Application for authorisation to place on the market NS-B5ØØ27-4 oilseed rape in the European Union, according to Regulation (EC) No 1829/2003 on genetically modified food and feed

EFSA-GMO-NL-2019-XXX/ EFSA-Q-2019-XXXXX

Part VII

Summary of Applications

1. GENERAL INFORMATION

1.1. Details of application

(a) Member State of application

The Netherlands

(b) Application number

Not available at the time of submission

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

Oilseed rape: NS-B5ØØ27-4; Aquaterra™ (oil for the aquaculture market); Nutraterra™ (oil for the nutraceutical market).

(d) Date of acknowledgement of valid application

Not available at the time of submission.

1.2. Applicant

(a) Name of applicant

Nuseed Pty. Ltd.

(b) Address of applicant

Nuseed Pty. Ltd.
103-105 Pipe Road
Laverton North VIC 3026
Australia

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

Nufarm B.V.
Rivium Quadrant 75-7
LC 2909 Capelle a/d IJssel
Nederland

1.3. Scope of the application

(a) Genetically modified food

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

(b) Genetically modified feed

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

(c) Genetically modified plants for food or feed uses

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

The scope of this application covers the import, processing and all uses of NS-B5ØØ27-4, as any other oilseed rape, except cultivation.

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

Yes ☐

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

In this application a risk assessment is presented based on data from field trials that were performed in several locations in Australia, Canada and the USA. The safety of NS-B5ØØ27-4 with regard to human and animal health and the environment has been demonstrated. In the following sections the respective elements of the risk assessment are summarised.

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

No ☐

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

The NS-B5ØØ27-4 event is authorised for cultivation in Australia and the USA. It is authorised for food and feed use in Australia and New Zealand.

Australia (cultivation/feed):	Submitted: 10-2-2017	Authorised: 13-2-2018
USA (cultivation):	Submitted: 27-2-2018	Authorised: 23-8-2018
Australia (food):	Submitted: 10-2-2017	Authorised: 20-12-2017
New Zealand (food/feed):	Submitted: 10-2-2017	Authorised: 20-12-2017
USA (food/feed):	Submitted: 31-3-2017	Authorised: Pending

Submissions for food, feed, and environmental approval have been made in Canada. Submissions have been made for import approvals in China and Japan.

Canada (food):	Submitted: 20-6-2017
Canada (cultivation):	Submitted: 20-6-2017
Canada (feed):	Submitted: 16-7-2018
China (import):	Submitted: 13-3-2018
Japan (food):	Submitted: 22-2-2019
Japan (feed):	Submitted: 30-7-2019

1.8. General description of the product

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

The commercial oilseed rape variety AV Jade has been modified to produce docosahexaenoic acid (DHA), an omega-3 long-chain polyunsaturated fatty acid (ω3 LC-PUFA), in the seed. Seven genes were inserted to introduce the new fatty acid biosynthesis pathway leading to the production of DHA.

The genes were derived from yeast and micro-algae species:

- *Lackl-Δ12D*, a Δ12-desaturase gene from the yeast *Lachancea kluyveri*;
- *Picpa-ω3D*, an ω3-/Δ15-desaturase gene from the yeast *Pichia pastoris*;
- *Micpu-Δ6D*, a Δ6-desaturase gene from the micro-alga *Micromonas pusilla*;
- *Pyrco-Δ6E*, a Δ6-elongase gene and *Pyrco-Δ5E*, a Δ5-elongase gene from the micro-alga *Pyramimonas cordata*;
- *Pavsa-Δ5D*, a Δ5-desaturase gene and *Pavsa-Δ4D*, a Δ4-desaturase gene from the micro-alga *Pavlova salina*;

Also, *pat*, the phosphinothricin-N-acetyltransferase (glufosinate ammonium resistance) gene from the bacterium *Streptomyces viridochromogenes*, was included as an initial selection marker. This marker was not used in the breeding process, nor is glufosinate ammonium resistance intended to be marketed in NS-B5ØØ27-4 oilseed rape varieties.

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

The scope of the application for authorisation of NS-B5ØØ27-4 oilseed rape in the EU is for all uses according to Art 3 (1) and 15 (1) of Regulation (EC) No 1829/2003, with the exception of cultivation.

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

The intended use of NS-B5ØØ27-4 oilseed rape is its oil. The grain will be used in the same way as any commercial oilseed rape in the EU. The same handling, processing and trading operators will be involved for grain or meal.

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

From the comparative analysis of NS-B5ØØ27-4 oilseed rape it was concluded that this oilseed rape is as safe as any other oilseed rape. NS-B5ØØ27-4 may be imported in the EU after authorisation and can be handled in the same way as any other oilseed rape grain and derived products produced within the EU. NS-B5ØØ27-4 oilseed rape will be grown in a closed-loop identity preservation manner outside of the EU in order to extract the value of the oil. Therefore, no specific conditions for use or handling are envisaged beyond maintaining identity preservation for NS-B5ØØ27-4. NS-B5ØØ27-4 grain and derived products will be labelled according to Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003.

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

The scope of this application is import, processing and all uses of NS-B5ØØ27-4, not cultivation. The commodity and derived products can be processed and used throughout the EU as any other commercial oilseed rape.

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

The scope of this application is import, processing and all uses of NS-B5ØØ27-4, not cultivation. The commodity and derived products are suitable for all appropriate uses in all regions of the EU.

(g) Any proposed packaging requirements

NS-B5ØØ27-4 oil will be marketed under its brands. The grain or meal will be handled and packaged as any other commercial oilseed rape. No specific packaging is required for NS-B5ØØ27-4.

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

Operators handling NS-B5ØØ27-4 shall be required to label products containing or consisting of NS-B5ØØ27-4 with the words "genetically modified oilseed rape with long chain omega-3 fatty acid" or "contains genetically modified oilseed rape with long chain omega-3 fatty acid". Food and feed products derived from NS-B5ØØ27-4 shall be labelled "produced from genetically modified oilseed rape containing long chain omega-3 fatty acid". In case the products are not individually labelled, operators shall ensure that an indication that the food or feed product is "produced from genetically modified oilseed rape containing long chain omega-3 fatty acid" is transmitted on an accompanying document to the operator receiving the product.

In accordance with the requirements of point A(8) of Annex IV to Directive 2001/18/EC, the labelling will consist of:

- Commercial name of the product;
- A statement that 'this product contains genetically modified oilseed rape';
- Name of the GMO or the unique identifier code;
- Name and full address of the person established in the Community who is responsible for the placing on the market;
- An indication on how to access the information in the publicly accessible part of the register.

According to Regulation (EC) No 1830/2003 concerning the traceability and labelling of GMOs and food and feed products produced from GMOs, traces of authorised GMOs in a proportion no higher than 0.9 %, provided that these trace amounts are adventitious or technically unavoidable, do not need labelling.

(i) Estimated potential demand

(i) In the EU

The EU is itself a big producer of oilseed rape. Oilseed rape is imported predominantly from Ukraine, Australia and Canada. There are no anticipated changes to the demand for oilseed rape as a result of the commercialisation of NS-B5ØØ27-4.

(ii) In EU export markets

The EU is not a major exporter of oilseed rape. Moreover, the current application is not applying for authorisation for cultivation of NS-B5ØØ27-4. The export demand for rapeseed oil is not expected to change.

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

NS-B5ØØ27-4.

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

As the scope of this application is import, processing and to all uses of NS-B5ØØ27-4 oilseed rape, except for cultivation, unintended release will likely occur during import, storage and processing. However, modern methods of grain handling minimise such losses and thereby limit environmental exposure. All oilseed rape crushers in the EU are HACCP compliant and will avoid spilling as much as possible. Furthermore, the locations of spillage will be predictable, since they will be near the storage facilities and along transportation routes. In many cases, environmental conditions at these sites are unlikely to be conducive to germination, growth and reproduction of oilseed rape. In ports and at processing facilities there are no or poor soil conditions. However, oilseed rape is able to establish self-perpetuating populations outside agricultural areas, mainly in seminatural and ruderal habitats. Oilseed rape prefers disturbed areas but is not able to compete with perennial vegetation. Usually feral populations decline over a period of years unless the site is repeatedly disturbed. In undisturbed natural habitats, oilseed rape lacks the ability to establish stable populations over successive years.

Oilseed rape may transfer genes to sexually compatible relatives. However, the genes introduced in NS-B5ØØ27-4 will not provide a selective advantage to the resulting hybrid. Tolerance to glufosinate ammonium would be advantageous only in situations where this herbicide would be applied, not in natural environments.

From the environmental risk assessment, it was concluded that accidental release of NS-B5ØØ27-4 would not lead to immediate or delayed environmental harm.

NS-B5ØØ27-4 oilseed rape is as safe as and can be used in the same way as any other commercial oilseed rape variety. NS-B5ØØ27-4 is not different from other oilseed rape, except for its fatty acid profile and glufosinate ammonium tolerance.

Consequently, specific measures to manage incidental unintended release or misuse are not considered necessary.

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

2.1. Complete name

(a) Family name: Brassicaceae
(b) Genus: *Brassica*
(c) Species: *napus* (2n = 38)
(d) Subspecies: *napus*
(e) Cultivar/breeding line: AV Jade
(f) Common name: Oilseed rape, canola, rape, rapeseed, turnip

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

Brassica napus has been cultivated in Europe and Asia since ancient times. Since the development of low erucic acid and low glucosinolate varieties (canola, double low, double zero), production has increased and expanded. Nowadays, oilseed rape is mainly grown in Canada, China, Europe, India, Australia and the USA.

Within the EU the main producers are France, Germany, Poland and the United Kingdom.

2.3. Information concerning reproduction (for environmental safety aspects)

(a) Mode(s) of reproduction

Oilseed rape reproduces by seed. The species is predominantly self-pollinating, but cross-fertilisation occurs as well. Cross-pollination occurs mainly through physical contact with neighbouring plants, but pollen is also transferred over longer distances by wind and insects, in particular honeybees (*Apis mellifera*) and bumblebees (*Bombus* sp.). The yellow flowers are produced in racemes. After fertilisation a cylinder-shaped silique is formed. Each oilseed rape plant produces hundreds of small, spherical, light brown to black seeds.

(b) Specific factors affecting reproduction

As with any crop, poor soil, pests and diseases, and harsh weather conditions will reduce the seed production capacity.

The presence of pollinating insects reduces the flowering time. Bee hives are usually introduced into oilseed rape fields to facilitate pollination and maximise seed set.

(c) Generation time

Spring oilseed rape develops from seed to seed in 90 to 210 days. Winter oilseed rape needs 11-12 months to complete the cycle.

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

Cultivated oilseed rape varieties

Oilseed rape readily cross-pollinates with neighbouring oilseed rape plants though physical contact. Small to long distances for pollen to be covered are facilitated by wind or pollinating insects. Winter cultivars flowering in early spring are more prone to wind-borne cross-pollination whereas spring cultivars, flowering in summer show an increase in bee borne cross-pollination. The vast majority of pollen travels less than 10 m and the

level of pollen decreases with the distance. However, covered distances up to 1.5 km were evidenced. Pollen movement will be influenced by wind direction, speed, topography and vegetation. When bees are involved, the majority of pollen is transported less than 5 m. However, bees may cover a distance of 1-2 km, and even 4 km.

Wild relatives

For interspecific crosses to be successful both pre- and post-fertilisation barriers needs to be overcome. Pre-fertilisation barriers include proximity and pollen movement, pollen longevity, synchronicity of flowering, breeding system, floral characteristics and competitiveness of pollen. Post-fertilisation barriers include sexual compatibility, hybrid viability and fertility.

Related species that can hybridise with *B. napus* and that are present in the EU are *B. carinata, B. juncea, B. oleracea, B. nigra, B. rapa, Hirschfeldia incana, Raphanus raphanistrum* and *Sinapis arvensis*. They are cultivated as a crop or present in the environment as feral or wild plants.

Generally, crosses between two species are possible only if the female species has a polyploidy level at least as high as the pollinating male species.

B. rapa is self-incompatible which favours outcrossing with relatives. *B. rapa* and *B. juncea* have the highest sexual compatibility with *B. napus*. However, *B. juncea* is self-compatible reducing the chances of cross-pollination. Interspecific hybrids with both species in the field have been reported in several countries.

Also, crosses between *B. napus* and *B. nigra* or *B. oleracea* may give viable progeny under controlled conditions. Crosses between *B. napus* and *B. carinata* or *R. raphanistrum* or *S. arvensis* are hard to accomplish. Also *H. incana* is able to form hybrids with *B. napus*. Often human intervention is needed for the cross to be successful. Reports on naturally occurring hybrids with these species exist, although cross-fertilisation occurs at very low frequencies.

Interspecific hybrids tend to be less vigorous with varying levels of sterility and genetic instability. For gene introgression to be successful, the resulting hybrid needs to survive, compete and be fertile for subsequent backcrossing. This second step is becoming very unlikely with weak or sterile hybrids.

Inter-genera cross-pollinations events are also reported between *B. napus* and other wild relatives. However, techniques such as manual pollination, emasculation, embryo-rescue etc. were necessary.

2.5. Survivability (for environmental safety aspects)

(a) Ability to form structures for survival or dormancy

The structures for oilseed rape to survive are the seeds. *B. napus* seeds have no primary dormancy, but secondary dormancy can be induced by abiotic stresses.

(b) Specific factors affecting survivability

The optimal temperature for *B. napus* to germinate is 20°C. However, seeds will also germinate at temperatures as low as 2-3°C. Below 10°C seeds will germinate progressively slower and the percentage of germinated seeds will drop.

Most seeds that are lost after harvest will germinate immediately if conditions of moist and temperature are favourable and be killed by frost later on. Others will deteriorate or be scavenged, and a small part will develop secondary dormancy. Unfavourable

environmental conditions (*e.g.* large temperature fluctuations, low soil moisture, prolonged darkness, low oxygen supply) may induce secondary dormancy in seeds. The susceptibility to induced dormancy is partly genetically determined. Dormant seed is able to persist and stay viable in the soil seedbank for several years and contributes to the oilseed rape weed population in subsequent crops. Dormancy can be reversed by several factors, such as exposure to light, cold stratification and alternating temperatures.

In disturbed soil seed may persist for 5-6 years, while in undisturbed soils seed may still germinate after a longer period up to 16 years. However, seed germination capacity is strongly reduced after a prolonged period of dormancy. Moreover, oilseed rape weeds can be managed using a diversity of techniques.

2.6. Dissemination (for environmental safety aspects)

(a) Ways and extent of dissemination

Pollen is disseminated by wind and pollinating insects. Most pollen is deposited within a few meters from the source plant. The density very soon drops with increasing distance. However, distances of a few kilometres have been recorded.

Seed dispersal may occur in several ways: via silique shatter prior to harvest, spills at harvest and during transport, by animals, by wind and water. Spilled seed on the field may be added to the seedbank. Along transportation routes and around agricultural land feral populations may arise. These populations are transient in nature, but may be replenished, *e.g.* along frequently used transportation lines. Populations may contain from a few plants to thousand plants per site.

(b) Specific factors affecting dissemination

Pollen dissemination and outcrossing rate varies according to cultivar, shape and size of the fields, local topography and environmental conditions. The use of cultivars with some level of sterility can lead to higher outcrossing rates than with conventional cultivars. Small or narrow fields tend to show higher outcrossing rates, as they may cause bees to forage into more distant areas to collect a load of pollen or nectar. Physical barriers such as woods and hedges may hinder pollen flow. Unfavourable weather conditions can seriously limit pollinating insect activity. Air-borne pollen transport is dependent on the wind velocity and airflow.

B. napus seeds can be disseminated to neighbouring, non-agricultural habitats. Unless disturbed on regular basis *B. napus* is not able to establish, as it is a poor competitor.

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

The sexually compatible species are present in the EU as wild plants or cultivated professionally or in private gardens and may be present as feral populations.

The vegetable-type relatives of *B. napus* are harvested before flowering.

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

Not applicable.

2.9. Other potential interactions, relevant to the genetically modified plant, of the plant with organisms in the ecosystem where it is usually grown, or used elsewhere,

including information on toxic effects on humans, animals and other organisms (for environmental safety aspects)

Oilseed rape interacts with micro-organisms, such as bacteria and fungi, and other organisms, such as invertebrates, birds and mammals.

B. napus contains naturally occurring toxicants, *i.e.* erucic acid and glucosinolates. Intensive breeding has reduced the level of these toxicants resulting in so-called double low or canola-type varieties. The genetically modified oilseed rape variety used for this application is a canola quality variety, *i.e.* it has a low erucic acid content in the fatty acid fraction and very low glucosinolate content in the meal. *B. napus* is not known to be allergenic.

3. MOLECULAR CHARACTERISATION

3.1. Information relating to the genetic modification

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

NS-B5ØØ27-4 was developed through *Agrobacterium*-mediated transformation of conventional oilseed rape cotyledonary petioles.

(b) Nature and source of the vector used

The binary vector plasmid pJP3416_GA7-ModB consists of the vector backbone, T-DNA border fragments and a T-DNA of 8 genes with their regulatory sequences. The size of the vector including the T-DNA is 31.5 kb. It contains seven genes for enzymes that collectively convert oleic acid (OA) to DHA. The T-DNA also contains the *pat* gene encoding phosphinothricin N-acetyltransferase, that was used as a selectable marker.

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

Table 1 list all components of pJP3416_GA7-ModB, their size, position, function and source organism.

Table 1. Genetic elements in vector pJP3416_GA7-ModB used for the development of NS-B5ØØ27-4

Genetic Element	Size (bp)	Location in Vector	Description, Function and Source
Vector Backbone (1 - 3,397 bp)			
nptIII	795	213 - 1007	Coding sequence of neomycin-kanamycin phosphotransferase type III
TrfA	1149	1306 - 2454	Coding sequence of plasmid replication initiator protein TrfA derived from plasmid PK2
Origin_ColE1	881	2512 - 3392	Origin of replication (Col E1) for maintenance of high copy number of plasmid in *Escherichia coli* (*E. coli*)
T-DNA (3,398 - 26,909 bp)			
T-DNA right border	163	3398 - 3560	*Agrobacterium tumefaciens* right border sequence used for transfer of T-DNA

Genetic Element	Size (bp)	Location in Vector	Description, Function and Source
Multiple cloning site	68	3561 - 3628	Multiple cloning site for vector construction
TER_Linus-Cnl2	538	3629 - 4166	Terminator of *Linum usitatissimum* conlinin2
Micpu-Δ6D	1395	4175 - 5569	Coding sequence of Δ6-desaturase from microalga *Micromonas pusilla*
Tobacco mosaic virus 5' UTR leader	65	5573 - 5637	Enhancer from tobacco mosaic virus 59
PRO_Linus-Cnl2	2033	5646 - 7678	Promoter of *Linum usitatissimum* conlinin 2
PRO_Arath-FAE1	934	7685 - 8618	Promoter of *Arabidopsis thaliana* fatty acid elongase1
Tobacco mosaic virus 5' UTR leader	65	8619 - 8683	Enhancer from tobacco mosaic virus 59
Pyrco-Δ5E	807	8687 - 9493	Coding sequence of Δ5-elongase from microalga *Pyramimonas cordata*
TER_Glyma-Lectin	334	9509 - 9842	Terminator of *Glycine max* lectin
PRO_Brana-FP1	358	9843 - 10200	Promoter of *Brassica napus* napin
Tobacco mosaic virus 5' UTR leader	65	10201 - 10265	Enhancer from tobacco mosaic virus 59
Pavsa-Δ5D	1281	10269 - 11549	Coding sequence of Δ5-desaturase from microalga *Pavlova salina*
TER_Agrtu-NOS	255	11550 - 11804	Terminator of *Agrobacterium tumerfaciens* nopaline synthase
MAR_Nicta-RB7	1168	11805 - 12972	Rb7 matrix attachment regions of *Nicotiana tabacum*
TER_Linus-Cnl1	734	12973 - 13706	Terminator of *Linum usitatissimum* conlinin1
Picpa-ω3D	1251	13707 - 14957	Coding sequence of Δ15−/ω3-desaturase form yeast *Pichia pastoris*
Tobacco mosaic virus 5' UTR leader	65	14961 - 15025	Enhancer from tobacco mosaic virus 59
PRO_Linus-Cnl1	450	15026 - 15475	Promoter of *Linum usitatissimum* conlinin1
PRO_Linus-Cnl2	2033	15476 - 17508	Promoter of *Linum usitatissimum* conlinin2
Tobacco mosaic virus 5' UTR leader	65	17509 - 17573	Enhancer from tobacco mosaic virus 59
Pavsa-Δ4D	1347	17577 - 18923	Coding sequence of Δ4-desaturase from microalga *Pavlova salina*
TER_Linus-Cnl2	538	18924 - 19461	Terminator of *Linum usitatissimum* conlinin2
PRO_Linus-Cnl1	450	19462 - 19911	Promoter of *Linum usitatissimum* conlinin1
Tobacco mosaic virus 5' UTR leader	65	19912 - 19976	Enhancer from tobacco mosaic virus 59
Lackl-Δ12D	1254	19980 - 21233	Coding sequence of Δ12-desaturase from yeast *Lachancea kluyveri*

Genetic Element	Size (bp)	Location in Vector	Description, Function and Source
TER_Linus-Cnl1	734	21234 - 21967	Terminator of *Linum usitatissimum* conlinin1
MAR_Nicta-RB7	1168	21968 - 23135	Rb7 matrix attachment regions of *Nicotiana tabacum*
PRO_Arath-FAE1	934	23144 - 24077	Promoter of *Arabidopsis thaliana* fatty acid elongase1
Tobacco mosaic virus 5' UTR leader	65	24078 - 24142	Enhancer from tobacco mosaic virus 59
Pyrco-Δ6E	870	24146 - 25015	Coding sequence of Δ6-elongase from microalga *Pyramimonas cordata*
TER_Glyma-Lectin	334	25016 - 25349	Terminator of *Glycine max* lectin
PRO_35S×2	538	25372 - 25909	Promoter of cauliflower mosaic virus gene encoding the 35S RNA
pat	552	25919 - 26470	Coding sequence of phosphinothricin N-acetyltransferase from bacterium *Streptomyces viridochromogenes*
TER_Agrtu-NOS	253	26479 - 26731	Terminator of *Agrobacterium tumerfaciens* nopaline synthase
T-DNA left border	161	26749 - 26909	*Agrobacterium tumefaciens* left border sequence used for transfer of T-DNA
Vector Backbone (26,910 - 31,564 bp)			
Origin_RiA4	4636	26924 - 31559	Origin of replication (RepA) for maintenance of plasmid in *Agrobacterium*

3.2. Information relating to the genetically modified plant

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

NS-B5ØØ27-4 oilseed rape was developed to produce DHA, a fatty acid that is normally not present in the crop. To that end seven genes were introduced for enzymes in a single pathway to convert OA into DHA (Figure 1). OA is converted to linoleic acid (LA) by the desaturase Lackl-Δ12D, LA is desaturated to α-linolenic acid (ALA) by Picpa-ω3D, ALA to stearidonic acid (SDA) by Micpu-Δ6D desaturase, SDA is converted to eicosatetraenoic acid (ETA) by Pyrco-Δ6E elongase, ETA to eicosapentaenoic acid (EPA) by Pavsa-Δ5D desaturase, EPA to docosapentaenoic acid (DPA) by Pyrco-Δ5E elongase and DPA to DHA by Pavsa-Δ4D desaturase.

The resulting phenotype is an oilseed rape plant that contains ω3 LC-PUFAs, *i.e.* DHA, DPA and EPA, in the seed oil fraction. DHA, DPA and EPA produced from oilseed rape aim to provide for an alternative for these fatty acids from fish or algae for human consumption as well as for feed, especially in aquaculture.

Furthermore, the *pat* gene was introduced to encode PAT that confers tolerance to phosphinothricin and glufosinate ammonium-based herbicides, it was used as a selectable marker in the transformation process to develop NS-B5ØØ27-4. It was not used in the breeding process, nor is it intended to be marketed in NS-B5ØØ27-4 oilseed rape varieties.

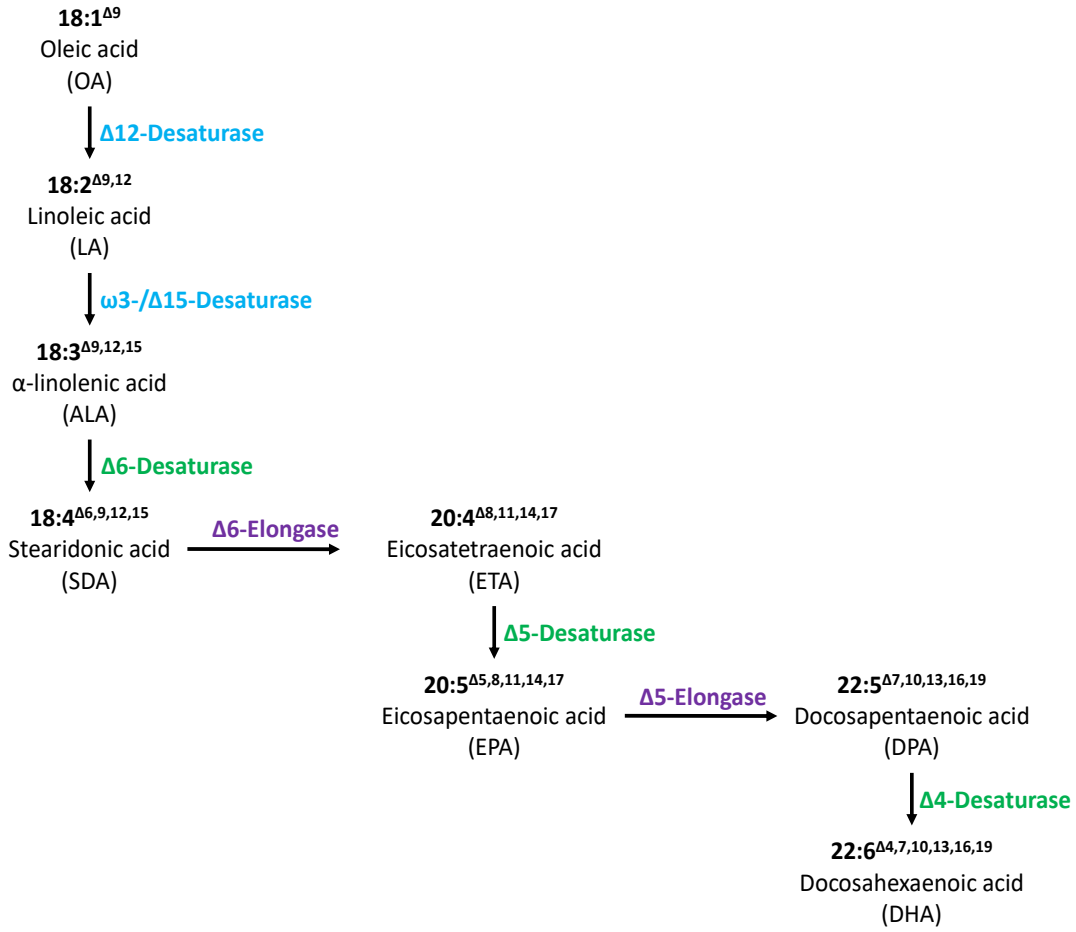

Figure 1 DHA biosynthesis pathway engineered into NS-B5ØØ27-4.

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

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

NS-B5ØØ27-4 contains two T-DNA inserts, one on chromosome A05 and the other on chromosome A02. The A02 T-DNA insert only has four fatty acid synthesis genes and the A05 T DNA insert has a duplicated eight-gene set.

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

No deletion was intended, but the A02 T-DNA insert replaced a 15 bp sequence from the 3' UTR of the *hpp* gene of unknown function. The A05 T-DNA insert replaced a 20 bp sequence in the 2nd exon of the Pto-Interacting (*pti*) gene. The *pti* gene encodes a serine/threonine kinase involved in hypersensitive response-mediated signalling and disease resistance.

However, agronomic, phenotypic and compositional analysis did not point to any deviation, probably because multiple homologous genes are present in the amphidiploid *B. napus* genome.

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

The subcellular location of both inserts in NS-B5ØØ27-4 was identified through vector-targeted, Illumina-based sequencing. One insert resides on chromosome A02,

the other on chromosome A05 (A-genome). Their location on the nuclear genome on separate chromosomes was confirmed by their independent Mendelian segregation in crossing experiments.

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

The A02 T-DNA insert contains the T-DNA right border (RB) with the genes *Micpu-Δ6D*, *Pyrco-Δ5E*, *Pavsa-Δ5D* and *Picpa-ω3D*. The A05 T-DNA insert has two sets of the eight-gene cassette from binary vector pJP3416_GA7-ModB. The two eight-gene sets are linked by 156 bp of palindromic T-DNA left border (LB) sequence and flanked by 40 bp of T-DNA RB sequence upstream and 42 bp of T-DNA RB sequence downstream. The two eight-gene sets form a palindromic structure with RB-LB:LB-RB orientation. No vector backbone sequences were inserted.

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

Not applicable

3.2.3. Information on the expression of the insert

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

The DHA pathway enzyme genes are each regulated by a seed specific promoter. Their expression is expected to be present in seeds, but absent in other tissues. The PAT protein is expected to be expressed in all tissues as the gene is driven by a constitutive promoter.

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

Protein expression analyses was performed on samples taken from two field trial sites in 2015 and three field trial sites in 2016, all in Australia. At each trial site samples were taken at different growth stages (5 time points; 7 fractions) representative of specific growth stages of oilseed rape allowing for collection of various tissue types, including leaves, roots, siliques and reproductive tissues. In this way it was possible to demonstrate the seed-specific expression of the DHA pathway proteins.

Quantification by liquid chromatography-mass spectrometric multiple reaction monitoring confirmed that none of the targeted peptides of the DHA biosynthesis pathway were detected in protein extracts from the non-seed tissues of NS-B5ØØ27-4 oilseed rape. All seven peptides representing the DHA biosynthesis pathway enzymes were detected in developing and/or mature seeds of NS-B5ØØ27-4 oilseed rape.

PAT expression was detected in all tissue types of NS-B5ØØ27-4.

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

The NS-B5ØØ27-4 event has been advanced seven generations through single seed descent. Via PCR analysis and Southern hybridisation the genetic stability of the inserts was demonstrated. Also crosses were performed showing the independent Mendelian segregation of both inserts and the stability in other genetic backgrounds.

Phenotypic stability was demonstrated analysing the fatty acids in each generation of selfed plants as well as in crosses by gas chromatography-flame ionisation detector.

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

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

Phenotypic and agronomic data were collected from 20 field locations over three consecutive years (8 locations in Australia in 2015, 4 locations in Australia in 2016, 2 locations in Canada in 2016, 3 locations in Canada in 2017, and 3 locations in the USA in 2017). In each trial NS-B5ØØ27-4 was compared to the conventional counterpart and commercial oilseed rape varieties.

No differences regarding reproduction characteristics have been observed during these field trials.

(b) Dissemination

See Section 3.2.5(a) above.

No differences regarding dissemination characteristics have been observed during these field trials.

(c) Survivability

See Section 3.2.5(a) above.

No differences regarding survivability characteristics have been observed during these field trials.

(d) Other differences

See Section 3.2.5(a) above.

No other differences have been observed during these field trials in relation to environmental safety.

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

(a) Plant to bacteria gene transfer

None of the genetic elements in NS-B5ØØ27-4 has a genetic transfer function. Therefore, no changes are expected in the ability of NS-B5ØØ27-4 to transfer genetic material to bacteria.

(b) Plant to plant gene transfer

Field trials did not reveal differences regarding reproduction characteristics compared to the conventional counterpart and commercial reference varieties. Therefore, the outcrossing frequency to other oilseed rape varieties or to wild relatives is unlikely to be different.

4. COMPARATIVE ANALYSIS

4.1. Choice of the conventional counterpart and additional comparators

Oilseed rape variety AV Jade, the recipient variety of NS-B5ØØ27-4, was used as the conventional counterpart to support the safety assessment of NS-B5ØØ27-4. Several commercial reference varieties with a history of safe use were included in the comparative assessments.

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

In 20 field locations over three consecutive years (8 locations in Australia in 2015, 4 locations in Australia in 2016, 2 locations in Canada in 2016, 3 locations in Canada in 2017, and 3 locations in the USA in 2017) NS-B5ØØ27-4 was compared to the conventional counterpart and commercial oilseed rape varieties. All trial sites were chosen to be representative for the commercial oilseed rape growing areas, including varying soil types and climatic conditions. The experimental design of each trial site was a complete randomised block design with 5 replicates. Difference and equivalence tests were conducted using statistical models provided in EFSA guidances.

4.3. Selection of material and compounds for analysis

The seeds of oilseed rape are harvested for their oil, predominantly for human consumption, and meal for animal feed. Therefore, the compositional analyses were performed on seeds collected from NS-B5ØØ27-4, the conventional counterpart AV Jade and 7 reference varieties, because oilseed rape oil fractions and meal are derived from seeds.

Compositional assessments were performed in accordance with the principles outlined in the OECD consensus document on compositional considerations for new varieties of low erucic acid rapeseed (canola). Compositional analysis included the following analytes: protein, fat, acid detergent fibre, neutral detergent fibre, crude fibre, ash, carbohydrates, fatty acids, amino acids, vitamins, minerals, phytosterols and key anti-nutrients.

4.4. Comparative analysis of agronomic and phenotypic characteristics

Results from the agronomic and phenotypic analysis indicate that NS-B5ØØ27-4 oilseed rape is not different from its conventional counterpart and/or equivalent to commercial oilseed rape reference varieties with the exception of the fatty acid profile. The glufosinate ammonium tolerance trait will not be commercialised as such and was therefore not tested in the field.

4.5. Effect of processing

Oilseed rape seeds are processed to obtain oil predominantly for human consumption but also to incorporate in animal feed. The remaining part is the meal that is used as a protein and fibre source for animals. Oil from NS-B5ØØ27-4 will be used as an ingredient for aquaculture, human nutrition supplement, and animal feed as an alternative to fish oil.

NS-B5ØØ27-4 oilseed rape will be processed in the same way as conventional oilseed rape. NS-B5ØØ27-4 oilseed rape will be processed in dedicated oil processing facilities, operated in an identity preserved manner to retain the commercial value of the product. The genetic modification has no effect on the oil extraction process.

5. TOXICOLOGY

(a) Toxicological testing of newly expressed proteins

All newly expressed DHA pathway enzymes in NS-B5ØØ27-4 are homologous to desaturase or elongase proteins universally present in the human diet. The PAT protein has been introduced in many GM crops that have been consumed without adverse effects to human or animal health.

Bioinformatic analyses demonstrated that Lackl-Δ12D, Picpa–ω3D, Micpu-Δ6D, Pyrco-Δ6E, Pavsa-Δ5D, Pyrco-Δ5E, Pavsa-Δ4D, and PAT proteins are not structurally or functionally related to toxic proteins that adversely affect human or animal health.

In addition, the Lackl-Δ12D, Picpa–ω3D, Micpu-Δ6D, Pyrco-Δ6E, Pavsa-Δ5D, Pyrco-Δ5E, Pavsa-Δ4D, and PAT proteins are expressed in very low levels in NS-B5ØØ27-4 seeds, lose their functional activity upon heating and are digested in gastric model systems.

(b) Testing of new constituents other than proteins

NS-B5ØØ27-4 was developed to produce the ω3 LC-PUFAs, EPA, DPA and DHA. These fatty acids are not synthesised by conventional oilseed rape. ω3 LC-PUFAs are essential fatty acids, meaning they are required for human health and obtained primarily from diet as they cannot be produced by the human body.

DHA, DPA and EPA have a history of safe use. Fish and fish products, especially fish oils are the most common source of EPA and DHA for enrichment of foods and supplementation and provide the highest amounts of DHA. Also, meat, dairy, margarine, and egg products, next to breast milk contain DHA.

(c) Information on natural food or feed constituents

NS-B5ØØ27-4 seed composition does not differ from conventional oilseed rape seed, except for the composition of fatty acids in the oil fraction. NS-B5ØØ27-4 was intended to produce DHA, a fatty acid not present in conventional oilseed rape, but with reported health effects.

The level of erucic acid in the oil and glucosinolates in the meal has not changed compared to its conventional counterpart.

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

Compositional analysis establishes that the seed is not different from conventional oilseed rape except for the oil composition. Any observed differences fell within the range of natural variability for oilseed rape with a history of safe use. In addition, the safety for humans and animals of the Lackl-Δ12D, Picpa–ω3D, Micpu-Δ6D, Pyrco-Δ6E, Pavsa-Δ5D, Pyrco-Δ5E, Pavsa-Δ4D, and PAT proteins has been demonstrated on the basis of extensive molecular characterisation, similarity to proteins with a history of safe use, lack of structural similarities with known protein toxins and allergens and rapid digestion in simulated digestive fluids. Taken together, there is no evidence of any adverse effects of these proteins expressed in NS-B5ØØ27-4 on human or animal health.

Nevertheless, even without indication of adverse effects, a 90-day feeding study with NS-B5ØØ27-4 oil and meal and a 28-day oral gavage toxicity study in rats was performed. No treatment-related clinical observations, ocular abnormalities, or changes in body weights, food consumption, clinical pathology parameters, or organ weights were seen. The same is true for the 28-day oral gavage toxicity study of NS-B5ØØ27-4 oil in rats.

6. ALLERGENICITY

(a) Assessment of allergenicity of the newly expressed protein

The Lackl-Δ12D, Picpa–ω3D, Micpu-Δ6D, Pyrco-Δ6E, Pavsa-Δ5D, Pyrco-Δ5E, Pavsa-Δ4D, and PAT proteins have been assessed for their potential allergenicity according to the recommendations of Codex Alimentarius.

Bioinformatic analyses did not result in significant matches with any allergen. Moreover, the source organisms for the newly expressed proteins are not known to be allergenic.

In addition, these proteins are rapidly digested in simulated gastric fluid, are not stable at high temperature treatments, and these proteins constitute a very small portion of the total protein present in the seed.

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

In general oilseed rape is not known to be an allergenic food crop. The genetic modification did not alter that.

The NS-B5ØØ27-4 food product is oil. The protein content is either very low or absent in rapeseed oil. Food allergy to low erucic acid rapeseed oil has not been reported in the scientific literature.

7. NUTRITIONAL ASSESSMENT

(a) Nutritional assessment of the genetically modified food

The nutritional composition of NS-B5ØØ27-4 oilseed rape is similar to conventional oilseed rape except for its oil that was intentionally modified to contain the ω3 LC-PUFAs EPA, DPA and DHA. NS-B5ØØ27-4 oil is intended to be a partial substitute of fish oil and algal oils that contain healthy omega-3 fatty acids.

The assessment of the anticipated intake of EPA, DPA and DHA from NS-B5ØØ27-4 indicated that the consumption of food products containing NS-B5ØØ27-4 oil would not substantially change EPA, DPA and DHA consumption compared to dietary recommendations. The changes of other fatty acids in NS-B5ØØ27-4 oil in comparison to conventional rapeseed oil, is not considered a risk for human health.

(b) Nutritional assessment of the genetically modified feed

Fish oil and fish meal derived from wild fish are major sources of the essential fatty acids EPA and DHA for use in salmon and trout aquaculture feeds. These fatty acids accumulate in the salmon and trout flesh and in turn are consumed by humans.

Feeding trials with Atlantic salmon confirm that oil from event NS-B5ØØ27-4 is a safe and effective replacement for fish oil in the fish feed.

The composition of NS-B50027-4 derived meal is similar to conventional oilseed rape meal except for the very small remaining oil fraction. A 42-day broilers study with NS-B50027-4 derived meal did not show any detrimental effects on animal health.

8. EXPOSURE ASSESSMENT — ANTICIPATED INTAKE/EXTENT OF USE

In order to derive commercial value from NS-B50027-4 oilseed rape, the crop will be grown and processed in an identity-preserved manner in oilseed rape growing regions of USA, Canada and/or Australia. The oil will be used in feed, food and nutraceutical applications where omega 3 fatty acid sources are currently being used. The by-product, NS-B50027-4 meal, has been shown to be compositionally comparable to other commodity oilseed rape meals and will be used in a manner similar to conventional oilseed rape meal.

Exposure/intake of humans

Exposure of humans to the newly expressed proteins is negligible as oil usually does not contain proteins.

The NS-B50027-4 oil will be refined for use as an alternate source of omega-3 fatty acids in existing food ingredient markets for fish oils or established omega-3 markets. The consumption of DHA in these foods is expected to remain on current trends. Also, in the event that NS-B50027-4 oil will be intermingled with conventional rapeseed oil for the food market, exposure to DHA will not raise safety concerns.

Exposure/intake of animals

Oilseed rape meal is used as a protein source for livestock, poultry and fish. Exposure of animals feeding on the meal to the newly expressed proteins is low as the expression level of these proteins in the seed is extremely low. Moreover, proteins will degrade during the oil extraction process.

Defatted oilseed rape meal only contains a low amount of residual oil. Feeding of NS-B50027-4 meal and taking into account the recommended maximum inclusion rates in feed for various farm animals, the exposure to DHA in the remaining NS-B50027-4 oil fraction will be low.

9. RISK CHARACTERISATION

Based on the hazard characterisation and exposure analysis, it can be concluded that NS-B5ØØ27-4 is as safe as conventional oilseed rape. The composition of the oil fraction in the seeds was modified as expected.

The molecular characterisation, the comparative analysis of agricultural and phenotypical characteristics and composition did not reveal any particular hazard.

Field trials comparing agronomic and phenotypic characteristics of NS-B5ØØ27-4 with its conventional counterpart and reference varieties demonstrated that the analysed traits fall within the normal ranges for oilseed rape. The composition of NS-B5ØØ27-4 seeds did not show any biologically relevant differences except for the intended modified fatty acid profile.

The safety of the food and feed derived from NS-B5ØØ27-4 was assessed studying the newly expressed proteins, Lackl-Δ12D, Picpa-ω3D, Micpu-Δ6D, Pyrco-Δ6E, Pavsa-Δ5D, Pyrco-Δ5E, Pavsa-Δ4D and PAT, using molecular and biochemical techniques.

The new constituents EPA, DPA and DHA have a history of safe use, and are beneficial for human health.

Toxicity studies on rats revealed no biologically or toxicologically relevant effects and support the conclusion that NS-B5ØØ27-4 oil and meal is as safe as conventional oilseed rape oil and meal.

The lack of hazardous findings combined with the low to negligible exposure of the newly expressed proteins Lackl-Δ12D, Picpa-ω3D, Micpu-Δ6D, Pyrco-Δ6E, Pavsa-Δ5D, Pyrco-Δ5E, Pavsa-Δ4D and PAT, in animal feed (meal) and oil respectively, confirms that feed derived from NS-B5ØØ27-4 oilseed rape is as safe as any oilseed rape feed product.

The human consumption of EPA, DPA and DHA contained in NS-B5ØØ27-4 oil will not pose a nutritional concern for the population. The decrease of intake of OA and LA and increase of ALA intake is not considered a risk for human health.

10. POST-MARKET MONITORING ON THE GENETICALLY MODIFIED FOOD OR FEED

Following the risk characterisation in the previous section, there are no intrinsic risks related to NS-B5ØØ27-4 oilseed rape.

Although NS-B5ØØ27-4 oilseed rape is initially targeted to fish feeding, it does not raise toxicity or allergenicity concerns if used for human or animal nutrition.

Recognising the health benefits of EPA, DPA and DHA in NS-B5ØØ27-4 oil, Nuseed believes there is no need for post-market monitoring.

11. ENVIRONMENTAL ASSESSMENT

The scope of this application under Regulation (EC) No 1829/2003 includes the import, processing and food and feed uses, but excluding the cultivation of NS-B5ØØ27-4 oilseed rape in the EU. This section includes a summary of the environmental risk assessment (ERA) as conducted in accordance with the principles of Annex II to Directive 2001/18/EC and following the EFSA ERA Guidances.

Since an extensive molecular, compositional and agronomic/phenotypic characterisation and environmental interaction assessment did not reveal any differences that might cause an adverse effect of NS-B5ØØ27-4, hazard characterisation for the import of NS-B5ØØ27-4 in the EU focuses principally on the characteristics of the Lackl-Δ12D, Picpa-ω3D, Micpu-Δ6D, Pyrco-Δ6E, Pavsa-Δ5D, Pyrco-Δ5E, Pavsa-Δ4D and PAT proteins and the resulting traits that might cause adverse effects in the environment.

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

NS-B5ØØ27-4 oilseed rape was developed to produce DHA in the oil fraction of the seeds. Within the scope of the application, NS-B5ØØ27-4 oilseed rape will not intentionally be released in the environment and no target organisms are associated with the modification.

Therefore, this section is not relevant to NS-B5ØØ27-4.

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

(a) Persistence and invasiveness

Extensive agronomic and phenotypic characterisation of NS-B5ØØ27-4 did not evidence changes in the reproduction, germination, seed persistence, invasiveness and hybridisation potential relative to the recipient variety or other reference varieties. Therefore, NS-B5ØØ27-4 is not more likely to be persistent or invasive than any other conventional oilseed rape variety.

(b) Selective advantage or disadvantage

The introduced traits do not represent an advantage given the scope of the application.

Laboratory tests revealed a reduced germination rate under stress conditions. This would be a disadvantage. Tolerance to glufosinate ammonium would be advantageous only in situations where this herbicide would be applied, not in natural environments.

(c) Potential for gene transfer

As this application excludes cultivation of NS-B5ØØ27-4 oilseed rape, for micro-organisms direct exposure routes would be the unintentional release of NS-B5ØØ27-4 seeds during handling and transporting of NS-B5ØØ27-4 and the exposure in the gastrointestinal tract after consumption of NS-B5ØØ27-4 products. Indirect exposure occurs via manure and faeces of animals fed with NS-B5ØØ27-4 products.

However, DNA is quickly degraded when released into the soil by endonucleases and DNases. Food and feed processing steps, like heating and solvent extraction, destroy most DNA of NS-B5ØØ27-4 seeds. When still present in the gastrointestinal tract the remaining DNA would be degraded by proteases, removing the protecting nucleoproteins, followed by nucleases. In the unlikely event that intact gene sequences would be presented to bacteria, homologous recombination would have to take place to be integrated in the bacteria's genome. None of the seven genes of the DHA biosynthesis pathway, if integrated in the genome of a micro-organism, would provide a selective advantage. Homologous recombination of the *pat* gene with a bacterial *pat* gene would result in replacement without adding a new trait. Therefore, the potential for horizontal gene transfer is negligible.

Environmental exposure to flowering NS-B5ØØ27-4 plants will be limited. Furthermore, field trials did not reveal differences regarding reproduction characteristics compared to the conventional counterpart and commercial reference varieties. Therefore, the outcrossing frequency to other oilseed rape varieties or to wild relatives is unlikely to be different.

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

Not applicable

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

Oilseed rape interacts with a variety of organisms when growing in the field. However, in an import scenario, non-target organisms would be primarily exposed to manure and faeces from animals fed with NS-B5ØØ27-4 products.

NS-B5ØØ27-4 oilseed rape does not differ from any other oilseed rape in composition except for the fatty acid profile and the presence of the newly introduced proteins. Micpu-Δ6D, Pyrco-Δ5E, Pavsa-Δ5D, Picpa-ω3D, Pavsa-Δ4D, Lackl-Δ12D, Pyrco-Δ6E and PAT are not known to be toxic or to have any other negative effects on non-target organisms.

(f) Effects on human health

NS-B5ØØ27-4 has no meaningful differences compared to conventional oilseed rape, except for the altered fatty acid profile and herbicide tolerance. The Micpu-Δ6D, Pyrco-Δ5E, Pavsa-Δ5D, Picpa-ω3D, Pavsa-Δ4D, Lackl-Δ12D, Pyrco-Δ6E and PAT proteins responsible for these traits were not found to be toxic or induce allergic reactions. Therefore, the hazard for workers handling and processing NS-B5ØØ27-4 seeds and meal is not different from the hazard of handling any conventional oilseed rape.

(g) Effects on animal health

Environmental hazards from NS-B5ØØ27-4 on animals would be expressed from contact to spilled seeds and feral plants, and from contact with manure and faeces from animals fed with NS-B5ØØ27-4 products. NS-B5ØØ27-4 oilseed rape does not differ from any other oilseed rape in composition except for the fatty acid profile and the presence of the newly introduced proteins. The Micpu-Δ6D, Pyrco-Δ5E, Pavsa-Δ5D, Picpa-ω3D, Pavsa-Δ4D, Lackl-Δ12D, Pyrco-Δ6E and PAT proteins are not known to be toxic, allergic or to have any other negative effects on animals.

Consumption of NS-B5ØØ27-4 seeds is not considered to represent a hazard, even with a changed fatty acid composition.

(h) Effects on biogeochemical processes

As with non-target organisms the exposure of micro-organisms involved in biogeochemical processes in an import scenario would be to manure and faeces from animals fed with NS-B5ØØ27-4 products.

NS-B5ØØ27-4 oilseed rape does not differ from any other oilseed rape in composition except for the fatty acid profile and the presence of the newly introduced proteins. Micpu-Δ6D, Pyrco-Δ5E, Pavsa-Δ5D, Picpa-ω3D, Pavsa-Δ4D, Lackl-Δ12D, Pyrco-Δ6E and PAT are not thought to have any adverse effect on soil micro-organisms or the biogeochemical processes they mediate.

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

Not applicable.

11.3. Potential interactions with the abiotic environment

Comparing the agronomic and phenotypic characteristics of NS-B5ØØ27-4 with its conventional counterpart and commercial reference varieties demonstrated that NS-B5ØØ27-4 is not different from conventional oilseed rape, except for the introduced traits. Therefore, there is no evidence that NS-B5ØØ27-4 would be any different from conventional oilseed rape regarding interactions with the abiotic environment.

11.4. Risk characterisation

Risk characterisation follows from the hazard characterisation, as explained in Sections 11.2 and 11.3, and the exposure potential.

The hazard characterisation concluded that NS-B5ØØ27-4 is not different from conventional oilseed rape in relation to human and animal health and the environment.

The exposure potential to NS-B5ØØ27-4 oilseed rape that would not be cultivated in the EU, but imported, processed and used as food and feed, is low to negligible. The potential exposure will be limited to: a) environmental exposure due to accidental spillage of viable NS-B5ØØ27-4 seeds; b) exposure through faeces of animals fed with NS-B5ØØ27-4 and c) exposure through organic plant matter derived from by-products of industrial processes that used NS-B5ØØ27-4.

Some incidental spillage of oilseed rape seeds may occur during import, handling, storage and processing and will be limited to ports and transport routes to storage facilities. Environmental conditions at these sites are unlikely to be conducive to germination, growth and reproduction of oilseed rape, as it predominantly grows in “disturbed land” habitats.

Exposure to the Lackl-Δ12D, Picpa-ω3D, Micpu-Δ6D, Pyrco-Δ6E, Pavsa-Δ5D, Pyrco-Δ5E, Pavsa-Δ4D and PAT via manure and faeces of animals fed with NS-B5ØØ27-4 will be negligible. In processing seeds to oil and meal for feed, proteins will degrade as a result of the high temperature and solvent extraction. Furthermore, the Micpu-Δ6D, Pyrco-Δ5E, Pavsa-Δ5D, Picpa-ω3D, Pavsa-Δ4D, Lackl-Δ12D, Pyrco-Δ6E and PAT proteins were shown to be quickly digested in simulated gastric fluid assays. Therefore, the probability of these proteins being present, intact and functional, in manure and faeces from animals fed with NS-B5ØØ27-4 products is negligible.

As a consequence, the risk potential for the import, processing and uses of food and feed, excluding cultivation, of NS-B5ØØ27-4 oilseed rape in the EU on human and animal health and the environment is not greater than for conventional oilseed rape. No immediate adverse effects are anticipated and therefore also the probability of long-term adverse effects is negligible.

12. ENVIRONMENTAL MONITORING PLAN

(a) General (risk assessment, background information)

Regulation (EC) No 1829/2003 requires by Article 5(5)(b) and 17(5)(b) that a Post-Market Environmental Monitoring (PMEM) plan for NS-B5ØØ27-4 is developed according to the principles and objectives outlined in Directive 2001/18/EC, Annex VII, and in Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC. Further guidance is provided by the Scientific opinion on guidance on the Post-Market Environmental Monitoring of genetically modified plants by EFSA.

(b) Interplay between environmental risk assessment and monitoring

An ERA was performed for NS-B5ØØ27-4 oilseed rape as required by Directive 2001/18/EC, Annex II, and in Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC. In a scenario of import, processing and use as food and feed of NS-B5ØØ27-4 in the EU, the ERA concluded that the risk for potential adverse effects on human and animal health or the environment is negligible, as summarised in Section 11.

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

As the ERA did not point to any risk in relation to the import, processing and use as food and feed of NS-B5ØØ27-4 in the EU, it is considered that there is no need for case-specific monitoring.

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

The objective of general surveillance is to detect any unanticipated adverse effects, to determine the harm to protection goals and to determine the causality between the detected unanticipated adverse effects and the genetically modified plant. The approach 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 NS-B5ØØ27-4 products.

Baselines have been established for oilseed rape. The baseline and controls for general surveillance will rely on the historical knowledge and experience with non-GM oilseed rape

and other GM oilseed rape. Operators (importers/traders, silo-operators, processors etc.) in the production countries (outside of the EU) directly handling the NS-B5ØØ27-4 grain as well as importers/traders of bulk oil within the EU will have a direct relationship with Nuseed and will be required to report any changes in handling, quality or unanticipated effect (specific company stewardship programmes).

Following the approval of NS-B5ØØ27-4 in the EU, Nuseed will approach existing networks of operators within the EU and inform them that the product has been authorised. Although import of viable grain in the EU is not intended, the operators are best placed to observe and report any adverse unanticipated effect in case of co-mingling with another viable rapeseed commodity.

Literature searches will also be conducted on relevant reports and peer-reviewed publications on the use of NS-B5ØØ27-4, in order to identify potential unanticipated effects linked to NS-B5ØØ27-4.

In the case of any unanticipated effect observed compared to the established baselines, Nuseed shall immediately investigate to determine harm, biological significance, and causality with the introduction of NS-B5ØØ27-4. Based on a scientific evaluation of the potential consequences of the observed unanticipated effect, Nuseed shall define and implement management measures to protect human health or the environment, as necessary, in collaboration with the European Commission, and 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. Nuseed shall submit an annual report including any results of 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 NS-B5ØØ27-4. The report shall include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of NS-B5ØØ27-4 and, as appropriate, the measures that were taken to ensure the safety of human health or the environment.

13. DETECTION AND IDENTIFICATION TECHNIQUES FOR THE GENETICALLY MODIFIED PLANT

NS-B5ØØ27-4 can be detected and identified using insert-specific PCR-based detection methods. These methods allow for discrimination between NS-B5ØØ27-4 oilseed rape and derived products and other commercial crops and products.

14. INFORMATION RELATING TO PREVIOUS RELEASES OF THE GENETICALLY MODIFIED PLANT (FOR ENVIRONMENTAL RISK ASSESSMENT ASPECTS)

14.1. History of previous releases of the genetically modified plant notified under Part B of Directive 2001/18/EC or under Part B of Council Directive 90/220/EEC (1) by the same notifier

(a) Notification number

NS-B5ØØ27-4 oilseed rape has not been released in the EU.

(b) Conclusions of post-release monitoring

Not applicable.

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

Not applicable.

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

(a) Release country

NS-B5ØØ27-4 has been field tested in Australia (2015 and 2016), in Canada (2016 and 2017) and in the USA (2017).

(b) Authority overseeing the release

Australia: Office of the Gene Technology Regulator (OGTR)

Canada: Canadian Food Inspection Agency

USA: United States Department of Agriculture (USDA)

(c) Release site

Australia: Ararat, Douglas, Green Lake, Gymbowen, Kaniva, Nurrabiel, Tooloondo, Wonwondah (Western Victoria)

Canada: Coalhurst (AB), Minto (MB,) Saskatoon (SK) and Vanguard (SK),

USA: Brookings (SD), Northwood (ND) and St. Cloud (MN)

(d) Aim of the release

Evaluation of the agronomic and phenotypic characteristics, seed production for compositional analysis, regulatory field trials.

(e) Duration of the release

Australia and Canada: two growing seasons

USA: one growing season

(f) Aim of post-releases monitoring

Assessment of volunteers

(g) Duration of post-releases monitoring

Two years

(h) Conclusions of post-release monitoring

Flushes of volunteers (1-3), as environmental conditions allowed, depleted any remaining seed at the trial sites. Rainfall and tillage were key factors for volunteer emergence. All volunteers were easily controlled with current agronomic management techniques.

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

Analysis of the results of the field trials with NS-B5ØØ27-4 revealed that NS-B5ØØ27-4 is as safe as its conventional counterpart and commercial reference varieties. No adverse effect to human health or to the environment was evidenced.