APPLICATION FOR AUTHORISATION OF GENETICALLY MODIFIED PLANTS AND DERIVED FOOD AND FEED IN ACCORDANCE WITH REGULATION (EC) No 1829/2003

73496 OILSEED RAPE

(DP-Ø73496-4 OILSEED RAPE)

Application
EFSA-GMO-NL-2012-XXX

Part VII – Summary

(Appendix I)

Submitted by:
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Original submission (CC1)
15 May 2012

1. GENERAL INFORMATION

1.1 Details of application

a) Member State of application The Netherlands
b) Application number [*To be provided*]
c) Name of the product (commercial and other names) The product described in this application is 73496 oilseed rape.
d) Date of acknowledgement of valid application [*To be provided*]

1.2. Applicant

a) Name of applicant	
Pioneer Hi-Bred International, Inc. as represented by Pioneer Overseas Corporation	
b) Address of applicant	As represented by:
Pioneer Hi-Bred International, Inc. 7100 NW 62nd Avenue P.O. Box 1014 Johnston, IA 50131-1014 U.S.A	Pioneer Overseas Corporation Avenue des Arts, 44 B-1040 Brussels Belgium
c) Name and address of the representative of the applicant established in theUnion (if the applicant is not established in the Union)	
Same as applicant	

1.3. Scope of the application

[x] GM food
[x] Food containing or consisting of GM plants
[x] Food produced from GM plants or containing ingredients produced from GM plants
[x] GM feed
[x] Feed containing or consisting of GM plants
[x] Feed produced from GM plants
[x] GM plants for food or feed use
[x] 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?

Yes [x]

A regulatory compliance dossier in the framework of Article 10 of Regulation (EC) No 396/2005 for the metabolism of glyphosate in genetically modified crops containing the glyphosate-N-acetyl transferase (GAT) gene in glyphosate tolerant oilseed rape has been submitted in Germany, BVL[1] and administrated in November 2011 under application number: RU3 006560-00/03.

1.5. Has the GM plant been notified under Part B of Directive 2001/18/EC?

No [x]

Agronomic performance, protein expression, composition, efficacy, yield and ecological studies on 73496 oilseed rape have been conducted in the US and Canada since 2007 in multiple locations. The risk assessment and risk characterisation of 73496 oilseed rape summarised in Part VII have been concluded on the basis of the data obtained from these studies.

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 [x]

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

Yes [x]

Notifications concerning all uses of 73496 oilseed rape, including cultivation of 73496 oilseed rape seed products, have been submitted in the US and Canada.

[1] Bundesamt für Verbraucherschutz und Lebensmittelsichereit, Dienstsitz Braunschweig, Pstfach 15 64 , 38008 Braunschweig

1.8. General description of the product

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

The recipient plant is oilseed rape (*Brassica napus* L.), which is extensively cultivated and has a history of safe use.

The genetic modification in 73496 oilseed rape resulted in the expression of the GAT4621 protein, which renders the crop tolerant to the herbicidal active ingredient glyphosate. The availability of 73496 oilseed rape will provide an alternative to currently available herbicide-tolerant oilseed rape lines.

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

The types of products planned to be placed on the market according to the authorisation applied for include 73496 oilseed rape for import, processing and all food and feed uses as any other oilseed rape in the EU in accordance with Regulation (EC) No 1829/2003.

However, this application does not include authorisation for the cultivation of 73496 oilseed rape seed products in the EU.

c) Intended use of the product and types of users

The 73496 oilseed rape products placed on the market will be used in a manner consistent with current uses of commercial oilseed rape products. The 73496 oilseed rape will undergo existing methods of production and manufacturing used for commercial oilseed rape by the same operators currently involved in the 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

Safety evaluation of 73496 oilseed rape has shown that no specific instructions and/or recommendations for use, storage and handling of 73496 oilseed rape are necessary. Therefore, 73496 oilseed rape can be used, stored and handled in the same way as is currently done for commercial oilseed rape.

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

Not applicable

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

Not applicable

g) Any proposed packaging requirements

The packaging currently used for commercial oilseed rape will apply. The 73496 oilseed rape products will be packaged in the same manner as other commercial oilseed rape products.

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.

1.- PROPOSAL FOR THE LABELLING OF 73496 OILSEED RAPE FOOD PRODUCTS ACCORDING TO ARTICLES 12 AND 13 OF REGULATION (EC) No 1829/2003

In accordance with Article 12(2) of Regulation (EC) No 1829/2003, labelling will apply to foods containing material which contains, consists of or is produced from 73496 oilseed rape in a proportion at or higher than 0,9 per cent of the food ingredients considered individually or of the entire food if consisting of a single ingredient.

In accordance with Article 13 of Regulation (EC) No 1829/2003, and without prejudice to the other requirements of Community law concerning the labelling of foodstuffs, foods containing, consisting of, produced from, or containing ingredients produced from 73496 oilseed rape should be labelled as follows:

(a) where the food consists of more than one ingredient, the words 'genetically modified' or 'produced from genetically modified maize' will appear in the list of ingredients provided for in Article 6 of Directive 2000/13/EC in parentheses following the ingredient concerned;
(b) where the ingredient is designated by the name of a category, the words 'contains genetically modified maize' or 'contains (name of ingredient) produced from genetically modified maize' will appear in the list of ingredients;
(c) where there is no list of ingredients, the words 'genetically modified' or 'produced from genetically modified maize' will appear clearly on the labelling;
(d) the indications referred to in (a) and (b) may appear in a footnote to the list of ingredients. In this case they shall be printed in a font of at least the same size as the list of ingredients. Where there is no list of ingredients, they will appear clearly on the labelling;
(e) where the food is offered for sale to the final consumer as non-pre-packaged food, or as pre-packaged food in small containers of which the largest surface has an area of less than 10 cm^2, the information referred to above will be permanently and visibly displayed either on the food display or immediately next to it, or on the packaging material, in a font sufficiently large for it to be easily identified and read.

No other particulars such as those referred to in Article 13(2)(a) and (b) and Article 13(3) of Regulation (EC) No 1829/2003 would need to be specified on the label of 73496 oilseed rape food products as 73496 oilseed rape has been shown to be equivalent to non-GM control oilseed rape in composition; nutritional value and nutritional effects; intended use; health characteristics; and, the genetic modification in 73496 oilseed rape does not give rise to any safety concerns.

2.- PROPOSAL FOR THE LABELLING OF 73496 OILSEED RAPE FEED PRODUCTS ACCORDING TO ARTICLES 24 AND 25 OF REGULATION (EC) No 1829/2003

In accordance with Article 24(2) of Regulation (EC) No 1829/2003, labelling will apply to feed containing material which contains, consists of or is produced from 73496 oilseed rape in a proportion at or higher than 0,9 per cent of the feed and of each feed of which it is composed.

In accordance with Article 25 of Regulation (EC) No 1829/2003, and without prejudice to the other requirements of Community law concerning the labelling of feed, feed referred to in Article 15(1) of Regulation (EC) No 1829/2003, *i.e.* 73496 oilseed rape for feed use, and feed containing, consisting

of or produced from 73496 oilseed rape, should be labelled as follows:

(a) where the feed contains or consists of 73496 oilseed rape, or where 73496 oilseed rape is used for the purpose of feed use, the words 'genetically modified maize' will appear in parentheses immediately following the specific name of the feed. Alternatively, these words may appear in a footnote to the list of the feed. It should be printed in a font of at least the same size as the list of feed.
(b) where the feed is produced from 73496 oilseed rape, the words 'produced from genetically modified oilseed rape' will appear in parentheses immediately following the specific name of the feed. Alternatively, these words may appear in a footnote to the list of the feed. It should be printed in a font of at least the same size as the list of feed.

No other particulars such as those referred to in Article 25(2)(c) and Article 25(3) of Regulation (EC) No 1829/2003 would need to be specified on the label of 73496 oilseed rape feed products as 73496 oilseed rape has been shown to be equivalent to non-GM control oilseed rape in composition; nutritional value and nutritional effects; intended use; health characteristics; and, the genetic modification in 73496 oilseed rape maize does not give rise to any safety concerns.

3.- PROPOSAL FOR THE LABELLING OF PRODUCTS CONSISTING OF, OR CONTAINING, 73496 OILSEED RAPE FEED ACCORDING TO ARTICLE 4, B(6) OF REGULATION (EC) No 1830/2003 AND ANNEX IV OF DIRECTIVE 2001/18/EC

As specified in Section **A.8** of Annex IV of Directive 2001/18/EC, the information provided on a label or in an accompanying document for the purpose of satisfying the labelling requirements regarding placing on the market of 73496 oilseed rape will include the following:

(a) Commercial name of the product and the statement that 'this product contains genetically modified organisms';
(b) Name of the GMO;
(c) Information referred to in Section **A.2.** of Annex IV of Directive 2001/18/EC (name and full address of the notifier established in the Community who is responsible for the placing on the market);
(d) An indication on how to access the information in the publicly accessible part of the register.

i) Estimated potential demand

(i) In the Union

The EU is the largest producer of oilseed rape with more than 20 million tonnes per year, corresponding to more than 30% of world production. India and China are also important producers of oilseed rape. However, although these two countries together produce almost 20% of world production, only a small quantity is exported since nearly all domestic production is used for home consumption. Canada is the main exporting country of oilseed rape in the world.

(ii) In export markets for EU supplies

The scope of this application does not cover cultivation in the EU.

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

A proposal for a unique identifier for the 73469 oilseed rape and derived products was developed as: DP-Ø73496-4.

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

Based on the conclusions from the environmental risk assessment of 73469 oilseed rape (**Part II** of this application), no specific measures need to be taken in case of unintended release or misuse or for disposal and treatment.

In case of unintended release of 73469 oilseed rape, current agronomic measures taken to control other commercially available oilseed rape can be applied, such as use of mechanical means and selective use of herbicides (with exception of glyphosate).

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

2.1. Complete name

a) Family name

Brassicaceae

b) Genus

Brassica

c) Species

B. napus L.

d) Subspecies

None

e) Cultivar/breeding line

Proprietary inbred line 1822B

f) Common name

Oilseed rape (OSR), Canola [2]

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

Canada, China, the EU and India are the top oilseed rape producers. However, this crop is also grown in Australia, South America and the United States.

The EU is the largest producer of oilseed rape with more than 20 million tonnes per year, corresponding to more than 30% of world production.

2.3. Information concerning reproduction (for environmental safety aspects)

(a) Mode(s) of reproduction

The normal means of reproduction of oilseed rape seed is through seeds; there are no reports of vegetative reproduction under field conditions. Oilseed rape has entomophilous flowers capable of both self- and cross-pollination. Fertilisation of ovules predominately results from self-pollination, since oilseed rape flowers produce a large amount of pollen and this usually outcompetes with the pollen from adjacent flowers or other pollen vectors. Oilseed rape is predominantly autogamous, but partially (12%-47%) allogamous.

[2] The term canola has been registered and adopted in Canada to describe the oil (seeds, plants) obtained from the cultivars *Brassica napus* and *Brassica campestris*. In 1986, the definition of canola was amended to refer to *B. napus* and *B. campestris* (now *Brassica rapa*) lines containing <2% erucic acid in the oil and <30 μmol/g glucosinolates in the air-dried, oil-free meal. (Canola Council of Canada, 2012).

(b) Specific factors affecting reproduction

The level of out-crossing varies depending on the availability of insect pollinators, cultivar and weather. Oilseed rape is out-crossed by three vectors, mechanical contact, wind and insects. The pollen is heavy and sticky, and can be transferred from plant to plant through physical contact. Approximately half of oilseed rape pollen travels less than three meters from the source, and the vast majority of pollen travels less than 10 meters, with the amount of pollen decreasing as the distance from the pollen source increases. Pollinating insects, in particular honeybees (*Apis mellifera*) and bumblebees (*Bombus* sp.), play a major role in *B. napus* pollination and are believed to be involved in the transfer of pollen over long distances.

(c) Generation time

Oilseed rape is an annual crop with a cultural cycle ranging from 6 months for spring sown oilseed rape up to 11 months for autumn sown (winter) oil seed rape.

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

The Brassicaceae family also contains a number of major weeds, including those in the genera *Sinapis, Capsella, Thlaspi, Erucastrium, Raphanus*, and others. Some *Brassica* crops and their wild relatives will hybridize only under artificial conditions in laboratories or highly contrived field conditions; others will hybridize at very low rates under natural conditions.

2.5. Survivability (for environmental safety aspects)

a) Ability to form structures for survival or dormancy

Oilseed rape is a non-dormant annual crop and seeds are the only survival structures. Natural regeneration of oilseed rape from vegetative tissue or vegetative reproduction is not known to occur.

b) Specific factors affecting survivability

Oilseed rape seed show virtually no signs of dormancy at maturity. However, non-dormant oilseed rape seed may enter dormancy if environmental conditions are unfavourable for germination (referred to as ‘secondary dormancy’). Induction of secondary dormancy in oilseed rape occurs in response to sub-optimal germination conditions such as large temperature fluctuations, low soil water availability (e.g. –2.0 MPa), long exposure to darkness and suboptimal oxygen supply.

2.6. Dissemination (for environmental safety aspects)

a) Ways and extent of dissemination

Oilseed rape dissemination occurs via seed and pollen. The fruiting bodies, or pods, produced by the Brassicaceae family are siliques. Each siliques produces between 15 and 25 seeds. Seeds are small, spherical, light brown to black color and are generally 1 to 2 mm in diameter. There are generally 250,000 to 300,000 seeds per kilogram.

B. napus is grown as a winter annual in regions where climate conditions do not result in very low temperatures, which would kill the plants. These biotypes typically require vernalisation before the onset of stem elongation, raceme development, flowering and seed set. In northern parts of Europe, a spring biotype of *B. napus* that requires no vernalisation prior to flowering is grown. These biotypes are typically lower yielding than the winter annual types, but require considerably less time to complete their life cycle.

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

Although compatible relatives of oilseed rape exist in throughout the EU, success of interspecific crossing is limited and dependant on exposure which would ultimately be low in the case of *B. napus* present in the environment through accidental spillage.

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 normally 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 extensively cultivated in the EU and has a long history of safe use. Oilseed rape is known to interact with other organisms in the environment including insects, birds, and mammals. It is susceptible to a range of fungal diseases and insect pests, as well as competition from surrounding weeds. Oilseed rape or derived products of oilseed rape are not considered to have toxic effects on humans, animals and other organisms.

3. MOLECULAR CHARACTERISATION

3.1. Information relating to the genetic modification

a) Description of the methods used for the genetic modification

73496 oilseed rape was produced by biolistic transformation with the *Hin*d III/*Not* I fragment, PHP28181A, from plasmid PHP28181.

b) Nature and source of the vector used

The PHP28181A fragment of the ColE1-type, non-binary plasmid PHP28181 contains the *UBQ10* promoter, the *gat4621* gene, and the *pin*II terminator. A gel-purified DNA fragment isolated from plasmid PHP28181 (containing the *gat4621* gene cassette) was used to generate 73496 oilseed rape.

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

Location on Fragment (base pair position)	Genetic Element	Size (base pairs)	Description
1 to 7	Polylinker Region	7	Region required for cloning genetic elements
8 to 1312	*UBQ10* Promoter	1305	Version of the promoter region from *Arabidopsis thaliana UBQ10* polyubiquitin gene
1313 to 1335	Polylinker Region	23	Region required for cloning genetic elements
1336 to 1779	*gat4621* Gene	444	Synthetic glyphosate N-acetyltransferase gene
1780 to 1796	Polylinker Region	17	Region required for cloning genetic elements
1797 to 2106	*pin*II Terminator	310	Terminator region from *Solanum tuberosum* proteinase inhibitor II gene
2107 to 2112	Polylinker Region	6	Region required for cloning genetic elements

3.2. Information relating to the GM plant

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

The expression of the GAT4621 protein in 73496 oilseed rape renders the crop tolerant to the herbicidal active ingredient glyphosate. No other phenotypic or metabolic modifications were intended by the genetic transformation.

Glyphosate inhibits the enzyme enolpyruvylshikimate-3-phosphate synthase (EPSPS), which is involved in the biosynthesis of aromatic amino acids. GAT4621 protein is an enzyme that acetylates the secondary amine of glyphosate giving rise to N-acetyl glyphosate, which has no herbicidal activity as it can no longer inhibit the activity of the plant EPSPS enzyme.

3.2.2. Information on the sequences actually inserted or deleted

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

Southern blot analysis was conducted to characterize the DNA insertion in 73496 oilseed rape. The analysis confirmed that a single, intact PHP28181A DNA fragment (except 3 bp deletion at 5' end) was inserted into the oilseed rape genome. A single copy of each of the *UBQ10* promoter, *gat4621* coding sequence, and *pin*II terminator genetic elements was present and was inherited during traditional breeding processes as expected. In addition, Southern blot analysis confirmed the absence of plasmid backbone sequences in 73496 oilseed rape.

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

Not applicable

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

The inserted DNA and the herbicide-tolerance phenotype in several self-and cross-pollination generations of 73496 oilseed rape segregate according to Mendel's laws of segregation and were consistent with the finding of a single locus and nuclear insertion of the *gat4621* cassette.

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

The inserted PHP28181A fragment and the 5' and 3' flanking genomic regions were sequenced and characterized in 73496 oilseed rape. Out of the total 6,150 bp that were sequenced, 2,003 bp were of the 5' flanking genomic region, 2,109 bp were of the PHP28181A insertion, and 2,038 bp were of the 3' flanking genomic region.

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

Characterisation of the insert flanking regions revealed the presence of a disrupted *tpt* (Triose phosphate/phosphate translocator) gene near the 5' border. Further analysis by Southern blot showed that oilseed rape contains three or four copies of the *tpt* gene. Northern blot and qRT-PCR analysis revealed a reduced *tpt* transcription in 73496 oilseed rape plants, confirming the *tpt* gene disruption. However, other *tpt* homologues in the oilseed rape genome seem to compensate at least partially for the loss of the disrupted *tpt* gene. Moreover, as 73496 oilseed rape is commercialised as

a hybrid product containing one intact and one disrupted copy of the *tpt* gene, the phenotypic and agronomic effect of the *tpt* disruption near the 73496 event is likely negligible.

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

Field data from nine locations showed that the inserted *gat4621* cassette was expressed in all tissues examined, which was in line with the use of the constitutive UBQ10 promoter to drive this gene. The mean GAT4621 concentration in seed was 5.6 ng/mg DW in both conventional herbicide-treated and glyphosate-treated 73496 oilseed rape; similar data are available for root and whole plant tissues.

b) Parts of the plant where the insert is expressed

Field tests have shown that the GAT4621protein is expressed in different plant tissues throughout oilseed rape development.

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

Genetic stability of the insert in 73496 oilseed rape was confirmed by molecular and segregation analysis of 73496 oilseed rape. Phenotypic stability of the traits was shown by comparative agronomic evaluation.

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

No unexpected changes in seed production or germination have been observed in field trials of 73496 oilseed rape compared to non-GM control oilseed rape.

b) Dissemination

Seed are the only survival structures for oilseed rape. The results of the assessment of related agronomic characteristics indicate no changes in the dissemination capacity of 73496 oilseed rape.

c) Survivability

Cultivated oilseed rape has been domesticated to the extent that it expresses low survival outside managed agricultural environments. The genetic modification in 73496 oilseed rape results in the expression of a protein conferring tolerance to the herbicide glyphosate. The survival characteristics of 73496 oilseed rape in the environment have remained unchanged in comparison to those of non-GM control oilseed rape.

d) Other differences

Except for the introduced herbicide tolerance trait, which is of agronomic interest, 73496 oilseed rape did not show any unexpected changes in reproduction, dissemination and survivability in comparison with non-GM oilseed rape in field trials.

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

The genetic modification in 73496 oilseed rape does not change the inability of oilseed rape to transfer genetic material to bacteria. In particular, no sequences are present on the inserted regions that could potentially be involved in transfer of genetic material between oilseed rape and bacteria.

b) Plant to plant gene transfer

The genetic modification in 73496 oilseed rape does not change the out-crossing ability of oilseed rape. As discussed in Section 2.7, although compatible relatives of oilseed rape exist in the EU, success of interspecific crossing is limited and dependant on exposure.

It should be noted that this application is for authorisation of 73496 oilseed rape for all food and feed uses, and for all food, feed and processed products derived from 73496 oilseed rape, and not for cultivation of 73496 oilseed rape seed products. Any plant to plant gene transfer is therefore limited to only occasional unintentional releases.

4. COMPARATIVE ANALYSIS

4.1 Choice of the conventional counterpart and additional comparators

The comparator chosen for the safety evaluation of 73496 oilseed rape consists of a non-GM near-isogenic conventional counterpart oilseed rape.

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

The field phase of the comparative assessment was conducted at nine site locations (five in Canada and four in the United States) selected on the basis of their inclusion in the commercial oilseed rape-growing regions of North America.

A randomized complete block design containing four blocks was utilized at each site. Each block contained conventional herbicide-treated 73496 oilseed rape, glyphosate-treated 73496 oilseed rape, conventional counterpart oilseed rape, and three of six commercial reference oilseed rape lines.

The comparative analysis was conducted via both difference test and equivalence test.

4.3 Selection of materials and compounds for analysis

The nutritional analysis was undertaken on a broad range of compounds such as protein, fiber, carbohydrates, fat, ash, minerals, fatty acids, amino acids, vitamins, glucosinolates and anti-nutrients in accordance with OECD guidelines for the assessment of genetically modified oilseed rape. The spectrum of analytes was extended to certain N-acetylated amino acids and free amino acids as well.

The results confirm that 73496 oilseed rape and derived food and feed are comparable to those of its comparator and to the non-GM reference oilseed rape lines, taking into account natural variation, except for the expressions of the introduced GAT4621 protein and the elevated levels of N-acetylaspartate (NAA), N-acetylglutamate (NAG) and N-acetylthreonine (NAT). These N-acetylated amino acids are natural constituents of the oilseed rape, and their increased concentration in 73496 oilseed rape is not unexpected, since the GAT4621 protein has been shown to acetylate certain amino acids with low catalytic efficiency.

4.4 Agronomic traits

The agronomic characteristics of 73496 oilseed rape were assessed from the same study performed for the compositional assessment. The agronomic data obtained support the conclusion that there are no unexpected agronomic differences between 73496 oilseed rape and non-GM control oilseed rape with comparable genetic background.

The results confirm that 73496 oilseed rape, except for the introduced glyphosate tolerance due to the expression of the GAT4621 protein, is comparable to its comparator and to the non-GM reference oilseed rape lines, taking into account natural variation.

It should be noted that this application is for authorisation of 73496 oilseed rape for all food and feed uses, and for all food, feed and processed products derived from 73496 oilseed rape, and not for cultivation of 73496 oilseed rape seed products.

4.5 Effect of processing

The production processes applied to oilseed rape are well known and have a long history of safe use. The 73496 oilseed rape will undergo existing production processes used for commercial oilseed rape.

The newly expressed proteins in 73496 oilseed rape are susceptible to proteolytic digestion and are readily degraded when heated. Therefore, the technologies applied in the production and processing of processed foods and feeds derived from oilseed rape will lead to the denaturation and degradation of the GAT4621 protein. The rapid denaturation and degradation of the GAT4621 protein was confirmed by analysis of the GAT4621 protein concentration in processed 73496 oilseed rape products.

5. TOXICOLOGY

a) Toxicological testing of newly expressed protein GAT4621

The toxicity of the newly expressed protein in 73496 oilseed rape i.e. GAT4621has been assessed taking into account the following considerations:

- the source organism of the *gat4621* gene have a history of safe use;
- the molecular and biochemical characteristics of the proteins does not indicate any toxicity risks;
- the protein has no significant amino acid sequence homology to known toxins or other biologically active proteins that could cause adverse effects in humans or animals;
- the protein shows no acute or subacute (28-day) toxicity to mammals.

b) Testing of new constituents other than proteins

Not applicable as the genetic modification in 73496 oilseed rape does not give rise to the expression of any new constituents other than the GAT4621protein.

c) Information on natural food and feed constituents

As mentioned under Section 3.4 the compositional analyses revealed elevated levels of NAA, NAG and NAT. Their potential health implications were assessed considering their physiological functions available from the scientific literature as well as their anticipated intake. In addition, toxicological studies with the use of experimental animals and *in vitro* systems were performed on all concerned N-acetylated amino acids concerned.
Collectively, the results indicate that dietary exposure to NAA, NAG or NAT does not present a risk for adverse effects.

d) Testing of the whole GM food/feed

A thirteen-week (90-day) oral toxicity study in rats fed with a diet prepared from 73496 oilseed rape indicates no toxicity to 73496 oilseed rape.

6. ALLERGENICITY

a) Assessment of allergenicity of the newly expressed protein

The assessment of the potential allergenicity of the GAT4621 protein expressed in 73496 oilseed rape consisted of the evaluation of the allergenicity of the relevant source organism; amino acid sequence comparison with known allergens; rapid degradation in simulated gastric and intestinal fluids; low level of expression; lack of glycosylation, and lack of thermal stability of the newly expressed protein. The results confirm that the novel protein expressed in 73496 oilseed rape is unlikely to be allergenic.

b) Assessment of allergenicity of the whole GM plant or crop

Oilseed rape, - the recipient of the *gat4621* gene- is not considered a common allergenic crop. The consumption of highly refined 73496 oilseed rape oil and derived products, which are the major food use of oilseed rape therefore, will not pose a risk to any increased allergenicity.

7. NUTRITIONAL ASSESSMENT

a) Nutritional assessment of GM food

The nutritional assessment of 73496 oilseed rape focused on the assessment of the bioavailability and biological efficacy of nutrients in the processed food and feed of 73496 oilseed rape products. The results of the compositional analysis of the diet prepared for the 90-day rat feeding study (referred above) have confirmed that foods derived from 73496 oilseed rape are nutritionally equivalent to those of comparator, taking into account natural variation.

b) Nutritional assessment of GM feed

The nutritional equivalence of feed prepared from 73496 oilseed rape and non-GM control oilseed rape has also been shown in a poultry feeding study where chickens were fed meal of 73496 oilseed rape and non-GM control oilseed over a 42-day period.

8. EXPOSURE ASSESSMENT – ANTICIPATED INTAKE/EXTENT OF USE

As the genetic modification in 73496 oilseed rape is an agronomic trait (glyphosate tolerance), the general intake of the oilseed rape crop is not expected to be changed. Since the concentration of the GAT6421 protein was below the lower limit of quantification in meal and oil (the only relevant oilseed rape products consumed) and no N-acetylated amino acids were measured in oil, the exposure assessment has focused on the exposure of farm animals to NAA, NAG and NAT through the consumption of toasted meal (the only relevant exposure route). On the basis of the inclusion rates of meal in animal diets, and the NAA, NAG and NAT concentration in the meal, the highest calculated Daily Dietary Exposure (DDE) to NAA was identified for poultry species, where the estimated exposure due to consumption of toasted meal from 73496 oilseed rape ranged from 21.00 mg/kg body weight/day for layers to 43.90 mg/kg body weight/day for turkeys. The no observed adverse effect level (NOAEL) for systemic toxicity from a 28-day repeated dose dietary exposure to NAA was 852.3 mg/kg body weight/day for male Sprague Dawley® rats, which yields a minimum margin of exposure to NAA of approximately 19-fold for turkeys consuming diets containing toasted oilseed rape meal from 73496 oilseed rape. The corresponding margin of exposure for turkeys for NAG and NAT was found to be 1187-fold and 21213-fold, respectively. These margins are safe margins of exposures for all three N-acetylated amino acids present in 73496 oilseed rape meal. It is concluded that exposure to 73496 oilseed rape and derived products raises no additional safety risks compared to non-GM oilseed rape and derived products.

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

A safety assessment performed on the basis of molecular, phenotypic, agronomic, compositional, toxicological and allergenicity studies has revealed no risk associated with the food and feed use of 73496 oilseed rape. As 73496 oilseed rape has not been claimed for any health effects and its nutritional composition or nutritional value have not been changed, no post-market monitoring of food and feed derived from 73496 oilseed rape is proposed.

10. POST-MARKET MONITORING ON GM FOOD/FEED

As 73496 oilseed rape has not been claimed for any health effects and its nutritional composition or nutritional value have not been changed, no post-market monitoring of food and feed derived from 73496 oilseed rape is proposed.

11. ENVIRONMENTAL ASSESSMENT

An environmental risk assessment (ERA) has been conducted following the recommendations outlined in the EFSA Guidance on the ERA of GM plants (hereafter referred to as the EFSA ERA Guidance), also considering the EFSA "Guidance for risk assessment of food and feed from genetically modified plants". The conclusions are summarized in the following sections.

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

73496 oilseed rape has been developed to confer tolerance to herbicides, 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 73496 oilseed rape is not applicable for this application.

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

a) Persistence and invasiveness

An assessment of whether 73496 oilseed rape will be more persistent than the conventional crop in natural or semi-natural habitats has been conducted. The results of this assessment allowed the conclusion that the risk that the import, processing or food and feed use of 73496 oilseed rape in the EU will result in no harm to sustainable agricultural production or biodiversity as a result of changes in persistence or invasiveness compared with the conventional crop is negligible.

b) Selective advantage or disadvantage

An assessment of whether 73496 oilseed rape will be more persistent than the conventional crop in agricultural habitats or more invasive in natural habitats has been conducted. The results of this assessment allowed the conclusion that the risk that the import, processing or food and feed use of 73496 oilseed rape in the EU will result in harm to sustainable agricultural production or biodiversity as a result of selective advantage or disadvantage compared with the conventional crop is negligible.

c) Potential for gene transfer

The *gat4621* gene expressed in 73496 oilseed rape is unlikely to be transferred to micro-organisms and, even if this would happen, it is unlikely that the transgene would become established in the genome of micro-organisms as the promoters would not be functional and expression would not occur. In the highly unlikely scenario where the *gat4621* gene would be transferred and expressed in a prokaryotic organism, that would not be considered as different from the natural presence of *gat* genes in bacteria, such as in the common soil bacterium *Bacillus licheniformis*, the source organism of the *gat4621* gene. In the very unlikely event that any of the genes were established in the genome of micro-organisms, no adverse effects on human and animal health or the environment are expected.

e) Interactions between the GM plant and target organisms

73496 oilseed rape has been developed to confer tolerance to herbicides 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 73496 oilseed rape is not applicable for this application.

e) Interactions of the GM plant with non-target organisms

73496 oilseed rape has been developed to confer tolerance to herbicides no target organisms are associated with this product. 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

The risks associated with the import, processing and food and feed use of 73496 oilseed rape in the EU on human health have been assessed in Section C of this application. No further risk characterisation is considered necessary.

g) Effects on animal health

The risks associated with the import, processing and food and feed use of 73496 oilseed rape in the EU on animal health have been assessed in Section C of this application. No further risk characterisation is considered necessary.

h) Effects on biogeochemical processes

The scope of this application covers the import, processing and food and feed use of 73496 oilseed rape in the EU. Cultivation of 73496 oilseed rape in the EU is not included in the scope. Although environmental exposure could occur through the accidental spillage of 73496 oilseed rape, or through manure or faeces of animals fed on 73496 oilseed rape, or through organic matter or by-products from 73496 oilseed rape, these routes of exposure would represent very low levels of exposure that would be limited spatially and temporally. Therefore an assessment of the impacts of 73496 oilseed rape on biogeochemical processes resulting from specific cultivation, management and harvesting techniques is not applicable given the scope of this application.

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

Not applicable as cultivation is not part of the scope of this application.

11.3. Potential interactions with the abiotic environment

Not applicable as cultivation is not part of the scope of this application.

11.4. Risk characterisation for the environmental risk assessment

The import, processing and food and feed use of 73496 oilseed rape in the EU will pose negligible risks to human and animal health or the environment.

12. ENVIRONMENTAL MONITORING PLAN

a) General (risk assessment, background information)

The scope of this application does not include authorisation for the cultivation of 73496 oilseed rape seed products in the EU. Exposure to the environment from the import of 73496 oilseed rape will be limited to unintended release of 73496 oilseed rape which can be controlled with current measures used to control unintended release of commercially available oilseed rape, such as use of mechanical means and selective use of herbicides (with the exception of glyphosate).

A proposal for an environmental monitoring plan for 73496 oilseed rape has been developed according to the principles and objectives outlined in Annex VII of Directive 2001/18/EC and Council Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC, and following the Guidance Document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified organisms and derived food and feed.

b) Interplay between environmental risk assessment and monitoring

The design of the environmental monitoring plan is based on the conclusions of the environmental risk assessment (ERA) carried out for this application for authorisation of genetically modified 73496 oilseed rape and derived food and feed in accordance with Regulation (EC) No 1829/2003.

The e.r.a. has been carried out in accordance with Annex II of Directive 2001/18/EC and Commission Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC. The overall conclusion obtained from the e.r.a. confirms that there are no identified adverse effects to human and animal health or the environment arising from 73496 oilseed rape. Therefore, the risk to human and animal health or the environment from 73496 oilseed rape and any derived products is as negligible as for any commercial oilseed rape and any derived products.

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

In accordance with Annex VII of Directive 2001/18/EC and Council Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC, case-specific monitoring should only be carried out in those cases where potential adverse effects have been identified in the e.r.a.

The e.r.a. concluded that the risk to human and animal health or to the environment from 73496 oilseed rape and any derived products is as negligible as for any commercial oilseed rape and any derived products. As a result, case-specific monitoring is not applicable for the use of 73496 oilseed rape for all food and feed purposes and the import and processing of 73496 oilseed rape.

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

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

The scope of this application is for the authorisation of 73496 oilseed rape for all food and feed uses in accordance with Articles 3(1) and 15(1) of Regulation (EC) No 1829/2003 and for import and processing of 73496 oilseed rape in accordance with Part C of Directive 2001/18/EC. In this application we are not seeking approval for cultivation of 73496 oilseed rape seed products in the EU.

As discussed in detail in the e.r.a., exposure to the environment will be limited to unintended release of 73496 oilseed rape. However, such limited exposure is highly unlikely to give rise to any adverse effect and, if necessary, can be controlled with current measures used to control unintended release of commercially available oilseed rape, such as use of mechanical means and selective use of herbicides (with the exception of glyphosate).

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 73496 oilseed rape will be undertaken for the duration of the authorisation.

e) Reporting the results of monitoring

As discussed in Sections **D.11.1** to **D.11.4**, case-specific monitoring is not applicable for the use of 73496 oilseed rape for all food and feed purposes and the import and processing of 73496 oilseed rape. As a result, no case-specific monitoring is proposed for this application for authorisation of 73496 oilseed rape.

The applicant will inform the European Commission, without delay, of any adverse effects reported arising from the handling and use of imported 73496 oilseed rape. Furthermore, the applicant will submit an annual monitoring report to the European Commission including results of the general surveillance in accordance with the conditions of the authorisation. The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of 73496 oilseed rape and, as appropriate, any measures that were taken to ensure the safety of human and animal health or the environment.

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

In accordance with Articles 5 (3) (i) and 17 (3) (i) of Regulation (EC) 1829/2003 and in accordance with Annex I to Regulation (EC) 641/2004, a quantitative event-specific PCR detection method for 73496 oilseed rape has been developed. This quantitative event-specific detection method for 73496 oilseed rape has been submitted for validation to the European Union Reference Laboratory for Genetically Modified Food and Feed (EURL-GMFF). Appropriate control samples have also been made available to the EURL-GMFF.

In addition, samples of 73496 oilseed rape have been submitted to the EC Institute for Reference Materials and Measurements (IRMM) in Geel, Belgium for the purpose of producing and distributing certified reference materials.

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
Not applicable.
b) Conclusions of post-release monitoring
Not applicable.
c) Results of the release in respect to any risk to human health and the environment (submitted to the Competent Authority according to Article 10 of Directive 2001/18/EC)
Not applicable.

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

a) Release country
Field testing of 73496 oilseed rape has been carried out in the US since 2007 and Canada since 2008.
b) Authority overseeing the release
US: United States Department of Agriculture (USDA) Canada: Canadian Food Inspection Agency (CFIA)
c) Release site
Release sites were selected to represent typical growing regions for spring-type oilseed rape in the US and Canada.
d) Aim of the release
Breeding, agronomic performance, efficacy, yield, ecological observations, product development, and regulatory data generation.
e) Duration of the release
Release durations included one growing season for the spring-type oilseed rapes in the US and Canada.
f) Aim of post-releases monitoring
Monitoring of volunteers
g) Duration of post-releases monitoring
36 months

h) Conclusions of post-release monitoring

If volunteers occur, destroy by herbicide treatment, hand weeding, mechanical cultivation, or killing frost or freeze.

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

Environmental release testing of 73496 oilseed rape showed no evidence of any adverse effects to human/animal health or the environment.