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

7-05
5 October 2005

INITIAL ASSESSMENT REPORT

APPLICATION A563

MEDIUM CHAIN TRIGLYCERIDES IN INFANT FORMULA PRODUCTS

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 16 November 2005
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED
(See 'Invitation for Public Submissions' for details)

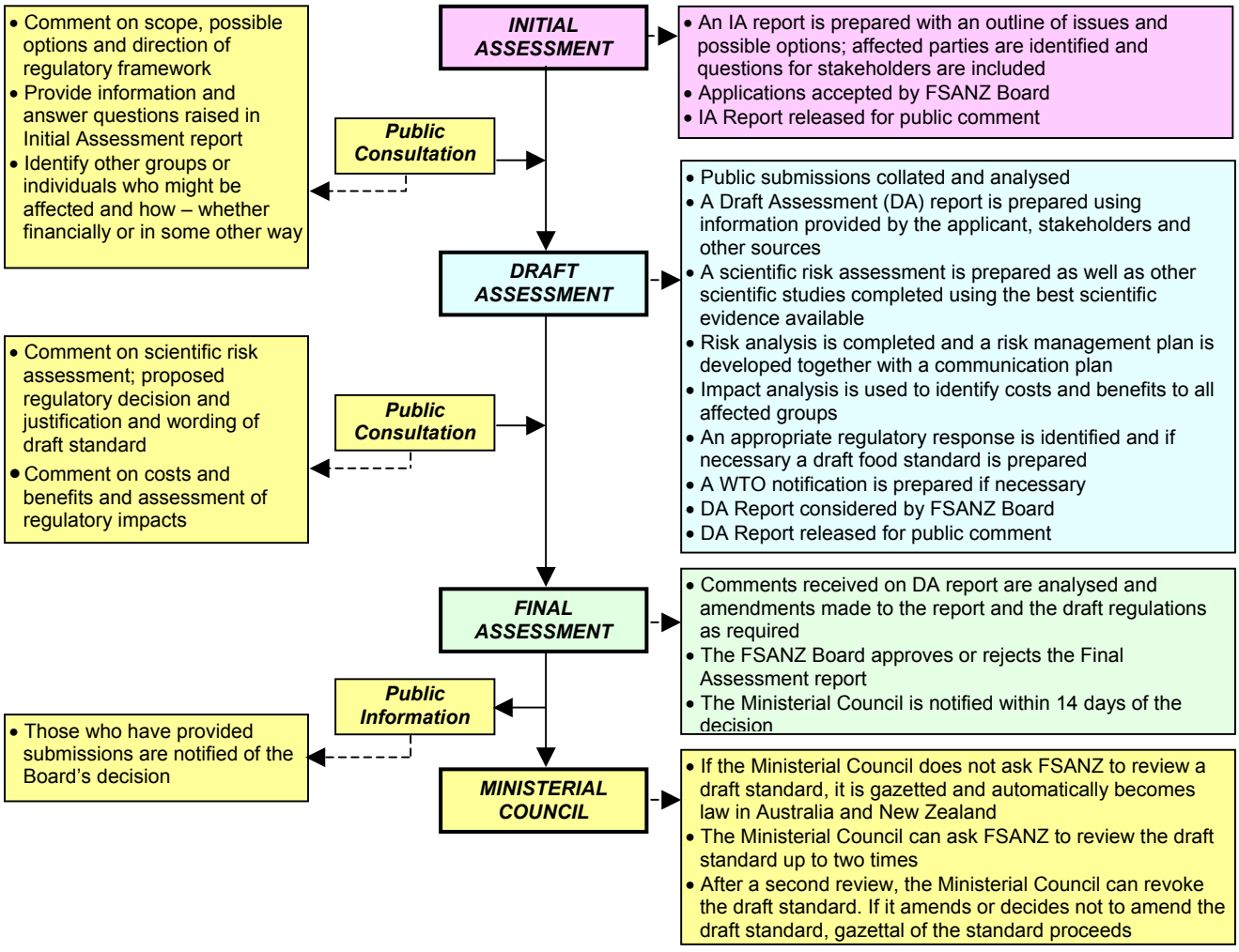
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 Australian Government; 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 Australian Government, 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 Australian Government, 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 for Application A563, 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 need to be received by FSANZ by 6pm (Canberra time) 16 November 2005.

Submissions received after this date will not be considered, unless agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ Website and will apply to all submitters.

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 Management 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

Food Standards Australia New Zealand (FSANZ) received an Application from DSM Nutritional Products Australia Pty Ltd to amend Standard 2.9.1 – Infant Formula Products, of the *Australia New Zealand Food Standards Code* (the Code), to permit the use of medium chain triglycerides (MCTs) in infant formula and follow-on formula as processing aids in preparations of permitted fat-soluble vitamins. The Applicant provided a specification for MCTs sourced from coconuts or palm kernels.

This Initial Assessment Report is not a detailed assessment of the Application but rather an assessment of whether the Application should undergo further consideration. The Report is based mainly on information provided by the Applicant and has been written to assist in identifying the affected parties and to outline expected relevant issues for completion of the assessment. Responses from public submissions will be included in the information assessed.

MCTs are defined as triacylglycerols (fats and oils) which contain predominantly the saturated fatty acids designated by 8:0 (caprylic acid) and 10:0 (capric acid). The Applicant contends that the use of small amounts of MCTs as carriers or processing aids for vitamin dispersion should not significantly affect the composition of infant formula. MCTs are currently permitted in infant formula and follow-on formula when present as natural constituents of dairy ingredients. The Applicant claims that MCTs will be increased by no more than 2% of the total fat content as a result of the use requested. MCTs are currently permitted for addition to infant formula products for specific dietary use based upon protein substitutes. MCTS may also be included in other specifically formulated infant formula products for special dietary use.

The Applicant contends that MCTs have advantages over alternative oils such as partially hydrogenated soybean oil in dispersing fat-soluble nutrients due to the allergen problem associated with soybean for some consumers. MCTs are obtained mainly from coconuts or from palm kernels and not from genetically modified sources of oils.

The Applicant wishes to use MCTs from fractionated coconut oil as processing aids in adding required fat-soluble vitamins to a wider range of infant formula and follow-on formula. Before a wider range of infant formula products containing MCTs from the specified sources can be approved for sale in Australia and New Zealand, MCTs must undergo a pre-market safety assessment through the application process.

The Applicant requested that the Application be progressed under section 36 of the FSANZ Act with only one round of public comment. The request was denied on the grounds that the Application raises some issues of significant complexity and omitting a round of comment could have a significant adverse effect on the interests of some individuals.

The objective of the Application is to establish whether it is appropriate to amend the Code to approve the use of MCTs derived from coconuts or palm kernels as processing aids in all infant formula and follow-on formula.

FSANZ DECISION

FSANZ recommends proceeding to Draft Assessment and to seek public submissions.

The Application has been assessed against the requirements of section 13 of the FSANZ Act and accepted for the following reasons:

- The Application seeks approval for use of MCTs derived from coconuts or palm kernels as processing aids used in preparations of permitted fat-soluble vitamins in all infant formula and follow-on formula.

- MCTs are currently permitted in infant formula products;

    - as constituents of milk-based ingredients in infant formula and follow-on formula;
    - when added to products for specific dietary use based upon protein substitutes;
    - when added or as constituents of ingredients where products are specifically formulated for premature or low birthweight infants; and
    - when added or as constituents of ingredients where products are specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions.

- The Application relates to a matter that warrants a variation to Standard 2.9.1, if further assessment supports such a variation.

- This Application is not so similar to any previous application that it ought not be accepted.

- At this stage, there is no indication that the costs that would arise from a variation to Standard 2.9.1 outweigh the benefits to the community, government or industry that would arise from the variation.

- There are no other regulatory measures, other than a variation to the Code available to permit the use of MCTs as processing aids in all infant formula and follow-on formula.

The Application is recommended for further consideration, so FSANZ now seeks submissions to assist in assessing the Application.

1. Introduction

Food Standards Australia New Zealand (FSANZ) has received an Application from DSM Nutritional Products Australia Pty Ltd to amend Standard 2.9.1 – Infant Formula Products of the Code, to permit the use of medium chain triglycerides (MCTs) from coconuts or palm kernels in infant formula and follow-on formula as processing aids in preparations of permitted fat-soluble vitamins.

Under subclause 1(2) of Standard 2.9.1:

> ***medium chain triglycerides*** *means triacylglycerols which contain predominantly the saturated fatty acids designated by 8:0 and 10:0.*

Subclause 23(a) of Standard 2.9.1 currently states that:

The fats in infant formula and follow-on formula must –

> *(a) not contain medium-chain triglycerides except where a medium chain triglyceride is present in a particular infant formula or follow-on formula as the result of being a natural constituent of a milk-based ingredient of that particular infant formula or follow-on formula…*

Division 3 of Standard 2.91 permits infant formula products to be specially formulated for premature or low birthweight infants, and for infants with other specific medical conditions. In these cases infant formula products may contain both added MCTs and ingredients containing MCTs.

In addition, clause 34 of Standard 2.9.1 specifically permits infant formula products for specific dietary use based on protein substitutes to contain added MCTs.

The Applicant states that lipophilic vitamins (A, D, E and K) are nutrients, which are susceptible to light and oxidation and are difficult to work into many food formulations. These vitamins need to be in a suitable form that is stable and easy to disperse into both liquid and solid food systems. Microencapsulation is a technique that can be used to help disperse fat-soluble nutrients into aqueous or dry foods.

The Applicant contends that a suitable method for microencapsulation is based on mixing MCTs oil as a processing aid with a fat-soluble nutrient. An aqueous solution of a suitable matrix material such as gelatine or gum acacia provides a hydrophilic phase that encapsulates and stabilises the lipophilic phase to provide appropriate particle sizes.

The Applicant contends that the use of small amounts of MCTs as carriers or processing aids for vitamin dispersion should not significantly affect the composition of infant formula. The Applicant claims that MCTs will be increased by no more than 2% of the total fat content as a result of the use requested and that MCTs can provide as much as 50% of total fat in some formulae intended for preterm infants.

The Applicant contends that MCTs have advantages over alternative oils such as partially hydrogenated soybean oil in dispersing these essential nutrients due to the allergen problem associated with soybean for some consumers.

MCTs are usually obtained from coconuts, although they can be sourced from palm kernels but not from genetically modified sources of oils.

2. Regulatory Problem

Standard 2.9.1 - Infant Formula Products, subclause 23 (a) – Fat, requires that infant formula and follow-on formula must not contain medium chain triglycerides except where present as the result of being natural constituents of milk-based ingredients. This prohibition prevents the use of MCTs as processing aids in the major category of infant formula products.

Clause 34 permits infant formula products for specific dietary use based upon protein substitutes to contain added MCTs. The permission for added MCTs in infant formula products for specific dietary use is not restricted on the basis of MCTs in milk-based ingredients. Other specifically formulated infant formula products for specific dietary use regulated in Division 3 of Standard 2.9.1 may also contain MCTs either as constituents of ingredients or by direct addition.

The Applicant wishes to use MCTs derived from coconuts or palm kernels as processing aids in dispersing required fat-soluble vitamins in infant formula and follow-on formula as in other countries. Before MCTs can be used as processing aids in a wider range of infant formula products in Australia and New Zealand, MCTs must undergo a pre-market safety assessment through the application process.

3. Objective

The objective of the Application is to establish whether it is appropriate to amend the Code to approve the use of MCTs derived from coconuts or palm kernels as processing aids in infant formula and follow-on formula.

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. Progress under section 36 of *Food Standards Australia New Zealand Act 1991*

The Applicant requested that the Application be fast tracked under the provisions of section 36 of the Act. The Applicant submitted the following arguments in support of this request:

There would be no significant adverse effects because:

- There is no safety issue as MCTs are permitted in infant formula products when derived from milk ingredients; human breast milk contains 8-10% MCTs and some formulas for preterm infants contain up to 50% of the fat as MCTs.
- It will not adversely affect manufacturers, as they support this Application.
- It will not adversely affect consumers and will benefit those who wish to avoid potential allergens and products derived from genetically modified organisms.
- It will not adversely affect the market as there will be no price differential between the current and proposed product formulations.
- It will not have any significant adverse effect on enforcement agencies as they already have to carry out the necessary investigation to ensure infant formula products comply with the current exemption and extending the exemption would not create any significant additional work.

It is claimed to be of minor significance because:

- There is no safety issue.
- MCTs from this source would not constitute more than 2% of the fat content of infant formula products compared to up to 50% from other sources found in some products designed for preterm infants.
- The proposed amendment is merely to address the presence of a generally permitted processing aid in an added micronutrient preparation, which is technically prohibited by a restriction in the infant formula standard, that was designed for other purposes.
- It will not have any significant adverse effects on the interests of anyone.

The Applicant also contends that only one of the criteria for omitting a round of public consultation need be met as the conjunction used in section 36 is 'or'.

4.1 Response to request for fast-tracking

Section 36 of the Act requires FSANZ to be satisfied that omitting the round of public consultation will not have a significant adverse effect on anyone's interests or that the application raises issues of minor significance or complexity only.

The current restriction on added MCTs is predominantly related to maintaining similarity with human breast milk as infant formula is a sole source of infant nutrition rather than due to a safety concern related to the chemistry of MCTs. The requested change however, raises some issues with potential for complexity.

The Application provides information about the efficacy of MCTs as carriers for nutritional additives for the delivery of essential fat-soluble vitamins. The Applicant claims that there are some disadvantages of possible alternatives due to potential labelling implications for ingredients such as soybean oil in infant formula products.

Omitting a round of comment will not provide adequate opportunity to address possible comments about allergenicity, declaration of ingredients or the possible use of alternatives.

The Applicant states that MCTs would be present in infant or follow-on formula as a result of their use as processing aids in preparations of permitted fat-soluble vitamins of that particular infant or follow-on formula at no more than 2% of the total fat content. The vitamins and minerals in infant formula products are required in specified ranges as it may be the sole source of nutrition for an infant.

The current restrictions on MCTs in infant formula products do not mention processing aids or preparations of vitamins. The encapsulation process used in the preparations of vitamins can also involve the use of food additives.

Acacia gum is provided as an example in the Application of an additive that can be used in capsules as a stabiliser for vitamin D dissolved in MCTs. Acacia gum is permitted as a processing aid in Australia and New Zealand but is not specifically permitted as a food additive in infant formula products.

Acacia gum is not included in the additives in the current draft Codex standard (Stan 72) for infant formula. Acacia gum is listed as a nutrient carrier in the Codex advisory list of mineral salts and vitamin compounds for infants and children.

There is a wide diversity of views about the appropriate composition of infant formula products. The use of MCTs sourced from coconuts or palm kernels as processing aids or carriers for essential fat-soluble vitamins could be controversial.

The decision not to accept the request will result in progress of the Application by proceeding to Initial Assessment with 2 rounds of comment required.

5. Background

5.1 Historical Background

FSANZ (formerly ANZFA) reviewed the provisions for addition of MCTs in infant formula products under Proposal 93 – Review of Infant Formula. FSANZ proposed to prohibit added MCTs in formulas for healthy infants and preterm infants and to allow only for the natural presence of MCTs in milk-based ingredients.

Strong opposition was raised by industry to the proposed prohibition on MCTs in preterm formula. Pre-term formulas with MCTs were already in use in Australia and New Zealand and this restriction may have disadvantaged preterm infants. Preterm formula is such a small market in Australia and New Zealand that restricting MCTs in pre-term formulas may have led to companies withdrawing their products from this market rather than reformulating them. Given the complexity of the issues involved, FSANZ decided that pre-term and other specialised infant formula products would be reviewed as part of a separate future process. FSANZ has not yet determined the timing of this process.

In the meantime, clause 25 of Standard 2.9.1 permits infant formula products for specific dietary use formulated for premature or low birthweight infants to be specifically formulated. Clause 27 of Standard 2.9.1 permits infant formula products for specific dietary use to be specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions. These provisions allow for the use of MCTs by addition or as constituents of ingredients in relevant infant formula products for specific nutritional purposes.

5.2 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.

6. Relevant Issues

6.1 Risk assessment of MCTs in infant formula products

The Applicant claims that MCTs as processing aids in infant formula products are unlikely to raise safety concerns, because of the following reasons:

- MCTs are proposed to be used at low levels as processing aids;
- MCTs are already permitted as constituents of dairy ingredients of some infant formula products;
- MCTs are permitted to be added to infant formula products for specific dietary use based upon protein substitutes;
- MCTs are permitted in some specifically formulated infant formula products; and
- MCTs are present in human breast milk.

The current restriction on MCTs in infant formula and follow-on formula is predominantly related to maintaining similarity with human breast milk. The safety of MCTs derived from fractionated coconut and palm kernel oils as processing aids in infant formula and follow-on formula will be assessed as part of the Risk Assessment Report at Draft Assessment.

The Applicant contends that the nutritional implications from the additional intake of MCTs in healthy infants as a result of its use as a processing aid in preparations of permitted fat-soluble vitamins are negligible. The nutritional implications and public health aspects of the changes requested will be considered in a Nutrition Report at Draft Assessment.

6.2 Technological justification and specification

The Applicant supplied 2 letters from companies supporting the use of MCTs to incorporate micronutrients into infant formula products as evidence of technological need. The technological justification will be investigated more fully in a Food Technology Report at Draft Assessment.

The MCTs used in micronutrient preparations comply with the European Pharmacopoeia standard for identity. MCTs are defined as being obtained from the oil extracted from the hard, dried fraction of the endosperm of *Cocos nucifera* L. or from the dried endosperm of *Elaeis guineensis* Jacq. They consist of a mixture of triglycerides of saturated fatty acids, mainly caprylic acid (C_8 $H_{16}O_2$) and caproic acid (C_{10} $H_{20}O_2$).

6.3 International regulatory standards

The Codex Standard for Infant Formula (Stan 72-1981) does not specifically prohibit the addition of MCTs to infant formula. This Standard is currently being revised and the possible inclusion of a category for nutrient carriers is included in proposed discussions.

The European Directive 91/321/EC on Infant Formula and Follow-on Formula prohibits the addition of sesame seed oil and cotton seed oil but not MCTs. This Directive is also being revised.

The United States of America's Code of Federal Regulations does not specify the ingredients to be used in infant formula and allows fatty acids for direct addition to foods under CFR 172.860. The Applicant contends that the US Food and Drug Administration (FDA) does not specifically prohibit the use of MCTs in infant formula unless the FDA has reasons to believe this is not consistent with good nutrition.

7. 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 Code will be analysed using regulatory impact principles at Draft Assessment.

There are no options other than a variation to the Code for this Application. Therefore the two regulatory options available for this Application are:

Option 1. Not approve MCTs as processing aids in infant formula and follow-on formula.

This option maintains the *status quo*.

Option 2. Approve MCTs as processing aids in infant formula and follow-on formula.

This option would result in an amendment to the Code, to permit the use of MCTs as processing aids in a wider range of infant formula products.

8. Impact Analysis

8.1 Affected Parties

The affected parties to this Application include the following:

1. those sectors of the food industry wishing to supply ingredients to manufacture or import and market infant formula and follow-on formula;

2. formula fed infants and their carers; and

3. Australian, State, Territory and New Zealand Government agencies that enforce food regulations.

8.2 Analysis

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. 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 will be assessed at Draft Assessment.

9. Consultation

9.1 Public consultation

The Initial Assessment Report is not a detailed assessment of this Application but rather an assessment of whether the Application should undergo further consideration. FSANZ is seeking public comment in order to assist in assessing this Application at Draft Assessment. A further round of public comment will occur after the Draft Assessment Report is completed to assist in the Final Assessment.

FSANZ is seeking public comment to assist in assessing the Application. Comments on, but not limited to, the following would be useful:

- technological justification for the use of MCTs as a processing aid in all infant formula products;

- safety considerations of using MCTs derived from coconut and palm kernel oils;

- nutritional aspects of using MCTs as processing aids in infant formula and follow-on formula;

- appropriate specifications for MCTs;

- other scientific aspects; and

- various costs and benefits of its use, including how infant formula product manufacturers anticipate they may use MCTs encapsulation processes and in which products, to assist FSANZ in assessing the impact of approving MCTs as processing aids in infant formula products.

9.2 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 Code to approve the addition of MCTs as processing aids to all infant formula products is unlikely to have a significant effect on trade. The use of MCTs as dispersants for fat-soluble vitamins is an internationally accepted practice so there does not appear to be a need to notify the WTO. 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 Barriers to Trade (TBT) or Sanitary and Phytosanitary Measures (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.

10. Conclusion and Recommendation

The Decision

The Application has been assessed against the requirements of section 13 of the FSANZ Act and accepted for the following reasons:

- The Application seeks approval for use of MCTs derived from coconuts or palm kernels as processing aids used in preparations of permitted fat-soluble vitamins in all infant formula and follow-on formula.

- MCTs are currently permitted in infant formula products;

    - as constituents of milk-based ingredients in infant formula and follow-on formula;
    - when added to products for specific dietary use based upon protein substitutes;
    - when added or as constituents of ingredients where products are specifically formulated for premature or low birthweight infants; and
    - when added or as constituents of ingredients where products are specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions.

- The Application relates to a matter that warrants a variation to Standard 2.9.1, if further assessment supports such a variation.

- This Application is not so similar to any previous application that it ought not be accepted.

- At this stage, there is no indication that the costs that would arise from a variation to Standard 2.9.1 outweigh the benefits to the community, government or industry that would arise from the variation.

- There are no other regulatory measures, other than a variation to the Code available to permit the use of MCTs as processing aids in all infant formula and follow-on formula.

The Application is recommended for further consideration, so FSANZ now seeks submissions to assist it in assessing the Application.