada/Chile: One growing season.

(f) Aim of post-releases monitoring

US/Canada/Chile: Assessment of volunteers.

(g) Duration of post-releases monitoring

US/Canada/Chile: 36 months.

(h) Conclusions of post-release monitoring

US/Canada/Chile: If volunteers occur, practice is to eliminate them manually or chemically to prevent occurrence in subsequent crops.

Volunteers have occurred in follow years after conducting oilseed rape trials with MON 88302. These volunteers have been controlled by hand, tillage and / or herbicides. The oilseed rape trials are monitored for 3 growing seasons (36 months) for volunteers and any volunteers found are controlled prior to flowering and seed set.

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

Field-testing provided no evidence that MON 88302 would be the cause of any adverse effects to human health or to the environment.