

Supporting document 2

Nutrition Risk Assessment – Application A1239

Food derived from EPA and DHA producing and herbicide-tolerant canola line LBFLFK

Executive summary

Application A1239 seeks to amend the Australia New Zealand Food Standards Code to permit the sale and use of food derived from canola that has been genetically-modified to contain the omega-3 (n-3) long-chain polyunsaturated fatty acids (LC-PUFA) eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), and for tolerance to imidazolinone herbicides. In addition to EPA and DHA, canola line LBFLFK also contains the n-3 LC-PUFA docosapentaenoic acid (DPA), the metabolic intermediate between EPA and DHA. As the oil from LBFLFK seed will be available for human consumption, FSANZ has conducted a risk assessment to identify whether any adverse health effects can be expected from a potential increase in the dietary intake of EPA, DPA and DHA.

Dietary intake of EPA, DPA and DHA is mainly from the consumption of seafood, with a contribution due to endogenous biosynthesis from dietary α -linolenic acid (ALA), an essential fatty acid (FA). As for fish oils, FAs in canola oil are predominantly in the form of triglycerides, and therefore the bioavailability of EPA, DPA and DHA from triglycerides in LBFLFK oil and fish oil is expected to be similar and not raise nutritional concerns. n-3 LC-PUFA have been associated with beneficial effects, particularly on cardiovascular health, however adverse effects have been reported in some studies. An Upper Level of Intake (UL), defined as the highest average daily nutrient intake level likely to pose no adverse health effects, has been established for n-3 LC-PUFA. The UL, defined as the sum of EPA, DPA and DHA, is 3 g/day for children, adolescents and adults.

A large number of randomised controlled trials of n-3 LC-PUFA have been conducted since the UL of 3 g/day was established. In non-pregnant adults, high intakes of n-3 LC-PUFA (up to 5 g/day) over long durations (up to 88 months) have not been associated with clear adverse effects. During pregnancy, n-3 LC-PUFA intake of up to 3 g/day was also not associated with adverse effects. In children and adolescents, an increase in the incidence of flatulence and belching was reported in one study at an n-3 LC-PUFA dose of 3 g/day but no clearly treatment-related adverse effects are evident in the published literature. It is concluded that the Upper Level of Intake (UL) of 3 g/day is sufficiently health protective and appropriate for use in risk characterisation.

The dietary intake assessment considered the usual intake of n-3 LC-PUFA (sum of EPA, DPA and DHA) from the current food supply (baseline intake) and two scenarios to account for potential additional intake of EPA, DPA and DHA due to the introduction to the food supply of oil from LBFLFK. The dietary intake estimates for all population groups assessed in both Australia and New Zealand were below the UL of 3 g/day for both scenarios. It is therefore concluded that consumption of oil from canola line LBFLFK will not pose a nutritional risk to the Australian and New Zealand populations.

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1 Introduction

Application A1239 seeks to amend the Australia New Zealand Food Standards Code to permit the sale and use of food derived from canola that has been genetically-modified to contain the omega-3 (n-3) long-chain polyunsaturated fatty acids (LC-PUFA) eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). In addition to EPA and DHA, canola line LBFLFK also contains the n-3 LC-PUFA docosapentaenoic acid (DPA)¹, which is formed as an intermediate in the conversion of EPA to DHA

Fish is typically the major contributor to dietary intake of EPA, DPA and DHA. n-3 LC-PUFA have been associated with beneficial effects, particularly on cardiovascular health, however adverse effects have been reported in some studies. An Upper Level of Intake (UL), defined as the highest average daily nutrient intake level likely to pose no adverse health effects, has been established for n-3 LC-PUFA. The UL, defined as the sum of EPA, DPA and DHA, is 3 g/day for children, adolescents and adults.

As the oil from canola line LBFLFK will be available for human consumption, FSANZ has conducted a risk assessment to identify whether any adverse health effects can be expected from a potential increase in the dietary intake of EPA, DPA and DHA. The risk assessment does not consider other nutrients (protein, carbohydrate, fibre, vitamins, minerals, phytosterols) or anti-nutritional factors (phytic acid, phenolics, glucosinolates) because the levels of these substances in LBFLFK are similar to those in conventional canola lines (see Supporting Document 1).

This risk assessment comprises a hazard assessment and a dietary intake assessment. The hazard assessment includes information on the UL for n-3 LC-PUFA, and considers systematic reviews which include detailed analyses of potential adverse effects associated with increased intake of n-3 LC-PUFA in a large number of trials in adults. Trials of n-3 LC-PUFA in children are also considered.

The dietary intake assessment considers the usual intake of n-3 LC-PUFA (sum of EPA, DPA and DHA) from the current food supply (baseline intake) and two scenarios to account for potential additional intake of EPA, DPA and DHA due to the introduction to the food supply of oil from canola line LBFLFK.

2 Nutrition hazard assessment

The nutrition hazard assessment includes:

1. information on the fatty acid (FA) composition of refined, bleached, deodorised (RBD) oil (i.e. "food-grade" oil) from canola line LBFLFK, and a comparison with oil from four conventional canola lines and four fish oils;
2. information on the biochemistry, bioavailability and physiology of n-3 LC-PUFA;
3. information on the derivation of the upper level of intake for n-3 LC-PUFA;
4. consideration of a recent systematic review of randomised controlled trials investigating increased n-3 LC-PUFA intake in adults. This systematic review includes meta-analyses of adverse effects reported in these trials, and was reviewed by the World Health Organization (WHO) Nutrition Guidance Expert Advisory Group (NUGAG);
5. consideration of a recent systematic review of randomised controlled trials investigating increased n-3 LC-PUFA intake in pregnancy;
6. consideration of adverse effects reported in trials with children.

¹ For an overview of the biosynthesis pathway engineered into LBFLFK, please see Figure 2 in Supporting Document 1.

2.1 Fatty acid composition of LBFLFK oil

The FA composition of refined, bleached, deodorised (RBD) oil (i.e. “food-grade” oil) from LBFLFK is reported by Andre et al. (2019), who also present FA composition data for RBD oil from four conventional canola lines and four different fish oils. The levels of EPA, DPA, DHA, and total omega-3 FAs, are shown in Table 1.

The sum of EPA, DPA and DHA levels, as a percentage of total FAs, is 6.5% for LBFLFK oil and 24 – 33% for the four fish oils tested. Levels of total omega-3 FAs are 15% for LBFLFK oil and 29 – 39% for fish oils.

Table 1: Levels of EPA, DPA and DHA (as % of total FAs) in LBFLFK oil, conventional canola oils and fish oils (Andre et al. 2019)

	LBFLFK oil ¹	Conventional canola oils ²	Fish oils ³
EPA	3.97	< LOQ ⁴	9.7 – 18
DPA	2.14	< LOQ	1.5 – 2.5
DHA	0.35	< LOQ	11 – 13
EPA+DPA+DHA	6.5	NA	24 – 33
Total n-3	15	2.5 – 7.3	29 – 39

¹ Mean levels.

² Range of mean levels in four conventional canola oils, including oil from the LBFLFK parent line (Kumily).

³ Range of mean levels in four fish oils.

⁴ LOQ: Limit of Quantification.

NA: Not Applicable.

2.2 Biochemistry, bioavailability and physiology of n-3 fatty acids

PUFAs have a backbone of ≥ 18 carbon atoms with two or more unsaturated (i.e. double) bonds. Depending on the position of the first double bond, PUFAs are categorised into two main groups: n-3 and omega-6 (n-6). The FA nomenclature for EPA (20:5n-3), DPA (22:5n-3) and DHA (22:6n-3) describes the number of carbon atoms in the backbone (20 for EPA, 22 for DPA and DHA), the number of double bonds (5, 5 and 6 respectively) and the position of the first double bond counting from the methyl end (n-3).

Linoleic acid (LA, 18:2n-6) and α -linolenic acid (ALA, 18:3n-3) are essential FAs that are metabolised, respectively, to n-6 and n-3 LC-PUFA containing ≥ 20 carbon atoms (Brenna et al. 2009). Conversion of dietary ALA to EPA, DPA and DHA is limited (Plourde and Cunnane 2007) and the enzymatic steps in the conversion pathway vary in efficiency and are influenced by the composition of dietary fats (Goyens et al. 2006; Harnack et al. 2009). Dietary intake of EPA, DPA and DHA is mainly from the consumption of seafood, with a contribution due to endogenous biosynthesis from dietary ALA (Holman 1998; Simopoulos 1991; Tinoco 1982).

The bioavailability of dietary n-3 LC-PUFA is influenced by factors such as their chemical form (e.g. free FAs, phospholipids, or triglycerides) and other nutrients present in the food matrix, particularly the presence of other fats in a meal which appears to improve absorption of n-3 LC-PUFA (Lawson and Hughes 1988; Schuchardt and Hahn 2013). As for fish, FAs in canola oil are predominantly in the form of triglycerides (92-99%; OECD 2011), and therefore the bioavailability of EPA, DPA and DHA from triglycerides in LBFLFK oil and fish oil is expected to be similar.

n-3 LC-PUFA play a role in several physiological functions including regulation of

inflammation and immune function, lipid metabolism, and cardiovascular function. Their multiple actions appear to involve mechanisms linking the cell membrane, the cytosol, and the nucleus (Calder 2012).

2.3 Upper Level of Intake

The Upper Level of Intake (UL) is a Nutrient Reference Value (NRV) that defines the highest average daily nutrient intake level likely to pose no adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects increases (NHMRC and MoH 2006 and www.nrv.gov.au).

In Australia and New Zealand, the UL for n-3 LC-PUFA, defined as the sum of EPA, DPA and DHA, is 3 g/day for children, adolescents and adults (NHMRC and MoH 2006). No ULs have been established for DHA, DPA or EPA alone. The assessment stated: (i) there is some evidence to suggest that high intake of these FAs may impair immune response and prolong bleeding time; (ii) the immune function tests were performed *in vitro* and it is unclear how the results would translate to the *in vivo* situation, and (iii) prolonged bleeding times have been seen in the Inuit, but it is not known if they were caused by high intake of n-3 LC-PUFA (NHMRC and MoH 2006).

The UL was based on a US Food and Drug Administration (US FDA) assessment which concluded that, when consumption of fish oils results in EPA and DHA intake of 3 g/day or less, there is no significant risk for increased bleeding time beyond the normal range (US FDA 1997).

2.4 Randomised controlled trials in non-pregnant adults

Abdelhamid et al. (2020) conducted a systematic review of randomised controlled trials (RCTs) reporting the effects of increased intake of n-3 LC-PUFA on prevention of cardiovascular disease. This Cochrane review, which is an update of Abdelhamid et al. (2018), was conducted to include results from three recent large-scale and long-term trials of n-3 LC-PUFA, and included detailed analyses of both the potential health benefits and adverse effects reported in these trials. The review update was requested by and reviewed by the WHO Nutrition Guidance Expert Advisory Group (NUGAG). NUGAG considered the following as key outcomes to inform their planned dietary guidance:

1. all-cause mortality;
2. cardiovascular disease mortality;
3. cardiovascular disease events;
4. coronary heart disease mortality;
5. coronary heart disease events;
6. stroke;
7. arrhythmia (atrial fibrillation);
8. serum lipids including total cholesterol, fasting triglycerides, high-density lipoprotein (HDL) and low-density lipoprotein (LDL);
9. measures of adiposity (body weight and body mass index (BMI)).

Trials were included in the review if they lasted at least 12 months and compared supplementation or advice to increase n-3 LC-PUFA or ALA intake, or both, versus usual or lower intake. A total of 86 RCTs (162,796 participants) were included. Trials were of 12 to 88 months' duration and included adults at varying cardiovascular risk, mainly in high-income countries. Participants who were pregnant were excluded from the review.

Most trials assessed n-3 LC-PUFA supplementation with capsules, but some used n-3 LC-PUFA-rich foods or dietary advice compared to placebo or usual diet. n-3 LC-PUFA doses ranged from 0.5 g/day to more than 5 g/day (19 RCTs gave at least 3 g/day, the value of the

Upper Level of Intake).

The analyses conducted for key outcomes (Table 2) suggested little or no effect of increasing n-3 LC-PUFA intake on all-cause mortality, cardiovascular mortality, cardiovascular events, stroke or arrhythmia, while increasing n-3 LC-PUFA intake may slightly reduce coronary heart disease mortality and coronary heart disease events. Increasing n-3 LC-PUFA intake had little or no effect on body weight, body mass index and serum lipids. The effect of n-3 LC-PUFA on bleeding was concluded by the authors to be unclear due to very low certainty evidence, however the 95% confidence interval (CI) for the risk ratio spanned the null value of 1.0. Evidence for pulmonary embolus or deep vein thrombosis (DVT) was also assessed as being of very low-certainty, however the 95% CI of the risk ratio also spanned the null. Overall, effects did not differ by trial duration or n-3 LC-PUFA intake in pre-planned subgroup and meta-regression analyses.

Regarding non-serious side effects (Table 3), 95% confidence intervals for risk ratios spanned the null value for all side effects, and there was no suggestion that increasing n-3 LC-PUFA intake was associated with an increase in combined side effects (risk ratio 1.01, 95% CI 0.95 to 1.08).

Table 2: Effects of increasing n-3 LC-PUFA intake on key health outcomes

	Risk ratio	95% confidence interval	Certainty of evidence¹
All-cause mortality	0.97	0.93 to 1.01	High
Cardiovascular disease mortality	0.92	0.86 to 0.99	Moderate
Cardiovascular disease events	0.96	0.92 to 1.01	High
Coronary heart disease mortality	0.90	0.81 to 1.00	Low
Coronary heart disease events	0.91	0.85 to 0.97	Low
Stroke	1.02	0.94 to 1.12	Moderate
Arrhythmia	0.99	0.92 to 1.06	Low
Bleeding	1.12	0.91 to 1.37	Very low
Pulmonary embolus or DVT	1.15	0.44 to 2.98	Very low
	Mean difference		
Serum lipids (mmol/L)			
Total cholesterol	0.01	-0.05 to 0.03	High
Triglycerides	-0.24	-0.31 to -0.16	High
High-density lipoprotein (HDL)	0.03	0.01 to 0.05	High
Low-density lipoprotein (LDL)	0.01	-0.01 to 0.03	High
Adiposity			
Body weight (kg)	0.00	-0.69 to 0.70	High
Body mass index (kg/m ²)	0.06	-0.14 to 0.25	High

¹ Certainty of evidence was assessed using GRADE (GRADE Working Group (2004)).

Table 3: Effects of increasing n-3 LC-PUFA intake on side-effects (non-serious)

	Risk ratio	95% confidence interval	Certainty of evidence
Abdominal pain or discomfort	1.05	0.91 to 1.20	Not assessed
Diarrhoea	1.02	0.87 to 1.19	Not assessed
Nausea	1.20	0.96 to 1.49	Not assessed
Any gastrointestinal side effect	1.10	0.97 to 1.26	Not assessed
Withdrawal from trial due to side effects	1.16	0.99 to 1.36	Not assessed
All side effects combined	1.01	0.95 to 1.08	Not assessed

2.5 Randomised controlled trials in pregnancy

Middleton al. (2018) conducted a systematic review of randomised controlled trials (RCTs) reporting the effects of increased intake of n-3 LC-PUFA during pregnancy on maternal, perinatal, and neonatal outcomes and longer-term outcomes for mother and child. This Cochrane review included meta-analyses and assessments of evidence certainty.

A total of 70 RCTs (involving 19,927 women at low, mixed or high risk of poor pregnancy outcomes) were included in the review. These RCTs compared n-3 LC-PUFA interventions (supplements and food) with placebo or no n-3 LC-PUFA, or study arms directly comparing n-3 LC-PUFA doses (up to 3 g/day) or types.

The main results of the analyses are shown in Table 4. There was a reduced risk of preterm birth and of low birthweight babies in women receiving n-3 LC-PUFA compared with no n-3 LC-PUFA. There was an increased risk of prolonged gestation in women receiving n-3 LC-PUFA, however the certainty of evidence was moderate for this outcome. For the remaining outcomes, the 95% confidence interval of the risk ratio spanned the null value of 1.0.

Table 4: Effects of increasing n-3 LC-PUFA intake in pregnancy

	Risk ratio	95% confidence interval	Certainty of evidence ¹
Preterm birth (< 37 weeks)	0.89	0.81 to 0.97	High
Early preterm birth (< 34 weeks)	0.58	0.44 to 0.77	High
Prolonged gestation (> 42 weeks)	1.61	1.11 to 2.33	Moderate
Perinatal death	0.75	0.54 to 1.03	Moderate
Neonatal care admissions	0.92	0.83 to 1.03	Moderate
Low birthweight	0.90	0.82 to 0.99	High
Large-for-gestational age	1.15	0.97 to 1.36	Moderate
Induction post-term	0.82	0.22 to 2.98	Low
Maternal serious adverse events	1.04	0.40 to 2.72	Low
Postnatal depression	0.99	0.56 to 1.77	Low
Pre-eclampsia	0.84	0.69 to 1.01	Low

¹ Certainty of evidence was assessed using GRADE (GRADE Working Group (2004)).

There were no effects of n-3 LC-PUFA on child outcomes of cognition, vision, neurodevelopment, behaviour, and body mass index (all very low certainty or low certainty of evidence).

2.6 Randomised controlled trials in children and adolescents

In children and adolescents, n-3 LC-PUFA have been investigated for their effects on several health conditions including allergy, attention deficit hyperactivity disorder (ADHD), and hypertriglyceridemia. The only potentially treatment-related side-effects that could be identified in the published literature were from an RCT in children (10-16 years old) investigating an n-3 LC-PUFA dose of 3 g/day for 12 weeks. An increase in the incidence of flatulence and belching was observed, from 6% in the placebo group to 41% in the n-3 LC-PUFA group; $p < 0.01$) (Del-Río-Navarro et al. 2019).

2.7 Hazard assessment discussion and conclusion

Conventional canola oils do not contain quantifiable levels of EPA, DPA and DHA. In LBFLFK oil, the sum of EPA, DPA and DHA levels, as a percentage of total FAs, is 6.5%, while levels in fish oils are 24 – 33%. As for fish oils, FAs in canola oil are predominantly in the form of triglycerides, and therefore the bioavailability of EPA, DPA and DHA from triglycerides in LBFLFK oil and fish oil is expected to be similar.

The Upper Level of Intake (UL) for n-3 LC-PUFA, defined as the sum of EPA, DPA and DHA, is 3 g/day for children, adolescents and adults. The UL was based on a US FDA assessment published in 1997. The assessment stated: (i) there is some evidence to suggest that high intake of these FAs may impair immune response and prolong bleeding time; (ii) the immune function tests were performed *in vitro* and it is unclear how the results would translate to the *in vivo* situation, and (iii) prolonged bleeding times have been seen in the Inuit, but it is not known if they were caused by high intake of n-3 LC-PUFA.

A large number of human trials of n-3 LC-PUFA have been conducted since the UL was established. In non-pregnant adults, evidence from randomised, controlled trials (RCTs) indicates that high intakes of n-3 LC-PUFA (up to 5 g/day) over long durations (up to 88 months) are not associated with clear adverse effects. During pregnancy, from an analysis of 70 RCTs, n-3 LC-PUFA intake of up to 3 g/day was also not associated with adverse effects. In children and adolescents, an increase in the incidence of flatulence and belching has been reported in one study at an n-3 LC-PUFA dose of 3 g/day, but no clearly treatment-related adverse effects are evident in the published literature.

It is concluded that the UL for n-3 LC-PUFA of 3 g/day is sufficiently health protective and appropriate for use in risk characterisation.

3 Dietary intake assessment

The purpose of this assessment was to estimate dietary intakes of n-3 LC-PUFA (sum of DHA+EPA+DPA) both currently (baseline) and after the introduction of LBFLFK oil (refined, bleached and deodorised). The assessment focusses on estimated intakes of n-3 LC-PUFA rather than individual FAs as there are nutrient reference values established for n-3 LC-PUFA but none specifically for EPA, DPA or DHA individually. Adequate Intake levels have been established for linoleic and alpha linoleic acid, however no Upper Levels of Intake (UL) have been set for these FAs because there is no known level at which adverse effects may occur (NHMRC and MoH 2006).

The presence of *trans* fatty acids (TFA) in refined LBFLFK canola oil is comparable to refined conventional canola oil. As a proportion of total energy, Australian and New Zealand mean intakes of TFA (0.6% and 0.7% of energy) (Reuss et al. 2009) are below the WHO target of less than 1% total energy derived from TFA (WHO 2018). Furthermore, it has been shown that around 60% to 75% of TFA intake in the Australian and New Zealand diet is contributed by ruminant foods (FSANZ 2009a). Hence, the TFA in canola line LBFLFK has not been considered for this dietary intake assessment.

3.1 Approach

Dietary intake assessments require data on the concentration of the chemical of interest in the food requested and consumption data for the foods that have been collected through a national nutrition survey. The dietary intake assessment was undertaken using FSANZ's dietary modelling computer program [Harvest](#)², using deterministic calculations and using published usual nutrient intake data.

A summary of the general FSANZ approach to conducting dietary intake assessments for applications is on the [FSANZ website](#). A detailed discussion of the FSANZ methodology and approach to conducting dietary intake assessments is set out in *Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes* (FSANZ 2009b).

3.2 Dietary intake assessment methodology

To estimate the potential changes in n-3 LC-PUFA intake in Australia and New Zealand from the introduction of canola line LBFLFK, FSANZ added the n-3 LC-PUFA that may enter the food supply from the LBFLFK (additional intake) to the usual intake of n-3 LC-PUFA reported for the current food supply (baseline intake). The assessment includes the following inputs:

- current (baseline) n-3 LC-PUFA usual intakes published by the Australian Bureau of Statistics (ABS) (ABS 2015a);
- food consumption data from the available Australian and New Zealand national nutrition surveys (NNS) – (mean amounts of canola oil and non-specified vegetable oil eaten by consumers only, see [FSANZ website](#) for details);
- population groups identified in the nutrition assessment;
- Nutrient Reference Values (NRV) for n-3 LC-PUFA (NHMRC and MoH 2006);
- market share data based on the different types of oil reported as consumed in the 2011–12 Australian National Nutrition and Physical Activity Survey (2011–12 NNPAS) (ABS 2015b).

² Harvest is FSANZ's custom-built dietary modelling program that replaced the previous program, DIAMOND, which does the same calculations just using a different software program.

3.2.1 Baseline intakes of n-3 LC-PUFA

The baseline intakes used in the assessment of n-3 LC-PUFA for Australians aged 2 years and above were the usual intakes of n-3 LC-PUFA published by the ABS from the 2011-12 nutrition survey component of the 2011-13 Australian Health Survey (ABS 2015a). Baseline n-3 LC-PUFA intakes for New Zealanders were not available in the 2002 New Zealand National Children's Nutrition Survey (2002 NZ CNS) and 2008-09 New Zealand Adult Nutrition Survey (2008-09 NZ ANS). Both the 2002 and 2008 National Surveys report data on PUFAs as a group, not individual FAs. Therefore, the baseline intake of n-3 LC-PUFA for an Australian population group was used to represent the baseline intake for the corresponding New Zealand age group. As such, this intake assessment assumes that the intake of n-3 LC-PUFA by New Zealand population groups is the same as by Australian population groups.

3.2.2 Food consumption data used

The food consumption data used for the dietary intake assessments were:

- 2002 New Zealand National Children's Nutrition Survey (2002 NZ CNS) (New Zealand Ministry of Health 2005) (one 24-hour recall for 3,275 respondents aged 5-14 years);
- 2008-09 New Zealand Adult Nutrition Survey (2008-09 NZ ANS) (New Zealand Ministry of Health 2011 a, b) (one 24-hour recall for 4,721 respondents aged 15 years and above);
- 2011-12 Australian National Nutrition and Physical Activity Survey (2011-12 NNPAS) (ABS 2015b) (12,153 respondents aged 2 years and above completed one 24-hour recall with 7735 respondents completing two 24-hour recalls).

The design of these nutrition surveys and the key attributes, including survey limitations, are set out on the [FSANZ website](#).

For the oil consumption component of this assessment, one day of food consumption data from both of the New Zealand surveys were used whereas the average of two days of data from the 2011-12 NNPAS was used for Australia. Two day average consumption amounts better reflect longer term estimates of food consumption and therefore produce a better estimate of chronic dietary intake.

3.2.3 Population groups assessed

The hazard characterisation did not identify any target or at-risk groups for which there were specific safety considerations in relation to n-3 LC-PUFA intakes. For Australia, the population groups used for the dietary intake assessment are the same as the Nutrient Reference Value (NRV) age groups.

Table 5: New Zealand age groups used in this assessment and their matching NRV age groups for deriving a baseline n-3 LC-PUFA dietary intake

New Zealand Survey age groups	Corresponding NRV age group
5-8	4-8
9-13	9-13
14	14-18
15-18	14-18
19-30	19-30
31-50	31-50
51-70	51-70
≥71	≥71

For New Zealand, the survey age groups and the NRV age groups do not exactly match. As

the n-3 LC-PUFA usual intakes reported by the ABS for the 2011-12 NNPAS are only available for the Australian population groups, this assessment assigns the best population intake match possible to the available New Zealand population groups based on NRV age/sex groups.

3.2.4 Concentration data used

The concentration data used in the dietary intake assessment for the LFBLFK canola oil was sourced from the Application. The n-3 LC-PUFA concentration (sum of DHA+EPA+DPA) in crude LFBLFK canola oil is 8.8%, equivalent to 8.8 g of n-3 LC-PUFA in 100 g of oil. The concentration from the crude oil was used in the dietary intake assessment, as opposed to that in the refined oil, as a worst case scenario.

In conventional canola oil, n-3 LC-PUFA are negligible (FSANZ 2017) and there is no baseline contribution from conventional canola oil to n-3 LC-PUFA intakes. Therefore, this assessment has used the n-3 LC-PUFA concentration of the LFBLFK canola oil, with no adjustments.

The concentrations used for all other foods in the baseline dietary intake assessment were from AUSNUT 2011-13, which was the nutrient composition dataset for the 2011-12 NNPAS.

3.2.5 Scenarios

To estimate the potential changes in n-3 LC-PUFA intakes in Australia and New Zealand from the introduction of LFBLFK canola to the food supply, FSANZ used two scenarios to model potential intakes additional to baseline:

Scenario 1: All canola oil is replaced with LFBLFK canola oil. This scenario assumed that refined oil from LFBLFK canola replaced all (100%) conventional canola oil currently in the food supplies of Australia and New Zealand, including canola oils used as an ingredient in mixed foods.

Scenario 2: All canola oil + 30% unspecified vegetable oils is replaced by LFBLFK canola oil. This assumed refined oil from LFBLFK canola replaced all (100%) of conventional canola oil and 30% of any *non-specified oil* that consumers reported eating in the national nutrition surveys. Non-specified oil is vegetable oil reported as consumed in a nutrition survey without any specific information about its source. Any vegetable oils (other than canola) that are specifically identified (e.g. olive oil, sunflower oil) are not included in the consumption data used for this part of the assessment. The 30% of non-specified oils used for the calculation reflects the proportion that canola oil from all identified oils reported as consumed in the 2011-12 NNAPS.

Both scenarios included estimated consumption of oil on a raw commodity basis, i.e. they included oil consumed when used on its own or as an ingredient in mixed foods or dishes (e.g. in salad dressing, steak fried in oil, fried rice etc.) based on FSANZ's recipe data used in the Harvest Raw Commodity model. If approved, food derived from canola line LFBLFK may enter the food supply via a range of canola based ingredients. *Canola oil, refined* was the commodity used in this assessment as no consumption of other canola products (i.e. canola meal, protein isolate or canola seed) was reported in the national nutrition surveys for Australia and New Zealand.

The scenarios included oil consumption values for Australian and New Zealand populations combined with the n-3 LC-PUFA concentrations as reported by the applicant for oil derived from LFBLFK canola to estimate additional n-3 LC-PUFA intakes from LFBLFK canola. The additional intakes of n-3 LC-PUFA were added deterministically to the usual mean (baseline) intakes of n-3 LC-PUFA.

3.2.6 Assumptions and limitations of the dietary intake assessment

The aim of the dietary intake assessment was to make the best estimate of dietary n-3 LC-PUFA intake as possible. Where significant uncertainties in the data exist, FSANZ uses conservative assumptions to ensure that the estimated dietary intake is not an underestimate (for example, assuming that the population consumes the mean consumer amount of canola oil over time over-estimates potential population increases in n-3 LC-PUFA intakes).

Assumptions made in the dietary intake assessment included:

- where estimates of dietary intake of EPA, DPA and DHA were not available, estimates of n-3 LC-PUFA are sufficient to identify any associated risks to the population from increased DHA intakes from LFBLFK canola;
- the usual intakes of n-3 LC-PUFA published by the ABS for Australia reflect current intakes and these are similar in both Australia and New Zealand;
- the intake of n-3 LC-PUFA is from food only; n-3 LC-PUFA intake from complementary or other medicines (e.g. dietary supplements) is not included in the usual intakes;
- the dietary intake assessment used the concentration of n-3 LC-PUFA in LFBLFK canola provided by the applicant. The variability and uncertainty around this concentration is unknown;
- all conventional canola oil reported as consumed is replaced by LFBLFK canola oil (**Scenario 1**– 100% LFBLFK canola oil);
- a proportion of 30% is used to reflect the share of canola oil in non-specified oils currently in the marketplace (**Scenario 2**– 100% LFBLFK canola oil + 30% unspecified oil);
- the FA profile of LFBLFK canola in the marketplace matches the applicant's data;
- canola meal and canola seed are not consumed by Australian and New Zealand populations.

In addition to the specific assumptions made in relation to this dietary intake assessment, there are a number of limitations associated with the nutrition surveys per se. A discussion of these limitations is included in Section 6 of the *Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes* (FSANZ 2009b).

3.3 Dietary intake estimate results

In this assessment, dietary intakes have been estimated for 'consumers only' (i.e. consumers of canola and vegetable oil). Nutrition survey respondents who had no consumption of these foods were excluded. The proportion of the population who are consumers varies between the different population groups assessed.

3.3.1 Estimated n-3 LC-PUFA dietary intakes for Australia

Baseline mean usual intakes of n-3 LC-PUFA for Australians aged 2 years of age and above ranged from 0.092-0.270 g/day (92-270 mg/day) across all NRV age/sex groups. The highest mean usual intake was for 31-50 year old men (Appendix 1, Table A) (ABS 2015a). Mean canola oil consumption for consumers ranged from 1.0 g/day for 2-3 year old children to 3.2 g/day for 14-18 year old males.

Additional intake of n-3 LC-PUFA from LFBLFK canola oil when this replaces all the conventional canola oil (Scenario 1) ranged from 0.179-0.485 g/day (Appendix 1, Table B). The highest n-3 LC-PUFA intake after adding the contribution of LFBLFK canola in Scenario 1 was 0.485 g/ day (485 mg/day) for 14-18 year old males. However, all mean n-3 LC-PUFA intakes were much lower than the UL of 3 g/day, ranging from 6-16% of the UL.

In the intake estimate where all the canola oil plus 30% of non-specified vegetable oils are replaced by LFBLFK canola oil (Scenario 2), mean oil consumption for consumers ranged from 3.8 g/day for 2-3 year old males to 9.9 g/day for 14-18 year old males (Appendix 1, Table C).

Consequently, the additional n-3 LC-PUFA intake from LFBLFK canola was much higher in Scenario 2, ranging from 0.430 to 1.074 g/day (430-1074 mg/day). The n-3 LC-PUFA intake increased much more substantially than in Scenario 1 for all population groups. For example, for 2-3 year old males mean intakes increased from the baseline of 0.096 g/day (96 mg/day) to 0.430 g/day (430 mg/day) in Scenario 2. The highest intake after adding the contribution of LFBLFK canola in Scenario 2 was 1.074 g/day (1074 mg/day) for 14-18 year old males. However, all intakes from the Scenario 2 assessment remained below the UL (14-36%).

3.3.2 Estimated n-3 LC-PUFA dietary intakes for New Zealand

This assessment assumes that New Zealand has the same baseline n-3 LC-PUFA intakes as Australia. This assumption is supported by similar PUFAs and total fat reported intakes between the countries, where the mean values differed by less than 4% (Elmadfa and Kornsteiner 2009).

The intakes reported in Appendix 1 (Tables B and D) for New Zealand are matched with their closest NRV age group from the Australian usual intakes data (ABS 2015b).

Mean canola oil consumption was higher in New Zealand than reported in Australia and ranged from 1.5 g/day for 14 year old females to 4.5 g/day for 31-50 year old males (Appendix 1). Additional intake of n-3 LC-PUFA from canola oil only (Scenario 1) ranged from 0.266-0.668 g/day (266 to 668 mg/day). Intakes from mean baseline plus canola oil were lower than the UL of 3 g/day, ranging from 9-22% (Appendix 1, Table B). The highest intake after adding the contribution of LFBLFK canola in Scenario 1 was 0.668 g/day (668 mg/day) for 31-50 year old males.

In Scenario 2 where all the canola oil plus 30% of non-specified vegetable oils are replaced by LFBLFK canola oil, mean oil consumption ranged from 7.3 g/day for ≥ 71 year old females to 15.0 g/day for 31-50 year old males. Additional n-3 LC-PUFA intake from LFBLFK canola in New Zealand ranged from 0.869 to 1.591 g/day (869-1591 mg/day). The n-3 LC-PUFA intake increased for all population groups, but intakes were still below the UL (29-53%).

3.3.3 Major food categories contributing to n-3 LC-PUFA dietary intakes

For Australians 2 years and above, the major contributors to baseline intakes of n-3 LC-PUFA were fish, seafood products and dishes (56%), meat, poultry and game products and dishes (21%) and cereals based products and dishes (10%) (ABS 2015a). Assuming similarity in food supplies, these contributions for New Zealand are most likely very similar to Australia.

3.4 Conclusion of the dietary intake assessment

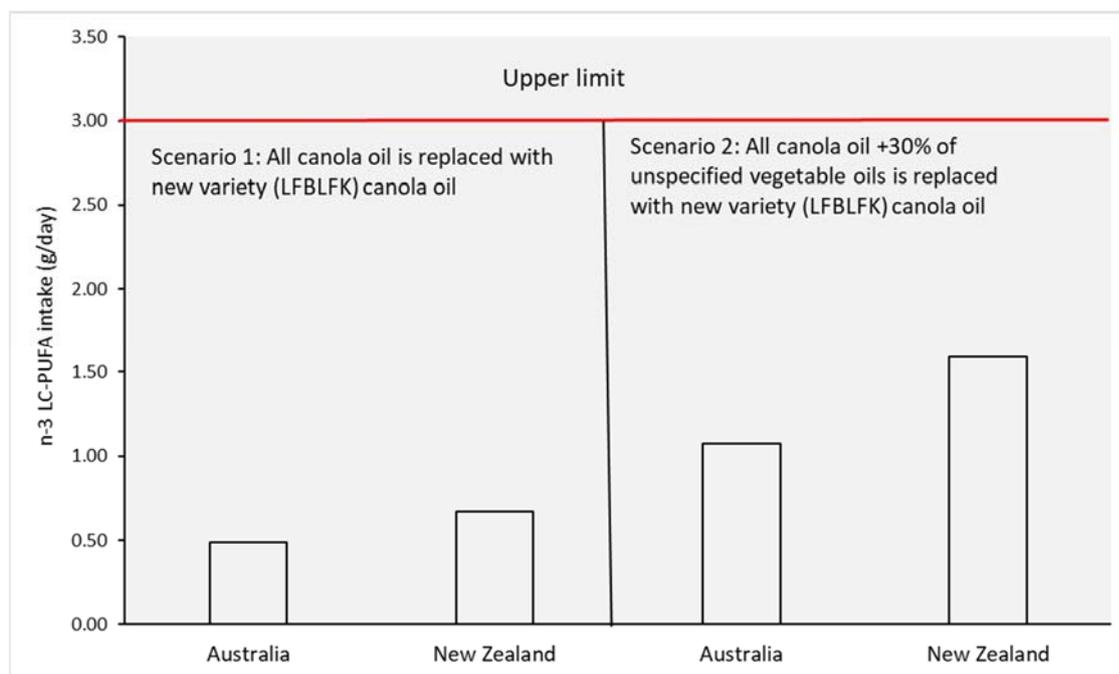
When all the conventional canola oil is replaced by LFBLFK canola oil (Scenario 1) the estimated highest mean intakes of n-3 LC-PUFA by Australian and New Zealand population groups was 0.485 g/day and 0.668 g/day respectively (Figure 1).

Alternatively, if LFBLFK canola replaced all canola oil plus 30% of non-specified oil (Scenario 2), the estimated highest mean intakes of n-3 LC-PUFA by Australian and New Zealand population groups was 1.292 g/day and 1.591 g/day respectively.

The estimated mean intakes of n-3 LC-PUFA for scenarios 1 and 2, all population groups and both countries were below the UL of 3 g/day (up to 22% of the UL for Scenario 1, and up

to 53% of the UL for Scenario 2). The true intakes of n-3 LC-PUFA would likely be lower because both scenarios assume that all canola oil in the marketplace is from LFBLFK canola, the amount eaten is based on mean consumers not mean per person, and the estimated consumption amount of canola oil is consumed every day over a lifetime. The intake estimates are intentionally highly protective of consumers to assess if there would be any concern associated with LFBLFK canola increasing n-3 LC-PUFA intake in Australia and New Zealand to levels exceeding the UL.

Figure 1 Highest estimated mean dietary intakes of n-3 LC-PUFA in Australia and New Zealand* under two scenarios: Scenario 1 – all canola oil is replaced with new variety (LFBLFK) canola oil and Scenario 2 – all canola oil+ 30% unspecified vegetable oils replaced by new variety (LFBLFK) canola oil.



* Including baseline n-3 LC-PUFA intakes.

4 Risk characterisation and conclusion

Conventional canola oils do not contain quantifiable levels of EPA, DPA and DHA. In refined LBFLFK canola oil, the sum of EPA, DPA and DHA levels, as a percentage of total FAs, is 6.5%. As the oil from LBFLFK seed will be available for human consumption, FSANZ has conducted a risk assessment to identify whether any adverse health effects can be expected from a potential increase in the dietary intake of EPA, DPA and DHA. As for fish oils, FAs in canola oil are predominantly in the form of triglycerides, and therefore the bioavailability of EPA, DPA and DHA from triglycerides in LBFLFK oil and fish oil is expected to be similar and not raise nutritional concerns.

An Upper Level of Intake (UL), defined as the highest average daily nutrient intake level likely to pose no adverse health effects, has been established for n-3 LC-PUFA. The UL, defined as the sum of EPA, DPA and DHA, is 3 g/day for children, adolescents and adults. A large number of randomised controlled trials of n-3 LC-PUFA have been conducted since the UL was established, and based on a lack of treatment-related adverse effects in these trials it is concluded that the UL of 3 g/day is sufficiently health protective and appropriate for use in risk characterisation.

The dietary intake assessment considered two scenarios. Scenario 1 assumed that all conventional canola oil reported as consumed is replaced by LBFLFK oil. Scenario 2 assumed that 30% of non-specified oils currently in the marketplace as well as 100% of conventional canola oil are replaced with LBFLFK oil (as per Scenario 1). The scenarios also included the usual intake of n-3 LC-PUFA (sum of EPA, DPA and DHA) from the current food supply (baseline intake). The dietary intake estimates for all population groups assessed in both Australia and New Zealand were below the UL of 3 g/day. It is therefore concluded that consumption of oil from canola line LBFLFK will not pose a nutritional risk to the Australian and New Zealand populations.

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Appendix 1: Estimated dietary intakes of n-3 LC-PUFA for Australian and New Zealand population groups under different scenarios.

Table A: Estimated dietary intakes of n-3 LC-PUFA for Australian population groups assuming that all conventional canola in the food supply will be replaced by LFBLFK canola oil (Scenario 1)

Age group (years)	Sex	Mean canola oil consumption (g/day) ¹	Additional intake n-3 LC PUFA from LBFLFK (g/day)	Baseline mean intake n-3 LC PUFA (g/day) ²	Predicted potential n-3 LC-PUFA intake (g/day)	% of UL
2-3	Female	1.0	0.087	0.092	0.179	6
	Male	1.0	0.084	0.096	0.180	6
4-8	Female	1.2	0.106	0.098	0.204	7
	Male	1.3	0.116	0.103	0.219	7
9-13	Female	1.7	0.154	0.162	0.316	11
	Male	1.9	0.166	0.176	0.342	11
14-18	Female	1.9	0.170	0.179	0.349	12
	Male	3.2	0.279	0.206	0.485	16
19-30	Female	2.0	0.178	0.187	0.365	12
	Male	1.9	0.170	0.262	0.432	14
31-50	Female	1.4	0.127	0.234	0.361	12
	Male	1.7	0.151	0.270	0.421	14
51-70	Female	1.5	0.132	0.241	0.373	12
	Male	1.5	0.135	0.258	0.393	13
>= 71	Female	1.1	0.097	0.229	0.326	11
	Male	1.4	0.122	0.229	0.351	12

¹two-day average weighted mean consumption, rounded to 1 decimal place, consumers only

² mean usual intakes for Australia (ABS 2015a), best match age group used (Table 5)

Table B: Estimated dietary intakes of n-3 LC-PUFA for New Zealand population groups assuming that all conventional canola in the food supply will be replaced by LFBLFK canola oil (Scenario 1)

Age group (years)	Sex	Mean canola oil consumption (g/day) ¹	Additional intake n-3 LC PUFA from LBFLFK (g/day)	Baseline mean intake n-3 LC PUFA (g/day) ²	Predicted potential n-3 LC-PUFA intake (g/day)	% of UL
5-8	Female	1.9	0.168	0.098	0.266	9
	Male	2.1	0.186	0.103	0.289	10
9-13	Female	2.4	0.207	0.162	0.369	12
	Male	2.7	0.235	0.176	0.411	14
14	Female	1.5	0.130	0.179	0.309	10
	Male	3.3	0.294	0.206	0.500	17
15-18	Female	2.4	0.215	0.179	0.394	13
	Male	3.4	0.297	0.206	0.503	17
19-30	Female	3.0	0.263	0.187	0.450	15
	Male	4.3	0.378	0.262	0.640	21
31-50	Female	3.0	0.261	0.234	0.495	16
	Male	4.5	0.398	0.270	0.668	22
51-70	Female	3.4	0.300	0.241	0.541	18
	Male	4.1	0.357	0.258	0.615	20
≥ 71	Female	3.1	0.271	0.229	0.500	17
	Male	3.9	0.347	0.229	0.576	19

¹ One-day mean consumption, rounded to 1 decimal place, consumers only

² mean usual intakes for Australia (ABS 2015a), best match age group used (Table 5)

Table C: Estimated dietary intakes of n-3 LC-PUFA for Australian population groups assuming that all canola and 30% of non-specified oil in the food supply will be replaced by LFBLFK canola oil (Scenario 2)

Age group (years)	Sex	Mean canola oil+30% vegetable non-specified oil consumption (g/day) ¹	Additional intake n-3 LC PUFA from LBFLFK (g/day)	Baseline mean intake n-3 LC PUFA (g/day) ²	Predicted potential n-3 LC-PUFA intake (g/day)	% of UL
2-3	Female	4.2	0.371	0.092	0.463	15
	Male	3.8	0.334	0.096	0.430	14
4-8	Female	5.4	0.477	0.098	0.575	19
	Male	5.6	0.491	0.103	0.594	20
9-13	Female	7.2	0.631	0.162	0.793	26
	Male	8.1	0.712	0.176	0.888	30
14-18	Female	7.3	0.640	0.179	0.819	27
	Male	9.9	0.868	0.206	1.074	36
19-30	Female	6.6	0.579	0.187	0.766	26
	Male	8.1	0.710	0.262	0.972	32
31-50	Female	5.4	0.477	0.234	0.711	24
	Male	7.3	0.640	0.270	0.910	30
51-70	Female	4.7	0.410	0.241	0.651	22
	Male	6.0	0.527	0.258	0.785	26
≥ 71	Female	4.4	0.389	0.229	0.618	21
	Male	5.4	0.474	0.229	0.703	23

¹ two-day average weighted mean consumption, rounded to 1 decimal place, consumers only

² mean usual intakes for Australia (ABS 2015a), best match age group used (Table 5)

Table D: Estimated dietary intakes of n-3 LC-PUFA for New Zealand population groups assuming that all canola and 30% of non-specified oil in the food supply will be replaced by LFBLFK canola oil (Scenario 2)

Age group (years)	Sex	Mean canola oil+30% vegetable non-specified oil consumption (g/day) ¹	Additional intake n-3 LC PUFA from LBFLFK (g/day)	Baseline mean intake n-3 LC PUFA (g/day) ²	Potential predicted n-3 LC-PUFA intake (g/day)	% of UL
5-8	Female	8.8	0.771	0.098	0.869	29
	Male	9.6	0.841	0.103	0.944	31
9-13	Female	10.5	0.926	0.162	1.088	36
	Male	12.2	1.075	0.176	1.251	42
14	Female	10.3	0.909	0.179	1.088	36
	Male	13.7	1.202	0.206	1.408	47
15-18	Female	9.8	0.860	0.179	1.039	35
	Male	14.2	1.250	0.206	1.456	49
19-30	Female	10.8	0.953	0.187	1.140	38
	Male	14.8	1.301	0.262	1.563	52
31-50	Female	9.2	0.808	0.234	1.042	35
	Male	15.0	1.321	0.270	1.591	53
51-70	Female	9.3	0.818	0.241	1.059	35
	Male	11.8	1.035	0.258	1.293	43
>= 71	Female	7.3	0.645	0.229	0.874	29
	Male	10.0	0.883	0.229	1.112	37

¹ One-day mean consumption, rounded to 1 decimal place, consumers only

² mean usual intakes for Australia (ABS 2015b), best match age group used (Table 5)