FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

1-04
18 February 2004

INITIAL ASSESSMENT REPORT

APPLICATION A522

DHA-RICH MICRO-ALGAL OIL FROM *ULKENIA* SP. AS A NOVEL FOOD

DEADLINE FOR PUBLIC SUBMISSIONS to FSANZ in relation to this matter:
31 March 2004
(See 'Invitation for Public Submissions' for details)

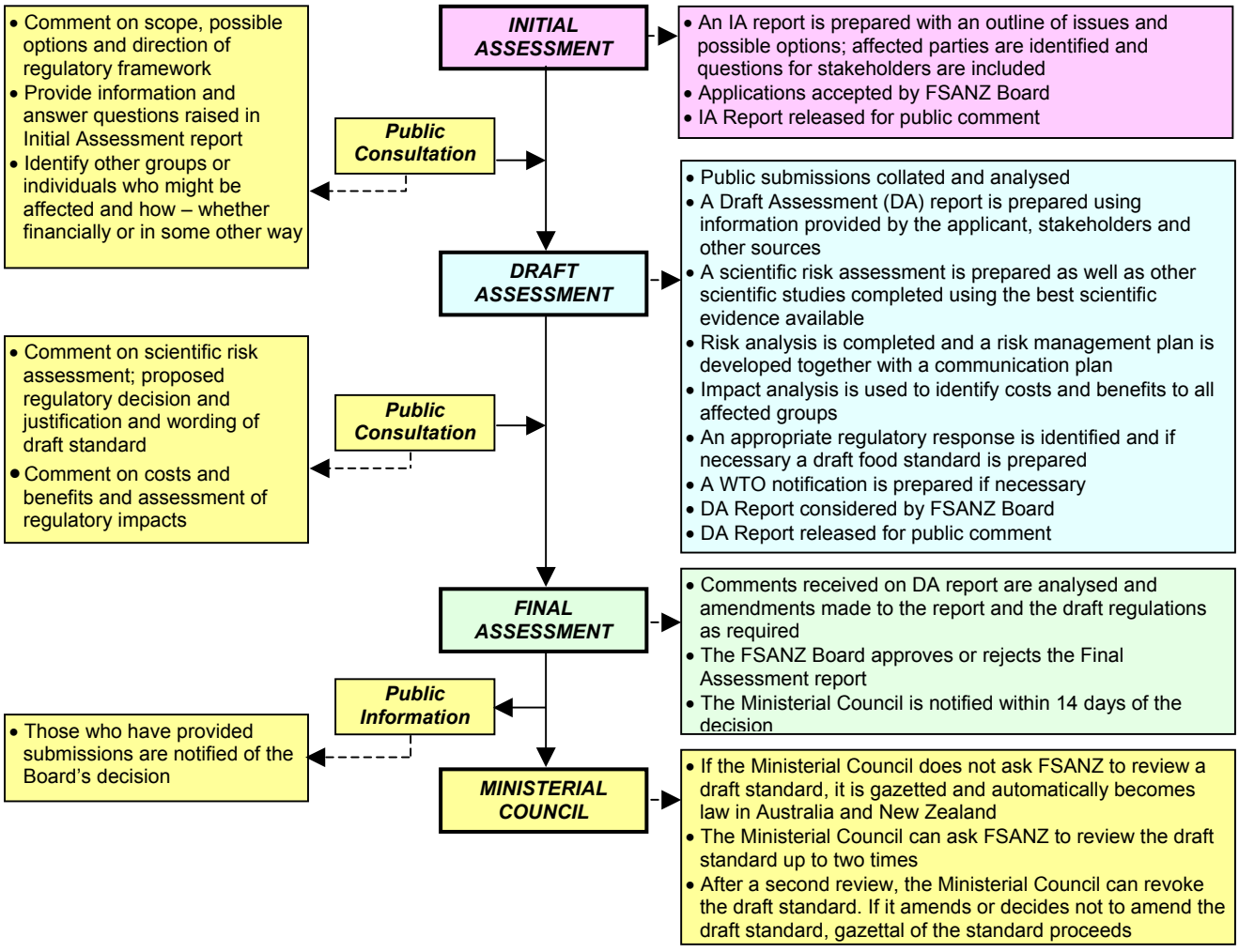
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Commonwealth; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Commonwealth, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Commonwealth, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared an Initial Assessment Report of Application A522, which includes the identification and discussion of the key issues.

FSANZ invites public comment on this Initial Assessment Report for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Draft Assessment for this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions should be received by FSANZ **by 31 March 2004**.

Submissions received after this date may not be considered, unless the Project Manager has given prior agreement for an extension.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Liaison Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

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Executive Summary

FSANZ received an Application from Nutrinova Australasia Pty Ltd on 5 December 2003 to amend Standard 1.5.1 – Novel Foods – of the *Australia New Zealand Food Standards Code* (the Code) to approve the use of Docosahexaenoic acid (DHA)-rich oil derived from marine micro-algae (*Ulkenia* sp.).

DHA is an omega-3 long chain polyunsaturated fatty acid derived from alpha-linolenic acid. Omega-3 long chain fatty acids, particularly DHA, have been identified as important dietary components. DHA is a normal constituent of the (non-vegan) human diet and the main source is cold-water fish.

The Applicant has provided the range of intended food uses and the levels of DHA-rich oil (*Ulkenia* sp.) intended to be used in those foods. The Applicant intends to market food products containing added DHA-rich oil (*Ulkenia* sp.) as an additional source of omega-3 fatty acids.

This Initial Assessment Report is not an assessment of the merits of the Application but rather is an assessment of whether the Application should be accepted for further consideration, according to criteria laid down in the FSANZ Act. It is the conclusion of this Initial Assessment that, having regard to the requirements of section 13 of the FSANZ Act, this Application should be accepted for Draft Assessment for the following reasons:

- The Application seeks approval for the use of DHA-rich oil (*Ulkenia* sp.) as a novel food – such an approval, if accepted, would warrant a variation to Standard 1.5.1 – Novel Foods. There are no measures other than a variation to the Code available to permit a novel food to be sold as food.

- DHA-rich oil (*Ulkenia* sp.) is considered to be a non-traditional food as there is no history of significant human consumption in Australia or New Zealand.

- DHA-rich oil (*Ulkenia* sp.) is also considered to be novel for the purposes of the Standard because it is a non-traditional food for which there is insufficient knowledge in the broad community to enable safe use in the form or context in which it is presented taking into account: the composition or structure of the product; levels of undesirable substances in the product; the potential for adverse effects in humans; and patterns and levels of consumption of the product.

- Although DHA-rich *Schizochytrium* sp. and DHA-rich oil derived from *Schizochytrium* sp. was the subject of a previous application to amend Standard 1.5.1, the current application seeks approval for DHA-rich oil from a different source (*Ulkenia* sp.) for which the safety has not yet been assessed. Therefore, the current application for DHA-rich oil (*Ulkenia* sp.) is not so similar to any previous application that it ought not to be accepted.

This Initial Assessment Report provides information supplied by the Applicant and raises issues in relation to: the safety of DHA-rich oil (*Ulkenia* sp.) as a novel food; estimated dietary intake; nutritional implications; food technology; and the costs and benefits to various affected parties.

Public submissions are invited on this Initial Assessment Report. Comments are specifically sought on the safety of DHA-rich oil (*Ulkenia* sp.), the nutritional and dietary implications of DHA-rich oil (*Ulkenia* sp.) as a food, and the costs and benefits to consumers, public health professionals, the food industry and government in general. Submissions received will be considered during the Draft Assessment.

1. Introduction

FSANZ received an application from Nutrinova Australasia Pty Ltd on 5 December 2003 to amend Standard 1.5.1 – Novel Foods – of the *Australia New Zealand Food Standards Code* (the Code) to approve the use of Docosahexaenoic acid (DHA)-rich oil derived from marine micro-algae (*Ulkenia* sp.), hereafter referred to as DHA-rich oil (*Ulkenia* sp.). The Application is made on behalf of Nutrinova Nutrition Specialities and Food Ingredients GmbH, Frankfurt, Germany.

DHA is an omega-3 long chain polyunsaturated fatty acid derived from alpha-linolenic acid. Omega-3 long chain fatty acids, particularly DHA, have been identified as important dietary components. DHA-rich dried marine micro-algae (*Schizochytrium* sp.) and DHA-rich oil derived from marine micro-algae (*Schizochytrium* sp.) were previously assessed by the then Australia New Zealand Food Authority (ANZFA) and are approved novel foods in Australia and New Zealand.

This Initial Assessment Report is not an assessment of the merits of the Application but rather is an assessment of whether the Application should be accepted for further consideration, according to criteria laid down in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act).

2. Regulatory Problem

Under the current food standards, novel foods are required to undergo a pre-market safety assessment, as per Standard 1.5.1 – Novel Foods. The purpose of Standard 1.5.1 is to ensure that non-traditional foods that have features or characteristics that may raise safety concerns will undergo a risk-based safety assessment before they are offered for retail sale in Australia or New Zealand.

Novel Food is defined in clause 1 of Standard 1.5.1 as:

> *a non-traditional food for which there is insufficient knowledge in the broad community to enable safe use in the form or context in which it is presented, taking into account;*
>
> *(a) the composition or structure of the product;*
> *(b) levels of undesirable substances in the product;*
> *(c) the potential for adverse effects in humans;*
> *(d) traditional preparation and cooking methods; or*
> *(e) patterns and levels of consumption of the product.*

Non-traditional food *means a food which does not have a history of significant human consumption by the broad community in Australia or New Zealand*.

Although DHA is a normal constituent of the (non-vegan) human diet with the main source being cold-water fish, DHA-rich oil (*Ulkenia* sp.) is considered **non-traditional** because it does not have a history of significant human consumption in the broad community in Australia and New Zealand. The safety of DHA-rich oil (*Ulkenia* sp.) with respect to levels of undesirable substances in the product and the potential for adverse effects in humans has not been assessed.

DHA-rich oil (*Ulkenia* sp.) is considered to be a **novel food** for the purposes of the Standard because it is a non-traditional food for which there is insufficient knowledge in the broad community to enable safe use in the form or context in which it is presented taking into account: the composition or structure of the product; levels of undesirable substances in the product; the potential for adverse effects in humans; and patterns and levels of consumption of the product.

3. Objective

The objective of this assessment is to determine whether or not it is appropriate to amend the Code to permit the use of DHA-rich oil derived from marine micro-algae (*Ulkenia* sp.) as a novel food. Such an amendment would need to be consistent with the section 10 objectives of the FSANZ Act.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 of the FSANZ Act. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

4. Background

4.1 Nature of the Novel Food

The DHA-rich oil is a refined oil containing typically 45% DHA derived from marine micro-algae (*Ulkenia* sp.) produced under controlled fermentation conditions. Other common names, as stated by the Applicant, include DHA45-TG, DHA containing lipid, micro-algal oil and Ulkenia oil. DHA45-oil does not have a chemical name, as it is primarily a complex mixture of triglycerides, containing mainly the omega-3 fatty acid DHA. The chemical name of the major fatty acid DHA is:

All-cis-4,7,10,13,16,19-docosahexaenoic acid (22:6) ;

and the molecular formula is: $C_{22}H_{32}O_2$

The Applicant stated their intention to add DHA-rich oil (*Ulkenia* sp.) as an ingredient in food products to provide an additional source of omega-3 fatty acids. Those food products containing DHA-rich oil (*Ulkenia* sp.) would be aimed at people interested in increasing their intake of omega-3 fatty acids, specifically DHA.

The Applicant states that while DHA-rich oil (*Ulkenia* sp.) is derived from a novel source and is high in DHA, it is similar to conventional sources of polyunsaturated fatty acids with the main difference being the different fatty acid composition. Omega-3 fatty acids found in fish oils are produced by marine micro-algae and proceed through the marine food chain into fish[1].

The Applicant has provided information on the taxonomical classification of *Ulkenia* sp. as follows:

- Domain *Eukaryota*
- Kingdom *Chromista*
- Subkingdom *Heterokonta*
- Phylum *Labyrinthulomycota*
- Class *Labyrinthulea (Labyrinthulomycetes)*
- Subclass *Thraustochytriade*
- Order *Thraustrochytriales*
- Family *Thraustochytiaceae*
- Genus *Ulkenia*
- Species *Ulkenia* sp.

The Applicant's proposed marketing name for DHA-rich oil (*Ulkenia* sp.) is DHActive™, DHActive CL. The Applicant's proposed alternate name is DHA45-oil.

4.2 Proposed uses of DHA-rich oil (*Ulkenia* sp.)

The Applicant has stated their intention to use DHA-rich oil (*Ulkenia* sp.) as a food ingredient in such foods as breads and rolls, cakes and biscuits, breakfast cereals, cream cheese, modified milk and milk products, beverages, fruit drinks, sports drinks, functional drinks, dairy/non-dairy products, grain-based energy bars, and margarines and spreads.

4.3 Nutritional role of omega-3 fatty acids and DHA

The following information is obtained from the Applicant's evaluation and summary of the nutritional information and is presented as background information on the role of DHA in the human diet.

[1] Yazawa, K., Watanabe, K., Ishikawa, C. Kondo, K., and Kimura, S. (1992) Production of eicosapentanoic acid from marine bacteria. In: Industrial Applications of Single Cell Oils. Kyle, D.J. and Ratledge, C. (Eds). American Oil Chemists Society, Champaign, USA.

There are two families of polyunsaturated fatty acids, the omega-6 (or n-6) family, and the omega-3 (or n-3) family. The omega-6 family is derived from linoleic acid (C18:2) which has two double bonds, and the omega-3 family is derived from alpha-linolenic acid (C18:3) which has three double bonds. These two fatty acids cannot be made in the human body and have to be provided in the diet. They are referred to as essential fatty acids.

DHA (22:6) is formed from alpha-linolenic acid by elongases (enzymes responsible for lengthening of the chain) and desaturases (enzymes responsible for the introduction of double bonds into the fatty acids). DHA is a normal constituent of the (non-vegan) human diet and the main source is cold-water fish in a range of 0.2-1.1 g/100 g. DHA is present as triacylglycerol and follows the normal fat absorption pathway.

DHA is an important structural element of cell membranes and is essential for the formation of new tissues. It plays a role in foetal neural development and has been implicated in decreasing the risk factors for coronary heart disease.

4.4 Previous application for DHA-rich dried marine micro-algae and oil derived from *Schizochytrium* sp. as novel foods

DHA-rich dried marine micro-algae (*Schizochytrium* sp.) and DHA-rich oil derived from *Schizochytrium* sp. were considered as novel foods in Application A428 by the then ANZFA. DHA-rich dried micro-algae (*Schizochytrium* sp.) and DHA-rich oil (*Schizochytrium* sp.) were approved as novel foods for the following reasons:

- The available data on DHA-rich micro-algae (*Schizochytrium* sp.) and on DHA-rich oil derived from *Schizochytrium* sp. did not raise any safety concerns at the predicted levels of exposure.
- The fatty acid composition of the dried *Schizochytrium* sp. micro-algae and the oil derived from *Schizochytrium* sp. were comparable to other traditional sources of DHA.
- Dried *Schizochytrium* sp. micro-algae and the oil derived from *Schizochytrium* sp. would provide an alternative source of omega-3 fatty acids in foods.

4.5 Regulation in other countries

The Applicant has indicated that DHA-rich oil (*Ulkenia* sp.) is permitted in the USA, Europe and Japan. The Applicant states that:

- in the USA, a panel of independent experts conducted a safety review of DHA-rich oil (Ulkenia sp.) and generally recognised as safe (GRAS) status was granted;

- the German competent authority (Federal Authority for Consumer Protection and Food Safety, Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)) determined that DHA-rich oil (*Ulkenia* sp.) was substantially equivalent to DHA-rich micro-algal oil from *Schizochytrium* sp. and is permitted on the European market; and

- in Japan, DHA-rich oil is considered a food and pre-market regulatory permission is not required.

The Applicant states that there is no approval for DHA-rich oil derived from *Ulkenia* sp. in either Brazil or Canada and indicated that Nutrinova intend to lodge applications for the approval of DHA-rich oil in those countries in the near future.

4.6 Work Plan Classification

This Application had been provisionally rated as Category of Assessment 3 (level of complexity) and placed in Group 3 on the FSANZ standards development Work Plan. This Initial Assessment confirms these ratings. Further details about the Work Plan and its classification system are given in *Information for Applicants* at www.foodstandards.gov.au.

5. Relevant Issues

5.1 Safety issues

The Applicant has submitted safety data in relation to DHA-rich oil (*Ulkenia* sp.) including:

- Analytical data on protein residues, sterol content, algal toxins, and residues and contaminants including lead, arsenic, mercury and hexane residues.
- A comparison of specifications for DHA-rich oil (*Ulkenia* sp.) and DHA-rich oil derive from other marine micro-algae (*Schizochytrium* sp.).
- Stability information regarding fat oxidation both alone and in intended food products.
- Toxicological profile including animal data (toxicokinetics, acute toxicity, allergenicity, sub-acute and sub-chronic toxicity, chronic toxicity, carcinogenicity, genotoxicity, reproductive toxicity, teratogenicity) and a summary of available human data.

The Applicant has indicated that, in relation to DHA-rich oil (*Ulkenia* sp.), there are no special requirements for processing or cooking before consumption.

A detailed safety evaluation for DHA-rich marine micro-algae (*Schizochytrium* sp.) and DHA-rich oil (*Schizochytrium* sp.) was prepared for Application A428. An evaluation of the safety data for DHA-rich oil (*Ulkenia* sp.) will be presented in the Draft Assessment Report.

5.2 Dietary exposure considerations

5.2.1 Current intake of polyunsaturated fatty acids and DHA

The Applicant states that the main source of DHA in the human diet is cold-water fish (in a range of 0.2-1.1 g DHA/100 g fish). The Applicant has provided the following reported intake levels for omega polyunsaturated fatty acids:

- DHA intake in European countries varies from 70 mg to 100 mg/day[2,3];

[2] Kolanowski, W., Swiderski, F., Lis, E. and Berger, S. (2001) **Enrichment of spreadable fats with polyunsaturated fatty acids omega-3 using fish oil**. *International Journal of Food Sciences and Nutrition* 52, pp 469-476.
[3] BNF (1999) Briefing Paper: N-3 Fatty Acids and Health. The British Nutrition Foundation, July 1999.

- DHA intake in the USA is 92 mg/day among fish eaters and 34 mg/day among non-fish eaters[4]; and
- Eskimos living in Greenland eating a traditional marine diet consume 5-10 g/day of omega-3 polyunsaturated fatty acids, mainly as eicosapentaenoic acid (EPA) and DHA[5].
- Long-chain omega-3 fatty acid intake (including DHA) in Europe is estimated to be approximately 0.1-0.5 g/day[6].

The dietary intake of DHA for the Australian population was estimated in the assessment of Application A428. Based on the 1995 Australian National Nutrition Survey, the mean exposure to DHA from existing food sources was estimated to be 100 mg/day for all respondents aged 2-100 years with high consumers (95th percentile) exposed to 480 mg/day. Estimates of dietary intake of DHA were not able to be determined for the New Zealand population as information on the levels of DHA in New Zealand foods was not available.

5.2.2 Dietary exposure assessment

The Applicant has provided the range of intended food uses and the levels of DHA-rich oil (*Ulkenia* sp.) intended to be used in those foods. This information is provided in Table 1 and this information will be used to undertake a dietary exposure assessment, the results of which will be presented in the Draft Assessment Report.

Table 1: Proposed levels of use and estimated DHA intake per serving from DHA-rich oil (*Ulkenia* sp.)

Product	DHA content (mg/100 g)	DHA per serving	Serving size
Regular breads and rolls	166	60	36 g
Breakfast cereals (plain, single and mixed source)	100	60	60 g
Savoury biscuits	171	60	35 g
Cake	200	60	30 g
Sweet biscuits and cookies	171	60	35 g
Polyunsaturated, monounsaturated table margarines and spreads, reduced fat margarines and other spreads	300	30	10 g
Modified milk, fluid (different types)	12	30	250 mL
Fruit and vegetable drinks	12	30	250 mL
Non-carbonated water based beverages	12	30	250 mL
Sour cream based dips	200	30	15 g
Cream cheese based products	300	30	10 g
Yoghurt products	30	60	200 mL
Salad dressings/mayonnaise	200	30	15 g
Meal replacement bars	40	60	150 g
Meal replacement drinks	24	60	250 mL
Infant cereal products	240	60	25 g
Infant foods	80	60	75 g
Infant drinks	48	60	125 mL

[4] cited in Becker, C. and Kyle, D. (1998) **Developing functional foods containing algal docosahexaenoic acid**. *Food Technology* 52(7), pp 68-71.
[5] Bønaa, K., Bjerve, K. and Nordy, A. (1992) **Habitual fish consumption, plasma phospholipids fatty acids, and serum lipids: the Tromso Study**. *Am. J. Clin. Nutr.* 55 (6), pp 1126-1134.
[6] Sanders, T. (2000) **Polyunsaturated fatty acids in the food chain in Europe**. *Am. J. Clin. Nutr*, 71(Suppl), pp 176S-178S.

Dietary modelling was used in the assessment of Application A428 to estimate the dietary exposure to DHA derived from the use of the micro-algae *Schizochytrium* both alone and in combination with dietary exposure to DHA from existing food sources. The mean total dietary exposure based on exposure to DHA solely from the use of DHA derived from *Schizochytrium* sp. was determined to be 260 mg/day in Australia and 280 mg/day in New Zealand, while the 95th percentile total dietary exposure was estimated to be 600 mg/day in Australia and 690 mg/day in New Zealand. Exposure to DHA from existing sources as well as from the proposed uses for the micro-algae *Schizochytrium* sp. was estimated to be 950 mg/day for Australian adults, the population group with the highest exposure. Further detail of the dietary exposure assessment can be obtained from the Final Assessment Report for Application A428 and is available on the FSANZ website, www.foostandards.gov.au.

A dietary exposure assessment based on the proposed food uses and levels as indicated in Table 1 will be presented in the Draft Assessment Report and will build on the dietary exposure assessment that was previously undertaken for Application A428.

5.3 Nutritional considerations

*5.3.1 Nutritional information for DHA-rich oil (*Ulkenia *sp.)*

The Applicant has provided the following nutrition information for DHA-rich oil (*Ulkenia* sp.), which is presented in Table 2.

Table 2: Typical energy and nutrient values for DHA-rich oil (*Ulkenia* sp.) per 100 g

Energy (kcal)	885
Energy (kJ)	3700
Moisture (g)	0
Fat (g)	100
Saturated fat (g)	35-45
Polyunsaturated fat (g)	55-65
Omega-3 polyunsaturated fat (g)	43-52
DHA (g)	38-47
Cholesterol (mg)	150-250
Total carbohydrate (g)	0
Protein (g)	0
Sodium (mg)	0

5.3.2 Dietary reference intakes

In relation to dietary reference intakes, the Applicant has stated that:

- for Australia and New Zealand there are no official recommended daily intakes for long chain polyunsaturated fatty acids such as DHA and EPA;
- in the Netherlands, dietary reference intakes were recently reviewed and the proposed adequate intake of omega-3 fatty acids for adults is 0.2 g/day[7]; and

[7] Health Council of the Netherlands (2001) Dietary reference intakes: energy, proteins, fats and digestible carbohydrates, publication no 2001/19, pp 15-20

- in 1992, the British Nutrition Foundation stated that there is a gap between the intake of omega-3 fatty acids (DHA and EPA), on an average of 0.15 g/day and the recommended intake of 1.2 g/day[8].

5.3.3 Health effects of DHA

Background information on the role of DHA in the human diet was addressed in section 4.3 of this Report. The Applicant has provided a detailed evaluation and summary of the available nutritional information with respect to DHA which covers the potential health effects with respect to: risk factors for coronary heart disease; diabetic disease; immune response; and infant development. This evaluation will be reviewed at Draft Assessment.

5.3.4 Issues for consideration

5.3.4.1 Use of DHA-rich oil

The Applicant states that DHA-rich oil (*Ulkenia* sp.) is intended as an additional source of DHA/omega-3 fatty acids and it will not necessarily replace other ingredients. However, the Applicant has acknowledged that, if permitted for use in food, it is possible for DHA-rich oil (*Ulkenia* sp.) to replace other sources of DHA in the diet, and for food products containing added DHA-rich oil (*Ulkenia* sp.), to replace other foods, most likely a similar product which does not contain DHA. The nutritional implications of any such substitution of a food product containing DHA for another food will be considered at Draft Assessment.

5.3.4.2 Appropriate food uses

With respect to the proposed food uses for DHA-rich oil (*Ulkenia* sp.) as indicated in section 5.2.2 of this Report, it is necessary to consider the appropriateness of these proposed food uses. The Applicant intends to market food products containing DHA-rich oil (*Ulkenia* sp.) as an additional source of omega-3 fatty acids/DHA, while the list of proposed food uses includes cake, savoury biscuits, sweet biscuits and cookies.

5.3.4.3 Nutrition claims

Clause 13 of Standard 1.2.8 – Nutrition Information Requirements – of the Code provides criteria that must be met in order for claims in relation to the omega fatty acid content of foods to be made. A claim must not be made in relation to the omega-3 fatty acid content of a food, other than fish or fish products that have no saturated fatty acids, unless the –

(a) total of saturated fatty acids and trans fatty acids is less than 28 per cent of the total fatty acid content of the food; or
(b) food contains no more than 5 g of saturated fatty acids and trans fatty acids per 100 g of the food.

Nutrition claims, including good source claims, may not be made unless the food contains a minimum prescribed amount of either alpha-linolenic acid or total of eicosapentaenoic acid and docosahexaenoic acid per serving.

[8] BNF (1999) Briefing Paper: n-3 Fatty Acids and Health. The British Nutrition Foundation, July 1999.

5.4 Food technology considerations

The Applicant has provided some details about the preparation process for DHA-rich oil (*Ulkenia* sp). It is produced through a multi-step conventional fermentation and refining process as follows:

- The first step of fermentation involves starting with shaker flasks containing glucose-based medium inoculated with one vial of *Ulkenia* sp. This culture is transferred to the first seed fermenter containing dextrose as the main carbon source. This culture is subsequently transferred to the next seed fermenter until the volume is sufficient for inoculation in the main fermenter.

- The second step of downstream processing involves separating the cells from the fermentation broth. The oil is separated from the biomass and any solvents present are removed by vacuum distillation.

- The refining process is similar to that used in the production of conventional vegetable oils. The crude DHA-rich oil is de-gummed, neutralised, bleached and deodorised. Additionally the resulting oil may be fractionated to remove solid fat.

The Applicant has also provided details of the influence of the production process on the composition of the DHA-rich oil (*Ulkenia* sp.).

A food technology report was prepared for Application A428, which covered: the chemical structure of DHA; a description of the product; the production process; and the composition of the extracted oil. An assessment of the food technology issues for DHA-rich oil (*Ulkenia* sp.) will be presented in the Draft Assessment Report.

6. Regulatory Options

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sectors of the community, which includes consumers, the food industry, governments in both Australia and New Zealand and often public health professionals. The benefits and costs associated with any proposed amendment to the Code will be analysed in a Regulatory Impact Assessment.

Novel foods or novel food ingredients used in Australia and New Zealand are required to be listed in Standard 1.5.1 – Novel Foods. As the use of DHA-rich oil (*Ulkenia* sp.) is being considered as a novel food, which requires pre-market approval under Standard 1.5.1 – Novel Foods, it is not appropriate to consider non-regulatory options to address this Application.

Two regulatory options have been identified for this Application:

Option 1 – Not permit the use of DHA-rich oil (*Ulkenia* sp.) as a novel food.

Option 2 – Permit the use of DHA-rich oil (*Ulkenia* sp.) as a novel food.

7. Impact Analysis

7.1 Affected Parties

Parties possibly affected by the regulatory options outlined in Section 6 include:

1. Consumers who may benefit as a result of new products containing DHA-rich oil (*Ulkenia* sp.).

2. Public health professions because of the role of DHA in human nutrition.

3. Those sectors of the food industry wishing to market foods containing DHA-rich oil (*Ulkenia* sp.) including potential importers, manufacturers of DHA-rich oil (*Ulkenia* sp.) and manufacturers of foods that may potentially contain DHA-rich oil (*Ulkenia* sp.).

4. Government agencies enforcing the food regulations.

7.2 Impact Analysis

7.2.1 Option 1 – Not permit the use of DHA-rich oil (Ulkenia sp.)

7.2.1.1 Consumers

There are no significant costs or benefits of not permitting the use of DHA-rich oil (*Ulkenia* sp.) identified for consumers. Consumers wishing to ensure they have an adequate dietary intake of omega-3 fatty acids, or DHA specifically, can obtain them from existing sources such as cold-water fish. Foods containing DHA-rich oil (*Schizochytrium* sp.) and DHA-rich marine micro-algae (*Schizochytrium* sp.) may also be available to consumers as these are approved novel food ingredients.

7.2.1.2 Public health professionals

There is no clear cost or benefit to public health professionals by not permitting DHA-rich oil (*Ulkenia* sp.) as a novel food. There are existing food sources of DHA which health professionals can recommend to clients for the purposes of increasing or maintaining their intake of omega-3 fatty acids, or DHA specifically.

7.2.1.3 Industry

The current situation of no permission for the use of DHA-rich oil (*Ulkenia* sp.) represents a cost to those industry sectors wishing to manufacture or import DHA-rich oil (*Ulkenia* sp.) for incorporation into food products or those wishing to manufacture or import final food products containing DHA-rich oil (*Ulkenia* sp.). The Applicant has indicated that the cost of using DHA-rich oil (Ulkenia sp.) is comparable to other DHA-rich oils. However, DHA-rich oil (*Schizochytrium* sp.) is an existing alternative to those industry sectors wishing to manufacture final food products, which provides a source of DHA.

7.2.1.4 Government

There is no cost or benefit identified to government by not permitting DHA-rich oil (*Ulkenia* sp.) as a novel food.

7.2.2 Option 2 – Permit the use of DHA-rich oil (Ulkenia sp.)

7.2.2.1 Consumers

Consumers may benefit from additional choice. As stated by the Applicant, the purpose of adding DHA-rich oil (*Ulkenia* sp.) to products is to provide the consumer with a value-added product consumed for its nutritional properties. There are existing sources of omega-3 fatty acids, including DHA. The Applicant has stated that the cost of using DHA-rich oil (*Ulkenia* sp.) is comparable to other DHA-rich oils and therefore there should be no negative or neutral positive price implications for consumers. Permitting the use of DHA-rich oil (*Ulkenia* sp.) is unlikely to significantly benefit consumers as there are existing alternatives, however, it would provide additional choice.

7.2.2.2 Public health professionals

Public health professionals may benefit from a wider range of foods providing omega-3 fatty acids, specifically DHA, which could be recommended to clients for the purposes of increasing or maintaining their omega-3 fatty acid intake.

7.2.2.3 Industry

Food manufacturers and importers are likely to benefit from permitting DHA-rich oil (*Ulkenia* sp.) as a novel food as there will be potential to develop and market new processed foods, which are a source of DHA. Manufactures of DHA-rich oil (*Ulkenia* sp.) will benefit from sales to food manufacturers.

7.2.2.4 Government

It is unlikely that there will be any significant costs or benefits to government agencies enforcing the food regulations. DHA-rich oil (*Schizochytrium* sp.) and DHA-rich marine micro-algae (*Schizochytrium* sp.) are already permitted as novel foods and there is no indication that this permission has had a significant impact on resources. Approval of DHA-rich oil (*Ulkenia* sp.) as a novel food would promote international trade in food products, potentially benefiting government.

7.2.3 Assessment of impacts

On the basis of this Initial Assessment, there is likely to be a slight benefit to consumers and public health professionals in offering additional choice of dietary omega-3 fatty acid sources. There is likely to be a benefit to industry sectors involved in the marketing of DHA-rich oil (*Ulkenia* sp.) as food. More detail will be incorporated into the impact analysis at Draft Assessment based on comments made in submissions to this Initial Assessment Report and other available data.

8. Consultation

8.1 Public consultation

FSANZ is seeking public comment in order to assist in assessing this Application. Public submissions will also be sought when the Draft Assessment Report is released.

Comments that would be useful could cover:

- **safety of DHA-rich oil (*Ulkenia* sp.);**
- **food technology issues associated with DHA-rich oil (*Ulkenia* sp.);**
- **nutritional and dietary implications of DHA-rich oil (*Ulkenia* sp.);**
- **potential impacts; and**
- **labelling of foods and food products containing DHA-rich oil (*Ulkenia* sp.).**

8.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards and amending the Code to allow DHA-rich oil (*Ulkenia* sp.) is unlikely to have a significant effect on international trade since FSANZ would be expanding permissions and the potential food applications for DHA-rich oil (*Ulkenia* sp.) is limited in terms of market size. This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia's and New Zealand's obligations under the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them. Application A428 was notified to the WTO because permission to use the DHA-rich dried micro-algae (*Schizochytrium* sp.) and the DHA-rich oil (*Schizochytrium* sp.) could lead to a liberalising effect on trade.

9. Conclusion and Recommendation

FSANZ received an application from Nutrinova Australasia Pty Ltd on 5 December 2003 to amend Standard 1.5.1 – Novel Foods of the Code to approve the use of Docosahexaenoic acid (DHA) – rich oil derived from marine micro-algae (*Ulkenia* sp).

It is the conclusion of this Initial Assessment that, having regard to the requirements of section 13 of the FSANZ Act, this Application should be accepted for Draft Assessment for the following reasons:

- The Application seeks approval for the use of DHA-rich oil (*Ulkenia* sp.) as a novel food – such an approval, if accepted, would warrant a variation to Standard 1.5.1 – Novel Foods. There are no measures other than a variation to the Code available to permit a novel food to be sold as food.

- DHA-rich oil (*Ulkenia* sp.) is considered to be a non-traditional food as there is no history of significant human consumption in Australia or New Zealand.

- DHA-rich oil (*Ulkenia* sp.) is also considered to be novel for the purposes of the Standard because it is a non-traditional food for which there is insufficient knowledge in the broad community to enable safe use in the form or context in which it is presented taking into account: the composition or structure of the product; levels of undesirable substances in the product; the potential for adverse effects in humans; and patterns and levels of consumption of the product.
- Although DHA-rich *Schizochytrium* sp. and DHA-rich oil derived from *Schizochytrium* sp. was the subject of a previous application to amend Standard 1.5.1, the current application seeks approval for DHA-rich oil (*Ulkenia* sp.) from a different source for which the safety has not yet been assessed. Therefore, the current application for DHA-rich oil (*Ulkenia* sp.) is not so similar to any previous application that it ought not to be accepted.

This Initial Assessment Report provides information supplied by the Applicant and raises issues in relation to: the safety of DHA-rich oil (*Ulkenia* sp.) as a novel food; estimated dietary intake; nutritional implications; food technology; and the costs and benefits to various effected parties.

Public submissions are invited on this Initial Assessment Report. Comments are specifically sought on the safety of DHA-rich oil (*Ulkenia* sp.), the nutritional and dietary implications of DHA-rich oil (*Ulkenia* sp.) as a food, and the costs and benefits to consumers, public health professionals, the food industry and Government in general. Submissions received will be considered during the Draft Assessment.