

INITIAL ASSESSMENT REPORT

APPLICATION A505

DIACYLGLYCEROL OIL

DEADLINE FOR PUBLIC SUBMISSIONS to FSANZ in relation to this matter:
27 August 2003

(See 'Invitation for Public Submissions' for details)

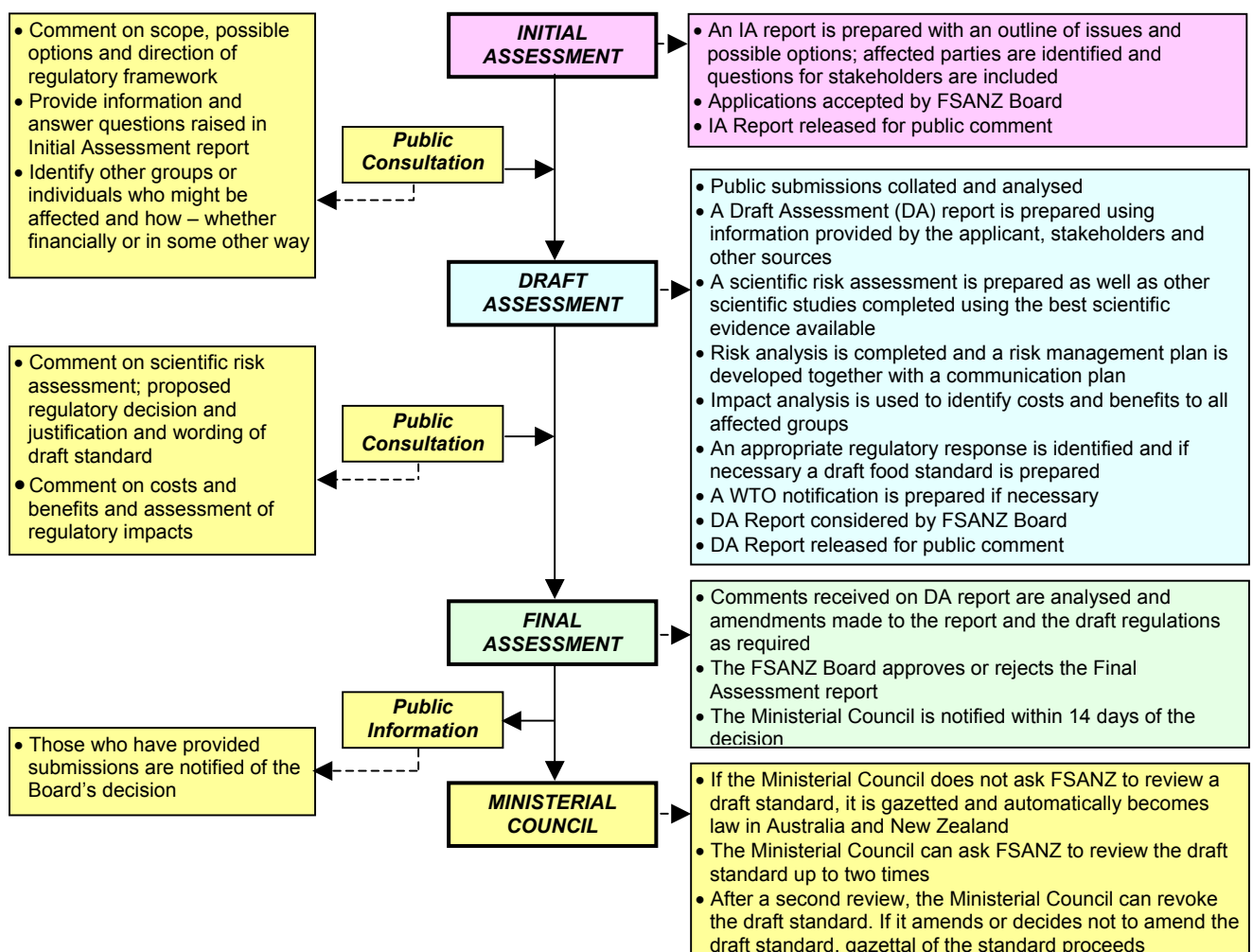
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 A505, 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 27 AUGUST-2003**.

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.

Further Information

Further information on this Application and the assessment process should be addressed to the FSANZ Standards Liaison Officer at one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
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Executive Summary and Statement of Reasons

FSANZ received a paid application on 10 June 2003 from ADM Kao LLC, a joint venture business between the Archer Daniels Midland Company and the Koa Corporation to approve the use of diacylglycerol oil (DAG-oil) as a novel food under Standard 1.5.1 - Novel Foods of the Food Standards Code. Novel foods may not be sold as food or for use as food ingredients unless listed in the Table to clause 2 of Standard 1.5.1. In deciding whether to list a novel food in the table FSANZ conducts a safety assessment of the food. If approved, the novel food must comply with any special conditions of use also listed in the Table.

It is proposed by the applicant to use DAG-oil as edible oil and as an ingredient in various foods. For a food to be considered novel, it must first be considered to be a non-traditional food. A non-traditional food is a food which does not have a history of significant consumption by the broad community in Australia or New Zealand. DAG-oil consists of >80% diglycerides, while edible oil normally consists of triglycerides and only small amounts of diglycerides. Therefore, the broad community may be currently only exposed to low levels of diglycerides. This means that although there may be a history of human consumption of the main component of DAG-oil in the broad community in Australia and New Zealand, this consumption may not be significant. Hence, DAG-oil may be a non-traditional food.

DAG-oil may be a novel food because the composition of the product is markedly different to traditional oils. DAG-oil contains >80% diglycerides, 20% triacylglycerol, 5% monoacylglycerol and <0.2% emulsifiers and antioxidants. In Standard 2.4.1 - Edible oils, edible oils are defined as the triglycerides of fatty acids of plant or animal origin. Edible oil may contain incidental amounts of free fatty acids, unsaponifiable constituents and other lipids. Due to this difference in composition when compared with edible oils, FSANZ may decide that there is insufficient knowledge in the broad community to enable safe use of DAG-oil in the form or context in which it is presented.

This Initial Assessment report is an assessment of whether the application should be accepted for further consideration, according to criteria laid down in the FSANZ Act.

FSANZ accepts this application following initial assessment for the following reasons.

- The application seeks approval for the use of DAG-oil as a novel food.
- DAG-oil may be a non-traditional food as there is no history of human consumption of DAG-oil or its main component, diglycerides, at significant levels in Australia or New Zealand.
- DAG-oil may be a novel food because, due to the markedly different composition of DAG-oil compared with edible oils, FSANZ considers that there is insufficient knowledge in the broad community to enable safe use of DAG-oil in the form or context in which it is presented.
- Therefore, the application relates to a matter that warrants a variation to Standard 1.5.1, if further assessment supports such a variation.
- The application is not so similar to any previous application that it ought not be accepted.
- There is no basis for considering, at this stage of assessment, that the costs that would arise from a variation to Standard 1.5.1 to permit DAG-oil would outweigh the direct and indirect benefits to the community, Government or industry.

- There are no measures other than a variation to the Food Standards Code available to permit a novel food to be sold as food or for use as a food ingredient.

Accordingly, FSANZ now seeks public comment on matters relevant to this application for consideration in making a Draft Assessment. If approved by FSANZ and agreed by the Ministerial Council, an amendment to Standard 1.5.1 would allow the use of DAG-oil derived from vegetable oils as a novel food and novel food ingredient.

The purpose of this report is to provide relevant information supplied by the applicant, to assist in identifying the affected parties and to outline the relevant issues necessary to complete assessment of the application, now that it has been accepted. The information needed to complete the assessment will include information received from public submissions.

1 Introduction

1.1 Nature of Application

An application was received from ADM Kao LLC, a joint venture business between the Archer Daniels Midland Company and the Kao Corporation, on 10 June 2003 seeking approval for the use of diacylglycerol oil (DAG-oil), marketed as ENOVA[™] Oil, derived from vegetable oils as a novel food as an edible oil and as an ingredient in various food applications under Standard 1.5.1 – Novel Foods of the Food Standards Code. Work commenced on this application on 10 June 2003. FSANZ has not previously received any applications for this type of oil or any similar type of oil.

2. Regulatory Problem

Standard 1.5.1 prohibits the sale of novel foods as food or for use as food ingredients unless listed in the Table to clause 2 of the Standard. In deciding whether to list a novel food in the table, FSANZ conducts a risk based safety assessment of the food.

In Standard 1.5.1 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.

Novel foods are defined in Standard 1.5.1 as 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; or
- levels of undesirable substances in the product; or
- known potential for adverse effects on humans; or
- traditional preparation and cooking methods; or
- patterns and levels of consumption of the product.

It is proposed to use DAG-oil as edible oil and as an ingredient in various foods. For a food to be considered novel, it must first be considered to be a non-traditional food. A non-traditional food is a food which does not have a history of significant consumption by the broad community in Australia or New Zealand. DAG-oil consists of >80% diglycerides, while edible oil normally consists of triglycerides and only small amounts of diglycerides. Therefore, the broad community may be currently only exposed to low levels of diglycerides. This means that although there may be a history of human consumption of the main component of DAG-oil in the broad community in Australia and New Zealand, this consumption may not be significant. Hence, DAG-oil may be a non-traditional food.

DAG-oil may be a novel food because the composition of the product is markedly different to traditional oils. DAG-oil contains >80% diglycerides, 20% triacylglycerol, 5% monoacylglycerol and <0.2% emulsifiers and antioxidants. In Standard 2.4.1 - Edible oils, edible oils are defined as the triglycerides of fatty acids of plant or animal origin. Edible oil may contain incidental amounts of free fatty acids, unsaponifiable constituents and other lipids. Due to this difference in composition when compared with edible oils, FSANZ will examine whether there is insufficient knowledge in the broad community to enable safe use of DAG-oil in the form or context in which it is presented.

Therefore, the application relates to a matter that warrants a variation to Standard 1.5.1, if further assessment supports such a variation.

3. Objective

The objective of this application is to establish if food standards should be changed to allow the use of DAG-oil as edible oil and as an ingredient in various foods. The list of products that are likely to include DAG-oil are: salad dressings, mayonnaise, viscous dressings, fat spreads / margarine, baked products (bread, cakes, crackers and cookies, croissants, pastries, pizza), health bars and meal replacements. Before DAG-oil can enter the food supply in Australia and New Zealand, FSANZ must undertake a safety assessment that considers the potential health impact of dietary exposure to DAG-oil on consumers. For approval, an amendment to the *Food Standards Code* must be agreed by the FSANZ Board, and subsequently be notified to the Australia New Zealand Food Regulation Ministerial Council (ANZFRMC). An amendment to the *Food Standards Code* may only be gazetted once the Ministerial Council process has been finalised.

In assessing the application to vary Standard 1.5.1 to approve the use of DAG-oil as novel food, 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 Historical background

DAG-oil is manufactured from natural edible plant oils such as soybean, canola (rapeseed) or corn oil and is composed largely of randomised diacylglycerols (DG). DAG-oil contains approximately 80% DG, 20% triacylglycerol, 5% monoacylglycerol and <0.2% emulsifiers (polyglycerol esters of fatty acids) and antioxidants (ascorbyl palmitate and tocopherol). The main constituent fatty acids of DAG-Oil are oleic (C18:1), linoleic (C18:2), and linolenic (C18:3) acids, present as 1,3- and 1,2-diacylglycerols at a ratio of 7:3, respectively. The constituents of DAG-oil are already present in the Australian and New Zealand diets as components of conventional dietary oils, as approved food additives i.e. mono- and diglycerides, and occur as metabolites of normal lipid metabolism following the consumption of dietary fat. Other ingredients used in the processing, manufacturing and packaging of DAG-oil are permitted and are listed in the Food Standards Code.

4.2 Work Plan Classification

This cost recovered Application had been provisionally rated as Category of Assessment 4 (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 Considerations

The safety of DAG-oil is supported by the submission of several acute, sub-acute, and chronic studies in rats; *in vitro* mutagenicity studies on diglycerides, and a series of clinical studies conducted to determine the human tolerance and nutritional effects of DAG-oil. These studies will be assessed in detail at Draft Assessment.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has evaluated monoglycerides and diglycerides in 1974. This evaluation and other evaluations in the safety of DAG-oil will be considered at Draft Assessment.

The safety of DAG-oil will be more fully considered at Draft Assessment.

5.2 Food Use

The Applicant claims DAG-oil demonstrated unique cooking characteristics and imparts improved organoleptic qualities to foods, indicating that it may provide a favourable taste and cooking alternative to conventional oils for consumers.

These and other data provided by the Applicant will be used at Draft Assessment to examine the food use of DAG-oil.

5.3 Nutritional Implications

The Applicant reports that the metabolism of DAG-oil is comparable to that of partial glycerides (mono- and diglycerides) and triglycerides. Furthermore, diglyceride-rich oils have energy values and digestibility coefficients equivalent to those of triglyceride oils of similar fatty acid composition. According to the applicant, the most important difference with the digestion of triacylglycerols and DAG-oil is that following the intake of diacylglycerols, the formation of 2-monoacylglycerols is limited. As a result, more fatty acids are broken down to release energy. Therefore, they are not available for re-synthesis in triacylglycerols and hence do not contribute to fat deposition. The applicant reports that consumption of DAG-oil, as compared to triglyceride oil, has the effect of producing lower level of serum triglycerides, as well as decreasing body weight and fat mass.

The nutritional implications arising from the use of DAG-oil will be more fully considered during Draft Assessment.

5.4 Dietary Implications

DAG-oil is edible oil that is equivalent in taste, physicochemical properties and caloric value to conventional vegetable oils. Therefore, on the basis of substantial equivalence to existing oils, the applicant is proposing the use of DAG-oil as a 1:1 (w/w) replacement for liquid vegetable oils (i.e. non hydrogenated oil) and as an ingredient incorporated into various foods.

The dietary implications arising from the use of DAG-oil will be more fully considered during Draft Assessment.

5.5 Labelling

The applicant proposes that DAG-oil is to be sold to 1) consumers as edible oil in a pre-packaged food product and 2) manufacturers as a food ingredient.

The applicant has submitted proposed labels for both DAG-oil products based on the current products that are marketed in the U.S. In light of the differences in the nutrition labelling requirements between Australia and New Zealand and the U.S, changes will need to be made to the nutrition information panel contained in the proposed label of DAG-oil for retail sale. In addition, consideration will need to be given to whether the ‘consumer information’ provided on the proposed label will be permitted under the Australia New Zealand Food Standards Code as it may be considered a health claim of the type prohibited by Standard 1.1A.2 – Health Claims.

The labelling implications arising from the use of DAG-oil will be more fully considered during draft assessment.

5.6 Consideration by other countries

In several countries DAG-oil is permitted as an edible oil and ingredient in various foods. The relevant regulations are:

- In Japan, DAG-oil was approved for food use by the Ministry of Health and Welfare on May 20, 1998. It is used as cooking oil, and as an ingredient in margarine, dressings for salads, canned tuna, curry roux and some baked goods.
- In the United States, an independent Expert Panel determined DAG oil to be GRAS in spreads and cooking oils (2000). The U.S. FDA subsequently granted a GRAS amendment in 2003 to expand the original uses of DAG-oil to include baked goods, pizza, mayonnaise, salad dressings, health bars (breakfast, snack and power bars), meal replacements, frozen entrées, and soups, soup mixes and gravies.
- The EU considers DAG as a novel food / food ingredient, because it meets the definition of a novel food pursuant to the EU Novel Food regulation. The application has been reviewed for an initial assessment by the Committee on Safety Assessment of Novel Foods of the Ministry of Health, Welfare and Sports of the Netherlands in December 2002. The Committee has set the safe level of exposure at 140 gram per 70 kilograms of body weight per day. As the next step in the EU regulatory process this initial assessment is now under review by the EC and the EU member states for final

regulatory approval.

- An application for the approval of DAG as a novel food / food ingredient has been submitted to the Health Canada regulatory agency for pre-market notification to permit DAG-oil for use as cooking oil and as an ingredient in baked goods, pizza, fats and oils, health bars, meal replacements, frozen entrees, and soups, soup mixes and gravies. Health Canada is currently assessing the application.

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, food industries and governments in Australia and New Zealand. The benefits and costs associated with the proposed amendment to the Food Standards Code will be analysed using regulatory impact principles.

There are no options other than a variation to the Food Standards Code available to permit a novel food to be sold as food or for use as a food ingredient.

Therefore, the following two regulatory options are available for this application:

- Option 1.** Maintain the status quo and not approve the use of DAG-oil as a novel food.
- Option 2.** Amend the Food Standards Code and approve the use of DAG-oil as a novel food

7. Impact Analysis

7.1 Affected Parties

The affected parties to this application include those listed below:

- consumers;
- the edible oil industry
- those sectors of the food industry wishing to produce and market food products produced using DAG-oil; and
- Australian Commonwealth, State, Territory and New Zealand government enforcement agencies.

7.2 Impact of Regulatory Options

In the course of developing food regulatory measures suitable for adoption in Australia and New Zealand, FSANZ is required to consider the impact of all options on all sectors of the community, including consumers, the food industry and governments in both countries. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and

benefits of the regulation, and its health, economic and social impacts.

The regulatory impact of the proposed change to the Food Standards Code will be considered in detail at Draft Assessment. Accordingly, at Initial Assessment there is no basis for considering whether the costs that would arise from a variation to Standard 1.5.1 to permit DAG-oil would outweigh the direct and indirect benefits to the community, Government or industry.

To assist in developing the impact analysis of the regulatory options proposed, FSANZ seeks comment on the following:

- What are the potential costs or benefits of this application to you as a stakeholder? Do the benefits outweigh the costs?
- What are the costs or benefits for consumers in relation to public health and safety, consumer information and labelling, etc?
- What are the costs or benefits for business – compliance, reporting, costs, savings, increased market opportunities both domestically and overseas?
- What are the costs or benefits for government – administration, enforcement, public health and safety, etc?

8. Consultation

8.1 Public consultation

The Initial Assessment Report is intended to seek early input on a range of specific issues known to be of interest to various stakeholders, to seek input on the likely regulatory impact at an early stage and to seek input from stakeholders on any matter of interest to them in relation to the application.

All stakeholders that make a submission in relation to the application will be included on a mailing list to receive further FSANZ documents in relation to the application. If readers of this Initial Assessment Report are aware of others who might have an interest in this application, they should bring this to their attention. Other interested parties as they come to the attention of FANZ will also be added to the mailing list for public consultation.

At this stage FSANZ is seeking public comment to assist it in assessing this application. Comments that would be useful could cover:

- scientific aspects of the application, in particular, any information relevant to the safety assessment;
- parties that might be affected by having this application approved or rejected;
- potential costs and benefits to consumers, industry and government.

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.

Amending the Food Standards Code to allow the use of DAG-oil as a novel food is unlikely to have a significant effect on international trade. This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia 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.

9. Conclusion and Recommendation

FSANZ accepts this application following initial assessment for the following reasons.

- The application seeks approval for the use of DAG-oil as a novel food .
- DAG-oil may be a non-traditional food as there is no history of human consumption of DAG-oil or its main component, diglycerides, at significant levels in Australia or New Zealand.
- DAG-oil may be a novel food because, due to the markedly different composition of DAG-oil compared with edible oils, FSANZ considers that there is insufficient knowledge in the broad community to enable safe use of DAG-oil in the form or context in which it is presented.
- Therefore, the application relates to a matter that warrants a variation to Standard 1.5.1, if further assessment supports such a variation.
- The application is not so similar to any previous application that it ought not be accepted.
- There is no basis for considering, at this stage of assessment, that the costs that would arise from a variation to Standard 1.5.1 to permit DAG-oil would outweigh the direct and indirect benefits to the community, Government or industry.
- There are no measures other than a variation to the Food Standards Code available to permit a novel food to be sold as food or for use as a food ingredient.

10. Implementation and review

This information will be provided once the Draft Assessment has been completed.