Part VII - Summary

Request for Authorization of

EPA+DHA Canola Event LBFLFK

for food and feed uses, and import and processing, in accordance with articles 5 and 17 of Regulation (EC) No 1829/2003

EFSA-GMO-DE-2019-157

Version CC2

Submitted on
1 October 2019

PART VII – SUMMARY

1. GENERAL INFORMATION

1.1. Details of application

(a) Member State of application

Germany

(b) Application number

EFSA-GMO-DE-2019-157

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

EPA+DHA Canola Event LBFLFK (OECD unique identifier: BPS-BFLFK-2), also referred to as LBFLFK canola hereafter.

(d) Date of acknowledgement of valid application

Not available at time of submission.

1.2. Applicant

(a) Name of applicant

BASF Plant Science Company GmbH

(b) Address of applicant

Carl-Bosch-Str. 38
D – 67056 Ludwigshafen
Germany

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

N/A

1.3. Scope of the application

(a) Genetically modified food

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

(b) Genetically modified feed

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

(c) Genetically modified plants for food or feed uses

☑ Products other than food and feed containing or consisting of genetically modified plants with the exception of cultivation

☐ Seeds and plant propagating material for cultivation in the Union

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

No ☐

Yes ☑ (in that case, specify)

The maximum residue level (MRL) established for imazamox in canola seed is set at 0.05 mg/kg, which is considered the lower limit of analytical determination (Commission Regulation (EU) No 2016/567).

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)

This application requests authorisation for food and feed uses, import and processing and does not include cultivation in the EU.

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

No ☑

Yes ☐ (in that case, specify)

1.7. 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

Submissions have been made in countries around the world and are at the different stages in the approval process. LBFLFK canola applications have been submitted in Canada, Korea and Japan and approved in the US.

1.8. General description of the product

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

LBFLFK canola has been developed by Agrobacterium-mediated transformation of a *Brassica napus* canola cultivar.

LBFLFK contains genes that impact the content of omega-3 long-chain polyunsaturated fatty acids (LC-PUFAs) in the seeds and contains a gene that confers tolerance to imidazolinone herbicides. The fatty acid trait is conferred by the introduction of a metabolic pathway consisting of ten genes encoding the following proteins: delta-12 desaturase from *Phytophthora sojae*, delta-6 desaturase from *Ostreococcus tauri*, delta-6 elongase from *Thalassiosira pseudonana*, delta-6 elongase from *Physcomitrella patens*, delta-5 desaturase from *Thraustochytrium* sp., omega-3 desaturase from *Pythium irregulare*, omega-3 desaturase from *Phytophthora infestans*, delta-5 elongase from *Ostreococcus tauri*, delta-4 desaturase from *Thraustochytrium* sp. and delta-4 desaturase from *Pavlova lutheri* to produce eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). The herbicide tolerance is conferred by the introduction of an acetohydroxy acid synthase (AHAS) gene from *Arabidopsis thaliana* with two amino acid substitutions ([A122T], [S653N]).

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

The scope of the current application is for authorisation of LBFLFK canola for food and feed uses, import and processing, in accordance with articles 5 and 17 of Regulation (EC) No 1829/2003, with the exception of cultivation.

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

LBFLFK canola will be grown and processed as a specialty canola with a fatty acid profile containing the omega-3 LC-PUFAs EPA and DHA.

Production and product handling will be under an Identity Preservation System (IDP). Cargill, in coordination with BASF, will conduct activities to support variety development, grain production, oil manufacturing, and other commercial activities to prepare LBFLFK canola for the marketplace as an alternative source of LC-PUFAs. For the production and processing of LBFLFK canola and derived products, the IDP system implemented by Cargill will oversee the value chain from certified seed to final use of the product. Import of LBFLFK canola grain to the EU is not intended.

The oil produced from LBFLFK canola will be consumed specifically for the purpose of providing specifically EPA and DHA to humans and to farmed aquatic species. The oil may be incorporated as an ingredient into consumer food items to provide individuals more options for dietary omega-3 LC-PUFAs. The refined oil may also be provided to dietary supplement manufacturers as an alternate source of omega-3 LC-PUFAs. Additionally, the oil may be used as an aquafeed input ingredient to international operations to provide omega-3 LC-PUFAs to farmed aquatic species.

The defatted meal, produced from LBFLFK canola as a by-product of canola oil production, will not be treated a specialty product and will be available for use in the same applications as conventional canola meal, including livestock feed. As canola meal is not a high value commodity, feed consumption of canola meal produced in the U.S. and Canada is expected to be exclusively within North America.

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

No specific conditions for use or handling are foreseen for food and feed produced from LBFLFK canola besides the labelling and traceability requirements according to the Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003.

(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.

This application requests food and feed uses and import and processing only and is not covering cultivation in the EU.

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

This application requests food and feed uses and import and processing only and is not covering cultivation in the EU.

(g) Any proposed packaging requirements.

No specific packaging is required for LBFLFK canola.

(h) Any proposed labelling requirements in addition to those required by other applicable EU legislation than (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.

The proposal for specific labelling of LBFLFK canola in accordance with Regulation (EC) No 1829/2003, Article 13(2) and Article 25(2)(c) is:

“Genetically modified rapeseed with eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)”.

In the case of intended import of LBFLFK canola grain to the EU, import documents should be labelled complying with the requirements of Annex IV of Directive 2001/18/EC and include the following statement:

“This product contains genetically modified rapeseed derived from transformation event LBFLFK with eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)”. A declaration of use will clearly state “the seed is only for processing and not for cultivation in the EU”.

(i) Estimated potential demand

(i) In the EU

There are no anticipated changes to the demand for rapeseed in the EU as a result of the introduction of LBFLFK canola. It is anticipated that the introduction of LBFLFK canola will replace some other rapeseed as well as EPA- and DHA-containing products in existing food and feed.

(ii) In EU export markets

There are no anticipated changes to the demand for rapeseed in EU export markets as a result of the introduction of LBFLFK canola. It is anticipated that the introduction

of LBFLFK canola will replace some other rapeseed as well as EPA- and DHA-containing products in existing food and feed.

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

BPS-BFLFK-2

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

Canola derived from LBFLFK canola remains susceptible to mechanic destruction such as crushing, ploughing and disking and is still susceptible to conventionally used herbicides, except imidazolinone herbicide products. Therefore, LBFLFK volunteer plants are readily controlled using non-selective herbicides, such as glyphosate and glufosinate, which are commonly used in the EU for weed control. The waste from LBFLFK canola can be treated similar to conventional canola waste.

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

2.1. Complete name

(a) Family name

Brassicaceae

(b) Genus

Brassica L.

(c) Species

Brassica napus L.

(d) Subspecies

oleifera

(e) Cultivar/breeding line

Kumily

(f) Common name

Oilseed rape, rapeseed (referred to as canola in North America and Australia)

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

Globally, canola production is concentrated in areas with dry weather and shorter growing seasons. Canola varieties of *B. napus* are the primary rapeseed varieties grown for oil production in North America. The major production areas are located in the Canadian prairie provinces of Manitoba, Saskatchewan and Alberta. In the U.S., canola is grown mostly in the north-western region of the country. The major rapeseed producing countries in the EU-28 area are France, Germany, Poland and the United Kingdom.

2.3. Information concerning reproduction (for environmental safety aspects)

(a) Mode(s) of reproduction

B. napus is an annual species and reproduces through seeds. The flowers of *B. napus* are bisexual, self-compatible and mainly self-pollinated. *Brassica* pollen is small, heavy and slightly sticky. It can be transferred from plant to plant by wind, through physical contact between neighbouring plants and by insects.

(b) Specific factors affecting reproduction

B. napus is mostly self-pollinated, with an average of 70% of the seeds resulting from self-pollination and 30% from cross-pollination occurring over very short distances (less than 10 m). *Brassica* pollen dispersal is mainly by wind. Its dispersal is described as presenting a leptokurtic distribution, a term that refers to the dispersal as showing a more acute peak and fatter tails than found in a normal statistical distribution. In addition to wind, insects (specifically honey bees), physical contact between flowers of neighbouring plants and animals, including humans, can act as a means of pollen dispersal.

(c) Generation time

The generation time for spring-sown canola (*B. napus*) in agronomic ecosystems in the EU is generally about 5–7 months.

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

Fourteen other *Brassica* species related to *B. napus* were identified in which gene introgression from *B. napus* could occur in rapeseed growing countries in Europe and North America. There are many conditions that must be met for such an event to occur, including pre-fertilisation conditions like physical proximity of the parents, pollen movement and longevity, synchrony of flowering, pollen-style compatibility and competitiveness of foreign pollen, sexual compatibility, hybrid fertility and viability in nature. In addition, many crosses produce only small seed, resulting in poor seedling establishment of the hybrids under field conditions.

2.5. Survivability (for environmental safety aspects)

(a) Ability to form structures for survival or dormancy

B. napus seeds have virtually no primary dormancy. Nevertheless, a small proportion of seed shattered on the ground may not germinate and enter secondary dormancy in unfavourable conditions. The key drivers to induce secondary dormancy in *B. napus* seed are elevated temperatures, darkness/burial, water stress and limited oxygen supply.

(b) Specific factors affecting survivability

Survival and persistence of *Brassica* seed is greatly influenced by environment and seed dormancy as well as crop and field management. Mature *B. napus* pods tend to shatter, leaving large but variable amounts of seed on the ground at harvest. Most seeds of the cultivated *Brassica* crops, if left on or near the soil surface, will germinate if moisture and temperature are adequate and be killed by frost, herbicides or cultivation or be eaten by rodents, birds and insects. However, there is the tendency for a proportion of the shattered seed to acquire secondary dormancy, induced by

abiotic stresses, so that a small percentage of shattered seed can remain dormant and viable for 10 years or more.

2.6. Dissemination (for environmental safety aspects)

(a) Ways and extent of dissemination

Pollen dispersal is mainly by wind and insects, primarily honey bees.

(b) Specific factors affecting dissemination

There are no specific factors affecting seed dissemination, and *B. napus* seeds have no specific features promoting transport.

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

The main compatible species of *B. napus* (*B. rapa*, *B. juncea*, *Hirschfeldia incana* and *Raphanus raphanistrum)* are found throughout Europe, mainly in feral populations or as weeds.

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, as *B. napus* is grown as a crop in the European Union.

2.9. Other potential interactions, relevant to the genetically modified plant, of the plant with organisms in the ecosystem where it is usually grown, or used elsewhere, including information on toxic effects on humans, animals and other organisms (for environmental safety aspects)

The scope of this application does not include cultivation of LBFLFK canola in the EU, and therefore no interactions with organisms in the ecosystem in the EU are anticipated. In regions where LBFLFK canola will be grown, such as North America, it is expected to interact with other organisms in the environment, including microorganisms, viruses, insects, birds and mammals, like every other plant.

3. MOLECULAR CHARACTERISATION

3.1. Information relating to the genetic modification

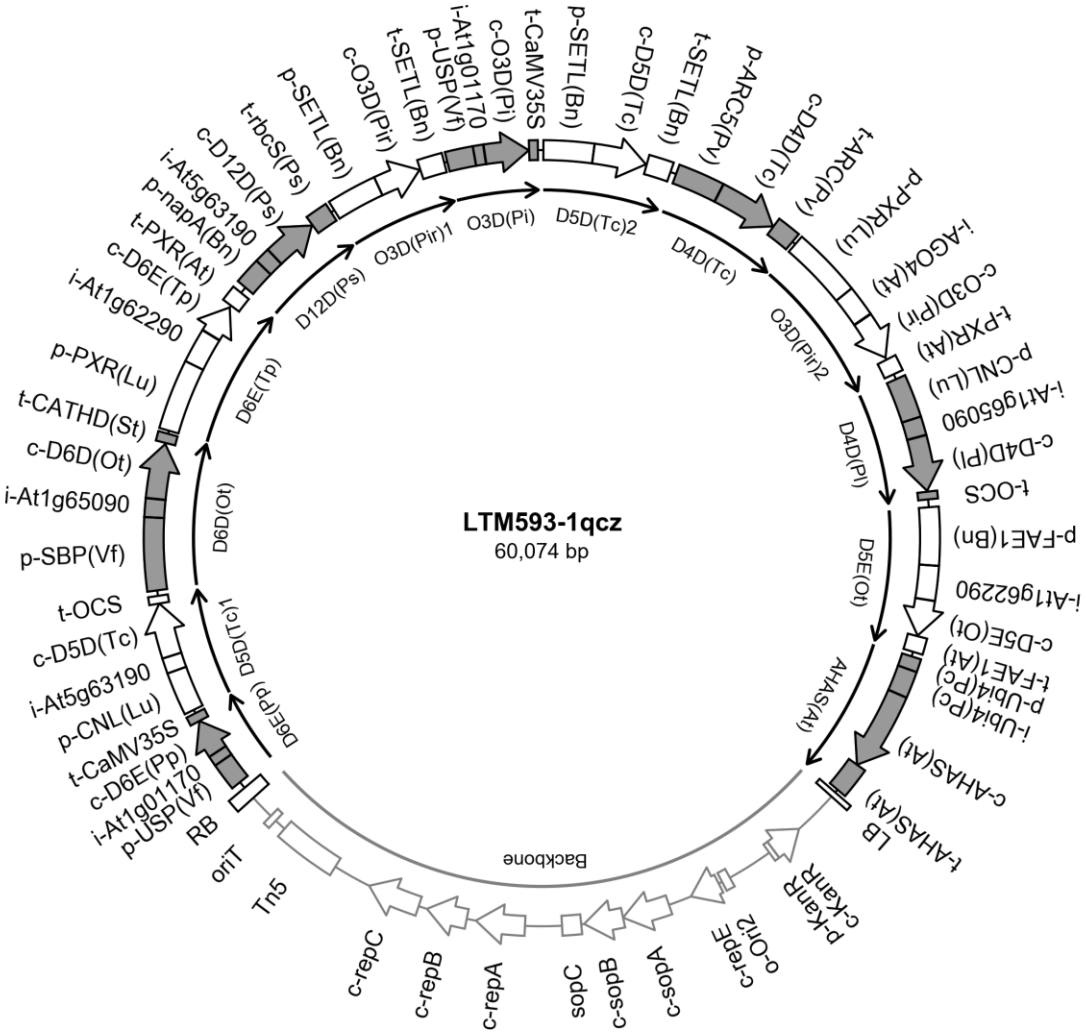
(a) Description of the methods used for the genetic modification

LBFLFK canola was developed through *Agrobacterium rhizogenes*-mediated transformation of conventional *B. napus* hypocotyls.

(b) Nature and source of the vector used

LBFLFK canola was produced by means of *Agrobacterium*-mediated transformation using the plasmid vector LTM593, also referred to as LTM593-1qcz (Figure 1).

Figure 1. Circular Map of Plasmid LTM593



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

Table 1. Summary of Genetic Elements in LTM593

Genetic element	Location in construct (size in base pairs)	Origin and function (reference)
RB	1–328 (328)	*Agrobacterium tumefaciens*, octopine-type Ti plasmid pTi15955, right T-DNA border region, identical to section of GenBank®[1] nucleotide accession number AF242881 (Barker et al., 1983)
intervening sequence	329–508 (180)	Region required for cloning of genetic elements
p-*USP*(*Vf*)	509–1192 (684)	*Vicia faba*, promoter region of unknown seed protein gene *USP* (Bäumlein et al., 1991), identical to section of GenBank® nucleotide accession number HJ187156, and highly homologous to section of GenBank® nucleotide accession number X56240
i-*At1g01170*	1,193–1,444 (252)	*Arabidopsis thaliana*, intron-containing 5' UTR of locus At1g01170 (Nakabayashi et al., 2005)
intervening sequence	1,445–1,446 (2)	Region required for cloning of genetic elements
***c-D6E*(*Pp*)**	1,447–2,319 (873)	*Physcomitrella patens*, delta-6 elongase (originally named as polyunsaturated fatty acid specific elongation enzyme 1, *PSE1*), codon optimized based on GenBank® nucleotide accession number AF428243 (Zank et al., 2000; Zank et al., 2002)
t-*CaMV35S*	2,320–2,535 (216)	Cauliflower mosaic virus, CaMV35S terminator region, identical to section of GenBank® nucleotide accession number AF234316 (Hajdukiewicz et al., 1994)
intervening sequence	2,536–2,627 (92)	Region required for cloning of genetic elements
p-*CNL*(*Lu*)	2,628–3,691 (1064)	*Linum usitatissimum*, seed-specific promoter of *conlinin* gene (Truksa et al., 2003), identical to section of GenBank® nucleotide accession number HJ187156
i-*At5g63190*	3,692–4,068 (377)	*Arabidopsis thaliana*, intron-containing 5' UTR of locus At5g63190 (Sharma et al., 2007; Wang et al., 2008)
intervening sequence	4,069–4,071 (3)	Region required for cloning of genetic elements
***c-D5D*(*Tc*)1**	4,072–5,391 (1320)	*Thraustochytrium* sp., delta-5 desaturase, codon optimized based on GenBank® nucleotide accession number AF489588 (Qiu et al., 2001)
t-*OCS*	5,392–5,583 (192)	*Agrobacterium tumefaciens*, octopine-type Ti plasmid pTi15955, terminator of octopine synthase gene (MacDonald et al., 1991), identical to section of the GenBank® nucleotide accession number NC_002377
intervening sequence	5,584–5,718 (135)	Region required for cloning of genetic elements
p-*SBP*(*Vf*)	5,719–7,517 (1799)	*Vicia faba*, promoter of a sucrose-binding protein-related gene (Grimes et al., 1992; Heim et al., 2001), active at late seed development stage, identical to GenBank® nucleotide accession number LQ576466
i-*At1g65090*	7,518–7,972 (455)	*Arabidopsis thaliana*, intron-containing 5' UTR of locus At1g65090 (Braybrook et al., 2006)

[1] Genbank is a registered trademark of the US Department of Health and Human Services.

Genetic element	Location in construct (size in base pairs)	Origin and function (reference)
intervening sequence	7,973–7,981 (9)	Region required for cloning of genetic elements
***c-D6D*(*Ot*)**	7,982–9,352 (1371)	*Ostreococcus tauri*, delta-6 desaturase, codon optimized based on GenBank® nucleotide accession number AY746357 (Domergue et al., 2005)
intervening sequence	9,353–9,379 (27)	Region required for cloning of genetic elements
t-*CATHD*(*St*)	9,380–9,614 (235)	*Solanum tuberosum*, terminator of cathepsin D inhibitor gene (Hannapel, 1993), identical to section of GenBank® nucleotide accession number HJ187168
intervening sequence	9,615–9,692 (78)	Region required for cloning of genetic elements
p-*PXR*(*Lu*)	9,693–11,419 (1727)	*Linum usitatissimum*, seed-specific promoter of peroxiredoxin like protein gene *PXR* (Duwenig and Loyall, 2006), identical to GenBank® nucleotide accession number HL700593
i-*At1g62290*	11,420–12,265 (846)	*Arabidopsis thaliana*, intron-containing 5' UTR of locus At1g62290 (Chen et al., 2002)
intervening sequence	12,266–12,278 (13)	Region required for cloning of genetic elements
***c-D6E*(*Tp*)**	12,279–13,097 (819)	*Thalassiosira pseudonana*, delta-6 elongase (Armbrust et al., 2004), codon optimized based on GenBank® nucleotide accession number XM_002288445
intervening sequence	13,098–13,152 (55)	Region required for cloning of genetic elements
t-*PXR*(*At*)	13,153–13,552 (400)	*Arabidopsis thaliana*, terminator of peroxiredoxin (PXR)-like protein gene *PER1* (GenBank® nucleotide accession number HL700651, At1g48130, (Haslekås et al., 1998))
intervening sequence	13,553–13,721 (169)	Region required for cloning of genetic elements
p-*napA*(*Bn*)	13,722–14,385 (664)	*Brassica napus*, seed-specific promoter of seed storage protein napin A/B gene (Ellerström et al., 1996; Rask et al., 1998), identical to GenBank® nucleotide accession number LQ576463
i-*At5g63190*	14,386–14,762 (377)	*Arabidopsis thaliana*, intron-containing 5' UTR of locus At5g63190 (Sharma et al., 2007; Wang et al., 2008)
intervening sequence	14,763–14,768 (6)	Region required for cloning of genetic elements
***c-D12D*(*Ps*)**	14,769–15,965 (1197)	*Phytophthora sojae*, delta-12 desaturase, codon optimized based on GenBank® accession number GY508423 (Cirpus and Bauer, 2006)
intervening sequence	15,966–15,983 (18)	Region required for cloning of genetic elements
t-*rbcS*(*Ps*)	15,984–16,541 (558)	*Pisum sativum*, terminator of RuBisCO small subunit gene (*rbcS*) E9 (Coruzzi et al., 1984; Smigocki, 1991), identical to section of GenBank® nucleotide accession number AY572837.
intervening sequence	16,542–16,633 (92)	Region required for cloning of genetic elements
p-*SETL*(*Bn*)	16,634–17,867 (1234)	*Brassica napus*, seed-specific promoter of *SETL* gene (Bauer and Senger, 2010), identical to a section of GenBank® nucleotide accession number HC307781
intervening sequence	17,868–17,869 (2)	Region required for cloning of genetic elements
***c-O3D*(*Pir*)1**	17,870–18,961 (1092)	*Pythium irregulare*, omega-3 desaturase, codon optimized based on GenBank® nucleotide accession number FB753541 (Cheng et al., 2010)

Genetic element	Location in construct (size in base pairs)	Origin and function (reference)
intervening sequence	18,962–18,982 (21)	Region required for cloning of genetic elements
t-*SETL*(*Bn*)	18,983–19,596 (614)	*Brassica napus*, terminator of *SETL* gene (Bauer and Senger, 2010), identical to GenBank® nucleotide accession number HC307782
intervening sequence	19,597–19,674 (78)	Region required for cloning of genetic elements
p-*USP*(*Vf*)	19,675–20,358 (684)	*Vicia faba*, promoter region of unknown seed protein gene *USP* (Bäumlein et al., 1991), identical to section of GenBank® nucleotide accession number HJ187156, and highly homologous to section of GenBank® nucleotide accession number X56240
i-*At1g01170*	20,359–20,610 (252)	*Arabidopsis thaliana*, intron-containing 5' UTR of locus At1g01170 (Nakabayashi et al., 2005)
intervening sequence	20,611–20,620 (10)	Region required for cloning of genetic elements
***c-O3D*(*Pi*)**	20,621–21,706 (1086)	*Phytophthora infestans*, omega-3 desaturase, codon optimized based on GenBank® nucleotide accession number XM_002902553 (Wu et al., 2005)
intervening sequence	21,707–21,714 (8)	Region required for cloning of genetic elements
t-*CaMV35S*	21,715–21,930 (216)	Cauliflower mosaic virus, CaMV35S terminator region, identical to section of GenBank® nucleotide accession number AF234316 (Hajdukiewicz et al., 1994)
intervening sequence	21,931–22,065 (135)	Region required for cloning of genetic elements
p-*SETL*(*Bn*)	22,066–23,299 (1234)	*Brassica napus*, seed-specific promoter of *SETL* gene (Bauer and Senger, 2010), identical to a section of GenBank® nucleotide accession number HC307781
intervening sequence	23,300–23,301 (2)	Region required for cloning of genetic elements
***c-D5D*(*Tc*)2**	23,302–24,621 (1320)	*Thraustochytrium* sp., delta-5 desaturase, codon optimized based on GenBank® nucleotide accession number AF489588 (Qiu et al., 2001)
intervening sequence	24,622–24,642 (21)	Region required for cloning of genetic elements
t-*SETL*(*Bn*)	24,643–25,256 (614)	*Brassica napus*, terminator of *SETL* gene (Bauer and Senger, 2010), identical to GenBank® nucleotide accession number HC307782
intervening sequence	25,257–25,402 (146)	Region required for cloning of genetic elements
p-*ARC5*(*Pv*)	25,403–26,553 (1151)	*Phaseolus vulgaris*, seed-specific *Arcelin-5* gene promoter, identical to GenBank® nucleotide accession number JC056714, and homologous to GenBank® nucleotide accession number Z50202 (Goossens et al., 1994; Goossens et al., 1999)
intervening sequence	26,554–26,563 (10)	Region required for cloning of genetic elements
***c-D4D*(*Tc*)**	26,564–28,123 (1560)	*Thraustochytrium* sp., delta-4 desaturase, codon optimized based on GenBank® nucleotide accession number GN042654 (Qiu et al., 2001)
intervening sequence	28,124–28,136 (13)	Region required for cloning of genetic elements
t-*ARC*(*Pv*)	28,137–28,736 (600)	*Phaseolus vulgaris*, terminator of *Arc5* gene, identical to section of GenBank® nucleotide accession number Z50202 (Goossens et al., 1994; Goossens et al., 1999)

Genetic element	Location in construct (size in base pairs)	Origin and function (reference)
intervening sequence	28,737–28,828 (92)	Region required for cloning of genetic elements
p-*PXR*(*Lu*)	28,829–30,555 (1727)	*Linum usitatissimum*, seed-specific promoter of peroxiredoxin like protein gene *PXR* (Duwenig and Loyall, 2006), identical to GenBank® nucleotide accession number HL700593
i-*AGO4*(*At*)	30,556–31,313 (758)	*Arabidopsis thaliana*, intron-containing 5' UTR of gene *AGO4*(*At*) (Zilberman et al., 2003)
intervening sequence	31,314–31,328 (15)	Region required for cloning of genetic elements
***c-O3D*(*Pir*)2**	31,329–32,420 (1092)	*Pythium irregulare*, omega-3 desaturase, codon optimized based on GenBank® nucleotide accession number FB753541 (Cheng et al., 2010)
intervening sequence	32,421–32,476 (56)	Region required for cloning of genetic elements
t-*PXR*(*At*)	32,477–32,876 (400)	*Arabidopsis thaliana*, terminator of peroxiredoxin (PXR)-like protein gene *PER1* (GenBank® nucleotide accession number HL700651, At1g48130 (Haslekås et al., 1998))
intervening sequence	32,877–33,011 (135)	Region required for cloning of genetic elements
p-*CNL*(*Lu*)	33,012–34,075 (1064)	*Linum usitatissimum*, seed-specific promoter of *conlinin* gene (Truksa et al., 2003), identical to section of GenBank® nucleotide accession number HJ187156
i-*At1g65090*	34,076–34,530 (455)	*Arabidopsis thaliana*, intron-containing 5' UTR of locus At1g65090 (Braybrook et al., 2006)
intervening sequence	34,531–34,539 (9)	Region required for cloning of genetic elements
***c-D4D*(*Pl*)**	34,540–35,877 (1338)	*Pavlova lutheri*, delta-4 desaturase, codon optimized based on GenBank® nucleotide accession number AY332747 (Tonon et al., 2003)
intervening sequence	35,878–35,898 (21)	Region required for cloning of genetic elements
t-*OCS*	35,899–36,090 (192)	*Agrobacterium tumefaciens*, octopine-type Ti plasmid pTi15955, terminator of octopine synthase gene (MacDonald et al., 1991), identical to section of the GenBank® nucleotide accession number NC_002377
intervening sequence	36,091–36,283 (193)	Region required for cloning of genetic elements
p-*FAE1*(*Bn*)	36,284–37,713 (1430)	*Brassica napus*, promoter of fatty acid elongase (*FAE1.1*) gene, identical to section of GenBank® nucleotide accession number HC474755, and highly homologous to section of GenBank® nucleotide accession number AF275254 (Han et al., 2001)
i-*At1g62290*	37,714–38,560 (847)	*Arabidopsis thaliana*, intron-containing 5' UTR of locus At1g62290 (aspartyl protease family protein) (Chen et al., 2002)
intervening sequence	38,561–38,567 (7)	Region required for cloning of genetic elements
***c-D5E*(*Ot*)**	38,568–39,470 (903)	*Ostreococcus tauri*, delta-5 elongase (Zank et al., 2005), codon optimized based on GenBank® nucleotide accession number CS020159
intervening sequence	39,471–39,486 (16)	Region required for cloning of genetic elements
t-*FAE1*(*At*)	39,487–39,886 (400)	*Arabidopsis thaliana*, terminator of fatty acid elongase gene (*FAE1*) (Rossak et al., 2001), identical to section of GenBank® nucleotide accession number HV571989

Genetic element	Location in construct (size in base pairs)	Origin and function (reference)
intervening sequence	39,887–40,004 (118)	Region required for cloning of genetic elements
p-*Ubi4*(*Pc*)	40,005–40,398 (394)	*Petroselinum crispum*, ubiquitin (Pcubi4-2) promoter, identical to section of GenBank® nucleotide accession number X64345 (Kawalleck et al., 1993)
i-*Ubi4*(*Pc*)	40,399–40,986 (588)	*Petroselinum crispum*, ubiquitin gene intron in the 5' UTR, identical to section of GenBank® nucleotide accession number JC289689, and highly homologous to section of GenBank® nucleotide accession number X64345 (Kawalleck et al., 1993)
intervening sequence	40,987–40,993 (7)	Region required for cloning of genetic elements
***c-AHAS*(*At*)**	40,994–43,006 (2013)	*Arabidopsis thaliana*, acetohydroxy acid synthase large-subunit (Mazur et al., 1987) with S653N substitution and A122T substitution, highly homologous to GenBank® nucleotide accession number NM_114714
t-*AHAS*(*At*)	43,007–43,786 (780)	*Arabidopsis thaliana*, terminator of *AHAS*(*At*) gene (Mazur et al., 1987), highly homologous to a segment in GenBank® nucleotide accession number CP002686
intervening sequence	43,787–43,874 (88)	Region required for cloning of genetic elements
LB	43,875–44,010 (136)	*Agrobacterium tumefaciens*, octopine-type Ti plasmid pTi15955, left T-DNA border region, identical to section of GenBank® nucleotide accession number AF242881 (Barker et al., 1983)

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

Seven desaturases and three elongases were introduced into EPA+DHA canola event LBFLFK, resulting in the synthesis of LC-PUFAs, including EPA and DHA, from endogenous oleic acid. In addition, tolerance to treatment with imidazolinone herbicides is conferred through the introduction of a modified acetohydroxy acid synthase (AHAS) protein from *A. thaliana* (Table 2).

Table 2. Designation and Donor Organisms of the Newly Expressed Proteins in EPA+DHA canola event LBFLFK

Enzyme full name	Enzyme abbreviation	Donor organism
Delta-12 desaturase (*Ps*)	D12D(*Ps*)	*Phytophthora sojae*
Delta-6 desaturase (*Ot*)	D6D(*Ot*)	*Ostreococcus tauri*
Delta-6 elongase (*Tp*)	D6E(*Tp*)	*Thalassiosira pseudonana*
Delta-6 elongase (*Pp*)	D6E(*Pp*)	*Physcomitrella patens*
Delta-5 desaturase (*Tc*)	D5D(*Tc*)	*Thraustochytrium* sp.
Omega-3 desaturase (*Pir*)	O3D(*Pir*)	*Pythium irregulare*
Omega-3 desaturase (*Pi*)	O3D(*Pi*)	*Phytophthora infestans*
Delta-5 elongase (*Ot*)	D5E(*Ot*)	*Ostreococcus tauri*
Delta-4 desaturase (*Tc*)	D4D(*Tc*)	*Thraustochytrium* sp.
Delta-4 desaturase (*Pl*)	D4D(*Pl*)	*Pavlova lutheri*
Acetohydroxy acid synthase	AHAS(*At*)	*Arabidopsis thaliana*

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

Two inserts, Insert1 and Insert2, are integrated at two separate loci in LBFLFK canola. Each insertion site consists of a single copy of the T-DNA from LTM593.

(b) In case of deletions, size and function of the deleted regions

LBFLFK canola contains an 8-bp deletion at the Insert1 integration site and a 31-bp deletion at the Insert2 integration site. No function can be assigned to the deleted base pairs.

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

LBFLFK canola Insert1 and Insert2 were determined to be integrated into the nuclear canola genome, confirmed by the observed Mendelian inheritance pattern as expected for two independent loci, as well as DNA flanking sequence analysis.

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

Next generation sequencing (NGS) of total gDNA and subsequent bioinformatics analysis demonstrated that LBFLFK canola contains two inserts integrated at two separate loci and confirmed the absence of vector backbone sequences in the genome of LBFLFK canola. Directed sequencing analyses revealed that each of the two inserts has the intended 13 gene expression cassettes. All cassettes were found to be identical to the LTM593 T-DNA except for two single nucleotide changes in Insert1 and one nucleotide change in Insert2.

A comparison to the sequence of the insertion site from the conventional counterpart Kumily demonstrated that an 8-bp deletion was created at the genome integration site of Insert1 and a 31-bp deletion was created at the genome integration site of Insert2 in Kumily. No genomic sequence rearrangements were found at either genomic integration site.

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

Not applicable.

3.2.3. Information on the expression of the insert

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

The expression of elongase and desaturase proteins as well as the AHAS(*At*) [A122TS653N] protein was determined in immature and mature seed from field-grown plants.

Each of the newly expressed integral membrane proteins under the control of a seed-specific promoter, with the exception of D6E(*Pp*), O3D(*Pi*) and D4D(*Tc*), were detected in either immature and mature seed across all field sites. The newly expressed AHAS(*At*) [A122TS653N] protein, driven by a constitutive promoter, was quantifiable in both immature and mature seed.

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

See (a) above.

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

The genetic stability of inserted T-DNA in LBFLFK canola across five generations was demonstrated by NGS analysis combined with bioinformatic analysis.

The stability of the LBFLFK canola phenotype was evaluated by testing the presence of the EPA+DHA trait by compositional analysis in the mature seed and herbicide tolerance by rating the damage to growing plants sprayed with imazamox. The stable presence of both introduced traits was demonstrated across multiple generations.

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

The EPA+DHA trait, including synthesis of LC-PUFAs including EPA and DHA, as well as the tolerance to imidazolinone herbicides, such as imazamox, have no effect on the mode and rate of reproduction.

(b) Dissemination

No differences in the dissemination compared to the conventional counterpart were observed in agronomic and phenotypic assessments conducted with LBFLFK canola.

The EPA+DHA trait as well as the herbicide tolerance trait have not affected dissemination characteristics of LBFLFK canola. LBFLFK canola retains the same growth rate and growth habit under typical growing conditions as conventional canola and disperses its seed in the same way as conventional canola.

(c) Survivability

No differences in the survivability compared to the conventional counterpart have been observed in agronomic assessments conducted with LBFLFK canola.

(d) Other differences

Except for the intentionally introduced traits, the comparative agronomic and phenotypic assessment did not reveal any biologically relevant differences between LBFLFK canola and its conventional counterpart, with the exception of seed germination characteristics impacted by the modified oil profile. A phenotype of delayed and reduced germination of LBFLFK canola was observed.

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

Horizontal gene transfer (HGT) of non-mobile DNA fragments between unrelated organisms is extremely unlikely to occur under natural conditions, and double homologous recombination scenarios are considered the most relevant for the assessment of potential HGT. Since neither insert in LBFLFK canola contains elements that would allow for double homologous recombination, the likelihood of HGT between the inserts within LBFLFK canola and microorganisms is negligible.

(b) Plant to plant gene transfer

There are no indications that the potential for successful exchange of genetic material has changed due to the genetic modification. Therefore, the out-crossing frequency to

other canola varieties or to wild relatives would be unlikely to be different for LBFLFK canola when compared to conventional canola varieties. Furthermore, the scope of the current application does not include the cultivation of LBFLFK canola varieties in the EU.

4. COMPARATIVE ANALYSIS

4.1. Choice of the conventional counterpart and additional comparators

The comparative assessment included LBFLFK canola, its conventional counterpart Kumily and six non-genetically modified (GM) reference varieties. Kumily was considered to be the appropriate conventional counterpart because it has the same genetic background as LBFLFK canola.

The commercial non-GM reference varieties were selected to represent a range of genetic backgrounds suitable for growth in the region where canola is commercially grown as a spring crop. The non-GM reference varieties represent a diverse range of phenotypic and compositional characteristics of conventional canola and are suitable for the agronomic and meteorological conditions of canola growing areas in the U.S.

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

In accordance with guidance from the European Food Safety Authority (EFSA), field trials were conducted at multiple sites in representative canola production areas in the U.S. in 2016 to allow for the comparative assessment of composition, agronomic performance and phenotypic characteristics of LBFLFK canola and its conventional counterpart Kumily. In addition, six non-GM commercial reference varieties were included at each location. Each field trial was conducted as a randomised complete block design with five replications per location.

All statistical analyses were performed following the statistical methodology outlined by EFSA. An analysis of variance (ANOVA) was conducted for each of the endpoints measured across all sites. The implemented methodology was designed to carry out a test of difference as well as a test of equivalence. Endpoints that were highly discrete or had little variation were excluded from ANOVA methods and analysed using descriptive statistics.

4.3. Selection of material and compounds for analysis

The components selected for compositional analysis were based primarily on the guidance provided in the OECD consensus document on compositional considerations for new varieties of low erucic acid rapeseed (canola). A total of 114 components were measured in grain.

The comparative assessment of grain composition identified no biologically relevant differences and/or lack of equivalence between LBFLFK canola and its comparators, except for the introduced EPA+DHA trait, taking into account natural variation. As intended, LBFLFK canola contains fatty acids with changed relative levels and newly introduced fatty acids, as compared to the conventional counterpart.

4.4. Comparative analysis of agronomic and phenotypic characteristics

An assessment of the phenotypic and agronomic characteristics of LBFLFK canola compared to its conventional counterpart has been performed in the field. Results of this field study showed that there are no biologically relevant changes in the agronomic or phenotypic characteristics of LBFLFK canola compared to the conventional counterpart, except germination characteristics, taking into account natural variation. The observed unintended effect of delayed and reduced germination of LBFLFK canola is most likely associated with the altered fatty acid trait and of no biological relevance for the food/feed safety assessment.

4.5. Effect of processing

LBFLFK canola will be grown and processed into food or feed fractions in the same manner as other commercialised canola. Processing of LBFLFK canola grain into defatted meal and oil fractions does not introduce or change nutritional components in a manner that might have an adverse impact on human or animal health. As intended, the EPA+DHA trait significantly impacted the fatty acid composition of the LBFLFK canola oil fractions. As with the conventional counterpart Kumily, processing of the meal and oil fractions derived from LBFLFK canola did not result in any unexpected changes.

The concentration of all introduced proteins was greatly reduced after processing. Only the proteins D6D(*Ot*), D6E(*Tp*) and O3D(*Pir*) were quantifiable and AHAS(*At*) [A122TS653N] was detectable in defatted meal. The rest of the proteins were not detectable in defatted meal. None of the proteins were detectable in oil samples.

5. TOXICOLOGY

(a) Toxicological testing of the newly expressed proteins

The information available on the newly expressed proteins in LBFLFK canola indicates that no adverse effects on human or animal health can be anticipated.

The protein sequence of each newly expressed protein was found to be structurally and functionally related to other proteins that are safely consumed by humans as food and by animals as feed, suggesting that humans and animals have been exposed to similar proteins as part of their diet and environment for many years without adverse effects. Bioinformatic analyses demonstrated that none of the newly expressed proteins in LBFLFK canola have significant homology to protein toxins.

The response of the newly expressed proteins to heat and pH treatment indicates that each of the proteins is not likely to remain intact or functional after commercial processing. In addition, each of the newly expressed proteins assayed were found to be susceptible to digestion under simulated gastric and intestinal conditions.

(b) Testing of new constituents other than proteins

The introduced fatty acid biosynthetic pathway in LBFLFK canola intentionally impacts the fatty acid profile in the seeds. Because of the expression of the newly introduced proteins, LBFLFK canola contains endogenous canola fatty acids with relative percent concentrations changed, as well as fatty acids newly introduced, including EPA and DHA.

All fatty acids with changed relative levels or newly introduced by the EPA+DHA trait are already present in foods that are considered safe for consumption. A

compositional analysis of various edible oils and fat containing foods confirmed the similarity of the fatty acid profile in refined, bleached and deodorised (RBD) oil derived from LBFLFK canola to Menhaden oil and other marine oils that are currently consumed. All fatty acids present in LBFLFK canola were shown to be present in other organisms and foods, indicating repeated dietary exposure.

(c) Information on natural food and feed constituents

No biologically relevant changes in the composition of LBFLFK canola were identified, except for the intentionally changed fatty acid profile in the seed.

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

Based on the available information, the consumption of the newly expressed proteins in LBFLFK canola are considered safe for humans and animals, and no further studies are considered necessary to confirm their safety. Likewise, no specific toxicity studies are needed to make a determination of safety for the fatty acid-containing products of LBFLFK canola. Even though no scientific uncertainties were identified during the safety assessment, a 90-day feeding study in rodents with whole food or feed was performed since it is a mandatory requirement according to Commission Implementing Regulation (EU) No 503/2013. The results of the repeated-dose 90-day oral toxicity study demonstrate the safety of LBFLFK canola defatted meal and RBD oil as compared to Kumily defatted meal and RBD oil when administered to male and female Wistar rats by repeated oral administration via the diet up to concentrations of 15% defatted meal and 4% RBD oil.

6. ALLERGENICITY

(a) Assessment of allergenicity of the newly expressed protein

No evidence was identified indicating that any of the donor organisms contain known or putative allergens or elicit an allergenic response. The newly expressed proteins in LBFLFK canola have no significant sequence homology to proteins that are known allergens or would have the potential to cause celiac disease.

The response of the newly expressed proteins to heat and pH treatment indicates that each of the proteins is not likely to remain intact or functional after commercial processing. In addition, each of the newly expressed proteins assayed was found to be susceptible to digestion under simulated gastric and intestinal conditions. Therefore, all newly expressed proteins in LBFLFK canola are considered unlikely to be allergenic.

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

Rapeseed is generally not considered an allergenic food. No biologically relevant changes in the composition of LBFLFK canola, with the exception of the introduced EPA+DHA trait, were identified in the compositional analysis. The proteins newly expressed in LBFLFK canola are unlikely to be allergenic. Accordingly, there is no evidence that LBFLFK canola has increased allergenic potential compared to non-GM canola varieties.

7. NUTRITIONAL ASSESSMENT

(a) Nutritional assessment of the genetically modified food

The fatty acid profile of LBFLFK canola differs from conventional canola due to the intended EPA+DHA trait. As a specialty canola containing EPA and DHA, the oil

produced by LBFLFK canola will be consumed specifically for the purposes of providing dietary omega-3 LC-PUFAs.

No unexpected or unintended effects were observed that adversely affect the nutritional value of LBFLFK canola seed as a result of the genetic modification. The fatty acid profile and nutritional value of LBFLFK canola oil is compositionally comparable to other currently consumed fish oils and fat-containing foods. No differences were observed that would require further assessment with respect to a potential impact on food and feed safety. No need was identified to perform any additional studies to address the nutritional safety of LBFLFK canola.

(b) Nutritional assessment of the genetically modified feed

LBFLFK canola differs from conventional canola due to the intentionally introduced EPA+DHA trait. For the other components measured, it is compositionally equivalent to other commercially available canola varieties, taking into account natural variation. The oil produced by LBFLFK canola will be consumed specifically for the purposes of providing dietary omega-3 LC-PUFAs to humans and to farmed aquatic species. The defatted meal from LBFLFK canola seed is compositionally similar to conventional defatted canola meal and will be distributed like other conventionally produced canola meal. Based on the information available with regard to the safety of the newly introduced fatty acids, specifically fish feeding studies that used oils similar to that produced by LBFLFK canola, no further nutritional studies with feed derived from LBFLFK canola are considered necessary.

8. EXPOSURE ASSESSMENT – ANTICIPATED INTAKE/EXTENT OF USE

The dietary exposure assessment to the newly expressed proteins was performed based on the consumption of RBD oil by humans, crude oil by fish in aquaculture and defatted meal by livestock, assuming that 100% of conventional canola seed, oil or meal would be solely obtained from LBFLFK canola. Only three of the eleven newly expressed proteins expressed in LBFLFK canola, namely D6D(*Ot*), D6E(*Tp*) and O3D(*Pir*), were quantifiable in defatted meal samples. AHAS(*At*) [A122TS653N] was detectable but not quantifiable, and all other newly expressed proteins were not detectable in the defatted meal samples. The assessment of chronic dietary exposure of European livestock to the newly expressed proteins in LBFLFK canola defatted meal indicated minimal to negligible exposure.

None of the newly expressed proteins were detected in either the crude or RBD oil samples. Accordingly, European consumers will not be exposed to the newly expressed proteins via the consumption of edible rapeseed oil derived from LBFLFK canola seeds. Likewise, the dietary intake of the newly expressed proteins in aquaculture fish was considered to be negligible because these proteins were not detected in the crude oil from LBFLFK canola seeds.

The dietary exposure to fatty acids contained in LBFLFK canola oil was evaluated based on the consumption of the corresponding foods that are likely to be replaced. The first assessment, replacing canola oil with LBFLFK canola oil, resulted in a decrease in monounsaturated fatty acids (MUFAs), an increase in PUFAs and negligible changes in saturated fatty acids (SFAs) and trans fatty acids. The nutritional implications of the changes in estimated intakes of fatty acids resulting from the substitution of canola oil with LBFLFK canola oil indicated that fatty acid levels generally remained at the original level, except for intake of EPA+DHA combined, which was increased to within the recommended levels for adult mean level consumers and young children, children and adolescent high-level consumers.

The second assessment aimed to determine the impact of replacing currently consumed EPA- and DHA-containing oils, specifically Menhaden oil, with LBFLFK canola oil. The substitution of Menhaden oil with LBFLFK canola oil resulted in a decrease in SFAs, slight increases in MUFAs and increases in total PUFAs. When used in similar ways and for human consumption, EPA and DHA contained in LBFLFK canola oil are expected to be as bioavailable as EPA and DHA from conventional sources.

The dietary intake assessment of fatty acids in feed considered fishmeal and fish oil as sources of EPA and DHA in the feed formulations of the aquaculture operations industry. The bioavailability of EPA and DHA from GM plant oils similar to that produced by LBFLFK canola is equivalent to that of fish oil. The fatty acid profile of LBFLFK canola oil is compositionally comparable to other fish oils, and both fish oil and canola oil are used as animal feed. Therefore, any replacement of oil in aquafeed with LBFLFK canola oil is not expected to alter the intake of EPA and DHA.

9. RISK CHARACTERISATION

A comprehensive risk characterisation of LBFLFK canola and derived foods and feed was conducted, considering all available evidence discussed throughout the application. The scientific evaluation of the characteristics of LBFLFK canola did not reveal any potential adverse effects or hazards for human or animal health. All available evidence was considered, including molecular characterisation, phenotypic, agronomical and compositional analysis, toxicology and allergenicity testing, nutritional assessment and exposure assessment.

The molecular characterisation of LBFLFK canola identified no changes due to the genetic modification that raised any safety concerns and did not identify any hazards. The genetic and phenotypic stability of LBFLFK canola was demonstrated over multiple generations and segregation analysis showed the independent inheritance of both inserts in LBFLFK canola according to Mendelian principles.

Each of the newly expressed proteins in LBFLFK canola, with the exception of D6E(*Pp*), O3D(*Pi*) and D4D(*Tc*), were detected in either immature and/or mature seed across all field sites.

The comparative assessment of compositional endpoints identified no differences of biological relevance, except the intended changes of the overall fatty acid composition in harvested LBFLFK canola grain. No differences were identified that would require further assessment with respect to a possible impact on food and feed safety.

The comparative assessment of agronomic and phenotypic characteristics identified no biologically relevant differences to its conventional counterpart, except the lower seed germination rates, which were an expected effect associated with the altered fatty acid profile in LBFLFK canola.

Processing of LBFLFK canola grain into defatted meal and oil fractions does not introduce or change nutritional components in a manner that might have an adverse impact on human or animal health.

The RBD oil and crude oil produced from LBFLFK canola will be consumed specifically for providing dietary EPA and DHA to humans and to farmed aquatic species, respectively. The defatted meal produced from LBFLFK canola does not have any significant differences in composition compared to conventional canola meal and will be used like other conventionally produced canola meal.

The assessment of the newly expressed proteins expressed in LBFLFK canola indicates that they are unlikely to pose adverse effects on human or animal health. None of the proteins newly expressed in LBFLFK canola shares significant homology to protein toxins or allergens.

The results of the toxicological and allergenicity assessment indicate that consumption of LBFLFK canola food and feed products will be as safe as consumption of equivalent products from conventional canola and as safe as comparable sources of EPA+DHA when considering the intended EPA+DHA trait. There is no evidence to suggest that LBFLFK canola has greater allergenic potential compared to conventional commercial canola varieties.

The nutritional assessment demonstrated that LBFLFK canola is as safe and as nutritious as conventional canola for food and feed use and that the nutritional impact of the altered fatty acid profile is comparable to that of currently consumed EPA- and DHA-containing foods and feeds, respectively. The fatty acids present in LBFLFK canola are present in food and feed that are safely and routinely consumed.

Different dietary exposure scenarios of consumers and animals to the newly expressed proteins as well as the fatty acids newly introduced or with altered relative levels showed no potential adverse effects from food and feed intake of products derived from LBFLFK canola and did not indicate any safety concerns.

The newly expressed proteins were not detected in crude oil and RBD oil derived from LBFLFK canola grain. Therefore, European consumers will not be exposed to the newly expressed proteins via the consumption of edible rapeseed oil derived from LBFLFK canola seeds. Likewise, the dietary intake of the newly expressed proteins in aquaculture fish was considered to be negligible. Consumption of oil containing EPA and DHA derived from LBFLFK canola is not expected to result in adverse effects or pose a risk. The consumption of food and feed derived from LBFLFK canola is not nutritionally disadvantageous to humans and animals.

The evidence presented throughout this application demonstrates that:

- The consumption of food and feed derived from LBFLFK canola is as safe as the food and feed which it is intended to replace;
- The food derived from LBFLFK canola is not nutritionally disadvantageous for the consumer compared to the food which it is intended to replace;
- The feed derived from LBFLFK canola is not nutritionally disadvantageous for animals compared to the feed which it is intended to replace;
- The food derived from LBFLFK canola does not mislead the consumer;
- The feed derived from LBFLFK canola does not harm or mislead the consumer by impairing distinctive features of the animal products compared to conventionally produced feed.

The proposal for labelling according to Regulation (EC) No 1829/2003, Article 13(2) and Article 25(2)(c) is: Genetically modified rapeseed with eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA).

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

The fatty acid profile of LBFLFK canola differs from conventional canola due to the intended EPA+DHA trait. LBFLFK canola contains fatty acids that are not present in conventional canola, and some fatty acids have altered relative levels as compared to conventional canola. Although the risk characterisation of LBFLFK canola identified negligible risk for potential adverse effects on human and animal health in the context

of the intended uses of LBFLFK canola, the applicant proposes to put in place the following post-market monitoring measures, in line with Article 7 of IR 503/2013, to confirm the expected consumption:

The authorisation holder will collect information on:

(a) quantities of LBFLFK canola oil and LBFLFK canola grain for oil extraction, imported into the European Union for the placing on the market as or in products for food.
(b) in case of imports of products referred to in (a), results of searches in the FAOSTAT database on the quantities of vegetable oil consumption by Member State, including shifts in quantities between the different types of oils consumed.
(c) in case of imports of products referred to in (a), data on the different categories of food and feed uses of LBFLFK canola oil in the EU.

The authorisation holder will review the nutritional assessment conducted as part of the risk assessment, based on the information collected and reported.

11. ENVIRONMENTAL ASSESSMENT

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

In this area of assessment, the main environmental concern, according to the EFSA Environmental Risk Assessment (ERA) Guidance, is that target organisms develop resistance to the insect or pathogen tolerance traits expressed by the GM plant. LBFLFK canola has been developed to confer the production of omega-3 LC-PUFAs and tolerance to treatment with the intended trait-specific imidazolinone herbicide active ingredient imazamox. Therefore, no target organisms are associated with this product, and so an assessment of the potential resistance development in target organisms resulting from the import, processing and food and feed use of LBFLFK canola is not relevant.

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

The scope of this application is for food and feed uses, import and processing and excludes cultivation. The environmental exposure is limited to accidental release of LBFLFK canola during the transportation and processing for food and feed.

(a) Persistence and invasiveness

The comparative analysis of agronomic and phenotypic characteristics showed that there are no harmful biologically relevant differences in characteristics indicative of differences in persistence or invasiveness potential between LBFLFK canola and the conventional counterpart. It can be concluded that the genetic modification in LBFLFK canola does not result in potentially harmful changes in persistence and invasiveness characteristics compared to the conventional crop.

(b) Selective advantage or disadvantage

The potential that the introduced traits confer a selective advantage or disadvantage to the GM crop has been assessed. The main limiting factors preventing the spread of the crop outside agro-ecosystems are human dependence and frost tolerance;

therefore, the EPA+DHA and herbicide tolerance traits are unlikely to confer selective advantage or disadvantage to canola.

(c) Potential for gene transfer

The molecular characterisation data gathered on LBFLFK canola and the results of the bioinformatics searches for similarities with microbes allow a full risk characterisation. The conclusion is that the 11 genes expressed in LBFLFK canola are unlikely to be transferred to microorganisms, and even if they were, this would not lead to human, animal or environmental harm. Thus, the likelihood that the import, processing or food and feed use of LBFLFK canola will result in harm to humans or animals or the environment is highly unlikely. Considering the function of the genes, the consequences of HGT can be considered marginal. Therefore, the risk will be negligible.

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

LBFLFK canola has been developed to confer the production of omega-3 LC-PUFAs and tolerance to treatment with imidazolinone herbicides, and no target organisms are associated with this product. Therefore, an assessment of the potential resistance development in target organisms resulting from the import, processing and food and feed use of LBFLFK canola is not relevant for this application.

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

The scope of this application covers the import, processing and food and feed use of LBFLFK canola in the EU, and no deliberate release of viable plant material in the EU environment is expected. Given the reproductive biology of canola, it is highly unlikely that accidental spillage of viable plant material would result in feral populations in the EU. Therefore, an assessment of potential direct effects of LBFLFK canola on non-target organism (NTO) populations is not relevant for this application. However, the assessment considers potential indirect adverse effects on NTO populations due to exposure through faeces of animals fed with LBFLFK canola.

Exposure to manure and faeces of animals fed with LBFLFK canola would lead to very low levels of environmental exposure. The newly expressed proteins are expressed at low levels in grain and readily degraded by enzymatic activity in the gastro-intestinal tract of animals. Likewise, the newly introduced fatty acids would be absorbed by the body and/or metabolised by microbes during the digestive process. Only minimal amounts of these proteins and fatty acids will be present in animal faeces. There would subsequently be further degradation of these proteins and fatty acids due to microbial processes. Exposure of soil and water environments to these proteins from disposal of animal wastes is likely to be very low and localised. Thus, exposure of potentially sensitive NTOs to LBFLFK canola is likely to be very low and of no ecological relevance.

(f) Effects on human health

Refer to Section 9.

(g) Effects on animal health

Refer to Section 9.

(h) Effects on biogeochemical processes

The scope of this application covers the import, processing and food and feed use of LBFLFK canola in the EU. Cultivation of LBFLFK canola in the EU is not included in the scope. Although environmental exposure could occur through the accidental spillage of LBFLFK canola, through manure or faeces of animals fed on LBFLFK

canola or through organic matter or by-products from LBFLFK canola, these routes of exposure would represent very low levels of exposure that would be limited spatially and temporally. It is highly unlikely that adverse effects on biogeochemical processes could occur. Therefore, an assessment of the impact of LBFLFK canola on biogeochemical processes resulting from specific cultivation, management and harvesting techniques is not relevant given the scope of this application.

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

The scope of this application covers the import, processing and food and feed use of LBFLFK canola in the EU. Cultivation of LBFLFK canola is not included in the scope. Therefore, an assessment of the impacts of specific cultivation, management and harvesting techniques is not relevant given the scope of this application.

11.3. Potential interactions with the abiotic environment

The scope of this application is the authorisation of LBFLFK canola for food and feed uses and for import and processing in accordance with articles 5 and 17 of Regulation (EC) No 1829/2003. The scope of this application does not include cultivation of LBFLFK canola in the EU.

11.4. Risk characterisation

The ERA has been conducted following the requirements and methodology described in EFSA guidance documents. The baseline considered for this risk assessment is the use of conventional canola in the EU, applying the concept of familiarity and considering the history of safe use of conventional canola.

A comparative safety assessment has been conducted using a weight-of-evidence approach, considering molecular characterisation data as well as compositional and agronomic comparisons between LBFLFK canola and its conventional counterpart. This assessment has been used to establish whether unintended changes in LBFLFK canola have occurred as a result of the genetic modification. The results of this comparative safety assessment demonstrated that the main differences of biological relevance identified between LBFLFK canola and the conventional counterpart are the intended traits: the altered fatty acid composition of the seeds and tolerance to imidazolinone herbicides. Accordingly, LBFLFK canola contains the intended proteins as well as newly introduced fatty acids and fatty acids with changed relative levels as compared to the conventional counterpart Kumily. In addition, a phenotype of delayed and reduced germination of LBFLFK canola was observed, which is most likely associated with the altered fatty acid trait. Therefore, the main focus of the ERA is potential harmful effects due to the intended traits, also considering delayed and reduced germination.

An assessment of whether LBFLFK canola will be more persistent than the conventional crop in agricultural habitats or more invasive in natural habitats has been conducted. The conclusion from this assessment is that the risk that the import, processing or food and feed use of LBFLFK canola in the EU will not result in harm to sustainable agricultural production or biodiversity as a result of changes in persistence or invasiveness compared with the conventional crop is negligible.

An assessment of whether the new genes present in LBFLFK canola could be transferred into microorganisms and become integrated into their genome leading to adverse effects in human and animal health or the environment has been conducted. The conclusion from this assessment is that it is very unlikely that these genes would become established in the genome of microorganisms in the environment or in the

human and animal digestive tract. In the very unlikely event that such HGT would take place, no adverse effects on human and animal health or the environment are expected.

Potential interactions with target and NTOs that could lead to harmful environmental effects have also been assessed. The conclusion from these assessments is that adverse effects on sustainable agricultural production or biodiversity due to adverse effects on populations of NTOs resulting from the import, processing or food and feed use of LBFLFK canola will be negligible.

No assessment of adverse environmental effects due to changes in management practices or effects on biogeochemical processes has been performed since cultivation of LBFLFK canola is not within the scope of this application.

Finally, risks associated with the import, processing and food and feed use of LBFLFK canola in the EU on human and animal health have been assessed. The conclusion from this assessment was that food and feed derived from LBFLFK canola is as safe for human and animal consumption as food and feed derived from the conventional crop and as safe as comparable sources of EPA and DHA when considering the intended EPA+DHA trait.

In summary the import, processing and food and feed use of LBFLFK canola in the EU will pose negligible risk to human and animal health or the environment. The uncertainties associated with this risk characterisation are considered very low, and no potential long-term adverse environmental effects are anticipated.

12. ENVIRONMENTAL MONITORING PLAN

(a) General (risk assessment, background information)

As required by Article 5(5)(b) and 17(5)(b) of Regulation (EC) No. 1829/2003, the proposed Post-Market Environmental Monitoring (PMEM) plan for LBFLFK canola has been developed according to the principles and objectives outlined in Annex VII of Directive 2001/18/EC and Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC. The PMEM also takes into account the Scientific Opinion on guidance on the Post-Market Environmental Monitoring of genetically modified plants.

(b) Interplay between environmental risk assessment and monitoring

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

An ERA was carried out for LBFLFK canola according to the principles laid down in Annex II to Directive 2001/18/EC and Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC. The scientific evaluation of the characteristics of LBFLFK canola in the ERA has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses of LBFLFK canola.

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

The scientific evaluation of the characteristics of LBFLFK canola in the ERA has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses of LBFLFK canola. It is therefore considered that there is no need for case-specific monitoring.

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

General surveillance is not based on a particular hypothesis, and it should be used to identify the occurrence of unanticipated adverse effects of the viable genetically modified organism or its use for human and animal health or the environment that were not predicted in the ERA.

The scope of this application is the authorisation of LBFLFK canola for import, processing and food and feed uses. The scope of the application does not include authorisation for the cultivation of LBFLFK canola seed products.

Therefore, exposure to the environment will be limited to unintended release of LBFLFK canola, which could occur for example via substantial losses during loading/unloading of the viable commodity including LBFLFK canola destined for processing into animal feed or human food products. Exposure can be controlled by clean up measures and the application of current practices used for the control of any adventitious rapeseed plants, such as manual or mechanical removal and the application of herbicides (with the exception of imidazolinone herbicides).

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 LBFLFK canola will be undertaken for the duration of the authorisation. The general surveillance will take into consideration, and be proportionate to, the extent of imports of LBFLFK canola and use thereof in the Member States.

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

(e) Reporting the results of monitoring

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

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

The authorisation holder will submit an annual monitoring report including results of the general surveillance in accordance with the conditions of the authorisation. The report will contain information on unanticipated adverse effects, if any, that have arisen from handling and use of viable LBFLFK canola.

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

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

accordance with Article 30 of Regulation (EC) No 1829/2003. Confidential parts of such report shall be submitted in separate documents.

13. DETECTION AND IDENTIFICATION TECHNIQUES FOR THE GENETICALLY MODIFIED PLANT

The detection method for LBFLFK canola was sent to the European Union Reference Laboratory for GM Food and Feed (EURL GMFF) of the Joint Research Centre of the European Commission (EC-JRC) for the purposes of experimental testing and validation. Appropriate control samples were also made available to the EURL.

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

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

(a) Notification number

Not applicable. Field trials with LBFLFK canola have not been conducted in the EU.

(b) Conclusions of post-release monitoring

Not applicable

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

Not applicable

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

(a) Release country

United States (U.S.)

(b) Authority overseeing the release

United States Department of Agriculture (USDA)

(c) Release site

Release sites were in several states throughout the U.S. where canola can be grown.

(d) Aim of the release

Regulatory trials, trait introgression and trait development, seed increase

(e) Duration of the release

The generation time for canola from planting to harvest was generally 5 to 6 months.

(f) Aim of post-releases monitoring

Volunteer monitoring

(g) Duration of post-releases monitoring

3 years minimum post-release monitoring

(h) Conclusions of post-release monitoring

Occurrence of volunteers not different from conventional canola

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

No risk to human health or the environment has been identified during the field releases.