

**EXPLANATORY STATEMENT**

**APPLICATION A563**

**MEDIUM CHAIN TRIGLYCERIDES IN INFANT  
FORMULA PRODUCTS**

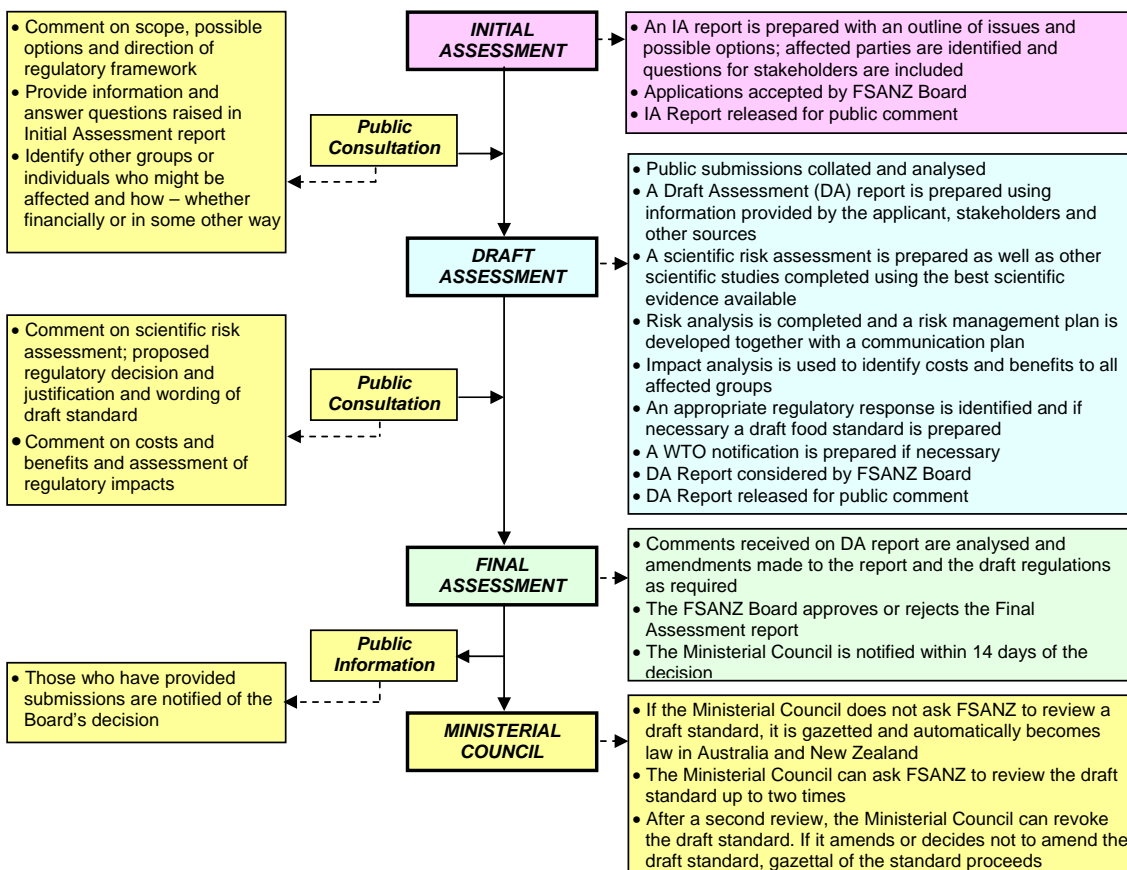
## FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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.



## **Final Assessment Stage**

FSANZ has now completed two stages of the assessment process and held two rounds of public consultation as part of its assessment of this Application. This Final Assessment Report and its recommendations have been approved by the FSANZ Board and notified to the Ministerial Council.

If the Ministerial Council does not request FSANZ to review the draft amendments to the Code, an amendment to the Code is published in the *Commonwealth Gazette* and the *New Zealand Gazette* and adopted by reference and without amendment under Australian State and Territory food law.

In New Zealand, the New Zealand Minister of Health gazettes the food standard under the New Zealand Food Act. Following gazettal, the standard takes effect 28 days later.

## **Further Information**

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

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Assessment reports are available for viewing and downloading from the FSANZ website [www.foodstandards.gov.au](http://www.foodstandards.gov.au) or alternatively paper copies of reports can be requested from FSANZ's Information Officer at [info@foodstandards.gov.au](mailto:info@foodstandards.gov.au) including other general inquiries and requests for information.

## CONTENTS

<b>EXECUTIVE SUMMARY AND STATEMENT OF REASONS .....</b>	<b>6</b>
STATEMENT OF REASONS.....	7
<b>1. INTRODUCTION.....</b>	<b>8</b>
1.1 NATURE OF THE APPLICATION .....	8
<b>2. REGULATORY PROBLEM.....</b>	<b>9</b>
2.1 CURRENT STANDARD.....	9
<b>3. OBJECTIVE .....</b>	<b>10</b>
<b>4. BACKGROUND .....</b>	<b>10</b>
4.1 HISTORICAL BACKGROUND .....	10
<b>5. RELEVANT ISSUES .....</b>	<b>11</b>
5.1 RISK ASSESSMENT .....	11
5.1.1 Safety Assessment.....	11
5.1.2 Nutrition Assessment.....	11
5.2 FOOD TECHNOLOGY ISSUES.....	12
5.3 INTERNATIONAL REGULATORY STANDARDS.....	13
5.4 ISSUES RAISED IN SUBMISSIONS.....	13
5.4.1 Risk Assessment Issues.....	13
5.4.2 Food Technology Issues.....	15
5.4.3 Source of MCTs.....	15
5.4.4 MCTs as processing aids or an ingredient? .....	16
5.4.5 Maximum limits for MCTs .....	17
5.4.6 Breastfeeding rates .....	18
5.5 RISK MANAGEMENT .....	18
<b>6. REGULATORY OPTIONS.....</b>	<b>18</b>
<b>7. IMPACT ANALYSIS .....</b>	<b>19</b>
7.1 AFFECTED PARTIES.....	19
7.2 IMPACT ANALYSIS .....	19
7.2.1 Option 1 – <i>Not approve MCTs as processing aids in infant formula and follow-on formula</i> .....	19
7.2.2 Option 2 – <i>Approve MCTs as processing aids in infant formula and follow-on formula</i> . 20	20
7.2.3 Assessment of Impacts.....	20
<b>8. CONSULTATION .....</b>	<b>20</b>
8.1 INITIAL ASSESSMENT .....	20
8.2 DRAFT ASSESSMENT .....	21
8.3 WORLD TRADE ORGANIZATION (WTO) .....	21
<b>9. CONCLUSION AND RECOMMENDATION .....</b>	<b>21</b>
<b>11. IMPLEMENTATION AND REVIEW .....</b>	<b>22</b>

<b>ATTACHMENT 1 - DRAFT VARIATIONS TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE.....</b>	<b>23</b>
<b>ATTACHMENT 2 - SAFETY ASSESSMENT REPORT .....</b>	<b>24</b>
<b>ATTACHMENT 3 - NUTRITION ASSESSMENT .....</b>	<b>33</b>
<b>ATTACHMENT 4 - FOOD TECHNOLOGY REPORT.....</b>	<b>38</b>
<b>ATTACHMENT 5 - SUMMARY OF SUBMISSIONS.....</b>	<b>42</b>

## Executive Summary and Statement of Reasons

Food Standards Australia New Zealand (FSANZ) received an Application on 9 May 2005 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.

The Applicant states that partially hydrogenated soybean oil has been used for the preparation of some of the commercial forms of fat-soluble nutrients they supply to industry. However, ‘peanuts, soybeans and their products’ must be declared on a product label if present in a food, in accordance with Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations. The declaration of soybean on product labels is of concern for customers of the Applicant who are intending to target consumers who prefer allergen-free and genetically modified organism (GMO)-free foods. This labelling concern has prompted the Applicant to replace partially hydrogenated soybean oil with MCTs in fat-soluble nutrient preparations. However, the addition of MCTs is currently prohibited from regular infant formula and follow-on formula.

Subclause 23(a) of Standard 2.9.1 – Infant Formula Products expressly prohibits the presence of MCTs in regular infant formula and follow-on formula unless present as a natural constituent of a milk-based ingredient for that particular infant formula or follow-on formula. This prohibition prevents the use of MCTs as processing aids in infant formula or follow-on formula (the major category of infant formula products).

Division 3 of Standard 2.9.1 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 the addition of MCTs to infant formula for specific dietary use based on protein substitutes.

The objective of this assessment is to determine whether it is appropriate to amend the Code to permit the use of MCTs as processing aids in infant formula and follow-on formula. Such an amendment would need to be consistent with the section 10 objectives of the FSANZ Act.

The safety assessment and nutrition assessment of MCTs indicate that there are no public health and safety concerns at the anticipated levels of use.

The only regulatory options identified were to approve or not approve the use of MCTs as processing aids in infant formula and follow-on formula. The impact analysis indicates, that on balance, there is likely to be a benefit to formula fed infants and their carers (by offering an alternative for those with concerns over allergen or GMO issues due to the use of soybean or peanut oil) and industry (potential to market new products without mandatory labelling declarations, such as those required for soybean products) from the approval of this Application. There is unlikely to be a significant impact on government enforcement agencies as a result of approval for the use of MCTs as processing aids in infant formula and follow-on formula.

Therefore, it is recommended that the prohibition on the addition of MCTs to regular infant formula and follow-on formula in subclause 23(a) of Standard 2.9.1 be amended to permit the use of MCTs as processing aids in preparations of permitted fat-soluble vitamins.

### **Statement of Reasons**

FSANZ recommends the approval of the use of MCTs in infant formula and follow-on formula as processing aids in preparations of permitted fat-soluble vitamins for the following reasons:

- The Safety Assessment Report concluded that the use of MCTs as a processing aid in food would not raise any public health and safety concerns.
- The Nutrition Assessment Report concluded that the use of MCTs as processing aids in infant formula and follow-on formula would not pose any significant nutrition related health risks for infant nutrition.
- The Food Technology Report indicates that the use of MCTs as processing aids in preparations of permitted fat-soluble vitamins in infant formula and follow-on formula is technologically justified, and represents an alternative source of oil that does not require a mandatory label declaration and is not sourced from genetically modified oils; both of which are issues associated with the use of soybean and/or peanut products.
- The proposed changes to the Code are consistent with the section 10 objectives of the FSANZ Act.
- The Regulatory Impact Statement indicates that for the preferred option, namely, to approve the use of MCTs as processing aids in preparations of permitted fat-soluble vitamins in infant formula and follow-on formula, the benefits of the proposed amendment outweigh the costs.

## **1. Introduction**

Food Standards Australia New Zealand (FSANZ) received an Application on 9 May 2005 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.

The Applicant states that partially hydrogenated soybean oil has been used for the preparation of some of the commercial forms of fat-soluble nutrients they supply to industry. However, the Table to clause 4 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations, specifies that ‘soybeans and their products’ must be declared on a product label if present in the food. The declaration of soybean on product labels is of concern for customers of the Applicant who may intend to target consumers who prefer allergen-free and genetically modified organism (GMO)-free foods. This labelling concern and the perception by some consumers that absolute certainty regarding GMO status of soybean oil cannot be guaranteed, has prompted the Applicant to replace partially hydrogenated soybean oil with MCTs in fat-soluble nutrient preparations. However, the addition of MCTs is prohibited from infant formula and follow-on formula under subclause 23(a) of Standard 2.9.1.

### **1.1 Nature of the Application**

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. Micro-encapsulation 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 micro-encapsulation 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.

MCTs are usually obtained from coconuts, although they can be sourced from palm kernels. The Applicant contends that MCTs have marketing advantages over alternative oils such as partially hydrogenated soybean oil, in dispersing these essential nutrients, due to the mandatory declaration required on the label of products containing soybean products and for those with concerns over potential allergy and GMO issues associated with soybean.

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 formula intended for preterm infants.

The Applicant provided calculations to show that MCTs would be present at between 1.26% and 1.80% of the total fat content of infant formula if added as processing aids in preparations of fat-soluble vitamins.



However, when FSANZ calculated the content of MCTs using the numbers provided by the Applicant, the range of MCTs present as a percentage of the total fat content of infant formula was 0.00126% to 0.00189% (see the Food Technology Report at Attachment 4 for more detail of the calculations). These lower levels were supported by two public submissions to the Initial Assessment Report and the Applicant has acknowledged that these levels are correct.

Therefore, the actual levels of MCTs likely to be added to infant formula as processing aids are much lower than originally identified in the Application and the Initial Assessment Report. For the purposes of the Final Assessment Report, FSANZ will consider that the level of MCTs will be increased by no more than 0.002% of the total fat content of infant formula and follow-on formula.

## **2. Regulatory Problem**

### **2.1 Current Standard**

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...*

This prohibition prevents the use of MCTs as processing aids in the major category of infant formula products; that is, infant formula and 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. These products are a departure from regular infant formula and follow-on formula, and 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 permission for added MCTs in infant formula products for specific dietary use is not restricted on the basis of MCTs in milk-based ingredients.

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. Background**

#### **4.1 Historical Background**

FSANZ (formerly ANZFA) reviewed the provisions for addition of MCTs in infant formula products under Proposal P93 – 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. The rationale for the prohibition was:

- that MCTs are not normally present in human milk (less than 2% of total fat);
- the long term effects of infants consuming a high percentage of saturated fats are unknown; and
- there is no convincing evidence that the inclusion of MCTs in infant formula has conferred any benefit to infants.

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.

These products are a departure from regular infant formula and follow-on formula. 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.

In addition, clause 34 of Standard 2.9.1 expressly permits the addition of MCTs to infant formula products based on protein substitutes.

## **5. Relevant Issues**

### **5.1 Risk Assessment**

#### *5.1.1 Safety Assessment*

The safety assessment of MCTs in infant formula products concluded that:

- MCTs are sourced from a traditional food and have a safe history of use.
- The MCT micronutrient preparation complies with European Pharmacopoeia purity standards.
- MCTs and their component fatty acids have a very low acute toxicity in animals regardless of the route of administration. In acute oral toxicity studies, levels of 25 ml/kg and 36 ml/kg did not cause mortality in mice or rats respectively.
- Studies in both experimental animals and humans indicate that MCT-based diets do not cause significant adverse health effects.
- MCTs administered in the diet had no adverse effect on rat reproductive or developmental parameters or on terminal gestational development and postnatal survival of pigs.
- There was no evidence of carcinogenicity in the chronic studies with MCT tricaprylin.
- MCTs show little evidence of genotoxic or mutagenic potential in *in vitro* assays.

From the available information, it is concluded that the use of MCTs as processing aids in food would not raise any public health and safety concerns.

The full Safety Assessment Report is at Attachment 2.

#### *5.1.2 Nutrition Assessment*

The Nutrition Assessment considered the nutritional consequences for Australian and New Zealand infants if permission was granted for the addition of MCTs as processing aids to infant formula and follow-on formula. The following points are derived from the Nutrition Assessment Report (full report is at Attachment 3):

- There is little data on the MCT content of human milk, however based on the available evidence it appears that MCTs (C8:0, C10:0 and C12:0) constitute approximately 5-15% of the fatty acids in human milk. The evidence indicates that the MCT content of human milk varies across different countries, most likely due to dietary differences. The variation in the levels of MCTs found in breast milk from various countries indicates that there is no tight physiological control required for the MCT content of breast milk.
- The primary nutritional role of MCTs is as a source of energy in the diet. FSANZ investigated the effects on growth of preterm infants from the administration of MCT rich formula. There was no statistical difference identified in short term growth rates for infants fed MCT formula versus similar intakes of formula containing long chain triglycerides. Therefore, there was no identified nutrition related health risk to infant energy intakes from the addition of MCTs to infant formula.
- The Nutrition Assessment concluded that there are no significant nutrition related health risks to infant nutrition that have been identified with the intake of MCTs. Therefore, the addition of MCTs to infant formula and follow-on formula as processing aids, does not pose any significant nutritional concerns, particularly given the low levels of use proposed for MCTs in this Application.

## 5.2 Food Technology Issues

Food technology issues have been considered in preparing this Final Assessment Report and the full Food Technology Report is at Attachment 4. The following points are derived from the Food Technology Report:

- The Applicant states that the MCTs used in their micronutrient preparations are in compliance with the monograph for MCTs included in the European Pharmacopoeia. The European Pharmacopoeia is recognised in Standard 1.3.4 – Identity and Purity as a secondary source of specifications for substances added to food. Therefore, it appears that the MCTs proposed for use by the Applicant, for addition to infant formula and follow-on formula, are in compliance with Standard 1.3.4.
- The European Pharmacopoeia recognises MCTs sourced from coconut (*Cocos nucifera*) and palm kernel (*Elaeis guineensis* Jacq) oils. The oils are hydrolysed to medium chain fatty acids and glycerol, with the fatty acids then fractionated and re-esterified with glycerol to form MCTs.
- Micro-encapsulation is a common method of incorporating fat-soluble nutrients into food preparations. Oils such as partially hydrogenated soybean oil and peanut oil are presently utilised as materials for the lipophilic phase (containing the dissolved fat-soluble nutrient) of the micro-encapsulation matrix.
- MCT oil is suitable for use as the lipophilic phase of a micro-encapsulation matrix, and does not have the allergy concerns associated with alternative oils such as partially hydrogenated soybean oil and peanut oil.

- The level of MCTs that would be added to infant formula should all fat-soluble vitamins be added at the maximum permitted levels (under Standard 2.9.1), and using MCT oil as a carrier, would be significantly less than 2% of the total fat content of such infant formula. The Applicant made an error in calculating the likely MCT content, so that after recalculating the numbers provided by the Applicant, FSANZ recognises that the actual level of MCTs is likely to be less than 0.002% of the total fat content. This is supported by two written public submissions to the Initial Assessment Report that queried the 2% level.
- The use of MCTs in infant formula and follow-on formula as a processing aid in preparations of permitted fat-soluble vitamins is technologically justified.

### 5.3 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.

### 5.4 Issues raised in submissions

To limit duplication the issues raised in submissions to both the Initial Assessment Report and Draft Assessment Report have been combined and addressed under their topic headings below. The submissions are summarised in **Attachment 5** – Summary of Public Submissions.

#### 5.4.1 Risk Assessment Issues

##### 5.4.1.1 Safety Assessment

The New Zealand Food Safety Authority (NZFSA) specifically raised concerns over the potential for increased consumption of coconut and/or palm kernel oil and whether the level of trans fatty acids will be increased with the use of MCTs. The NSW Health Department identified a potential public health concern for some individuals related to a metabolic disorder called 'medium chain acyl CoA dehydrogenase deficiency' (MCAD). However, the NSW Health Department also indicated that there should be no problem with small amounts of MCTs up to 2% in infant formula.

At Draft Assessment, the Department of Human Services, Victoria asked whether there was an issue regarding the bioavailability of fat-soluble vitamins provided by an MCT carrier. It was noted that varying the carrier can affect the absorption of the substance in question.

An example of the drug, cyclosporin, having decreased absorption when MCT is a carrier compared to long chain triglycerides.

### **FSANZ consideration**

The level of MCTs likely to be added to infant formula and follow-on formula as a carrier for fat soluble nutrients is significantly less than the 2% of total fat content initially proposed by the Applicant. As indicated in section 5.2 of this report and in the Food Technology Report at Attachment 4, the actual level of addition of MCTs is likely to be less than 0.002% of total fat content. Therefore, the potential increased consumption as a result of the addition of MCTs at the levels indicated will be negligible.

MCTs are composed of saturated fatty acids and therefore do not undergo hydrogenation during the production process. It is the partial hydrogenation step for unsaturated fatty acids that can produce some trans fatty acids. Therefore there should not be any introduction of trans fatty acids from the addition of MCTs in a food product.

The NSW Health Department states that expert advice provided to them indicates that for those individuals suffering from MCAD, there should be no problem with small amounts of MCTs up to 2% in infant formula. The FSANZ Chief Medical Advisor agreed that the small amounts of MCTs proposed in the Application would be extremely unlikely to result in an increase in symptomatic presentation of the MCAD disorder. In addition, the safety assessment conducted by FSANZ (Attachment 2) reports that the medical treatment of MCAD is a diet permitting adequate nutrition while avoiding fasting periods longer than 4-5 hours, with the potential for the additional administration of carnitine to prevent the excretion of toxic intermediates.

Given that the actual levels of MCT added to infant formula and follow-on formula are likely to be significantly less than 2% of the total fatty acid content, it is unlikely that MCAD sufferers will be adversely affected.

With respect to the issue of bioavailability, the Applicant provided information to indicate that when consumed with food, the bioavailability and absorption of fat-soluble vitamins (in this case, vitamin D3) is no different when delivered in an MCT carrier versus a long chain triglyceride carrier. As MCTs are intended to carry fat-soluble vitamins into the infant formula (the infant's food), the bioavailability of these vitamins is likely to be similar to that of a carrier utilising long chain triglycerides.

#### 5.4.1.2 Nutrition Assessment

The NZFSA indicated it would be useful to know the levels of naturally occurring MCTs in term infant formula products. The Dietitians Association of Australia (DAA) requested further information on the implications of the addition of MCT oils to infant formula, such as the impact on the overall nutritional composition of infant formula.

## **FSANZ consideration**

There is limited data available on the current MCT content of infant formula products in Australia and New Zealand. Data provided by the Applicant (sourced from the United States Department of Agriculture National Nutrient Database) indicates that milk-based infant formula in the US contains an average level of MCTs of 15.3% of total fat content (based on random sample of seven commercial infant powder formulae).

The impact of the addition of MCTs to the overall nutritional composition of infant formula should be negligible, particularly given the small amounts of MCTs required to fulfil their intended technological role (see Food Technology issues discussed in Section 5.2 of this report and at Attachment 4).

### *5.4.2 Food Technology Issues*

Unitech Industries Limited queries the claim that the level of MCTs will be increased by no more than 2% of the total fat content. Rather, they propose that MCTs will contribute no more than 0.005% of the total fat content, even if all fat-soluble vitamins were added to infant formula at the maximum allowable levels permitted under Standard 2.9.1 and MCTs represented 20% of the encapsulation matrix for each of these vitamins.

Similarly, Pyx Ltd contends that the levels of MCTs added, should all fat-soluble vitamins be added at their maximum allowable levels using MCTs as a carrier, would be significantly less than 0.01% of the total fat content of infant formula.

## **FSANZ consideration**

The Applicant provided an example calculation of the content of MCTs that might be required to be added to infant formula as part of the micro-encapsulation matrix that acts as a carrier for vitamin D. The Applicant's calculations indicated that the level of MCTs added would be in the range of 1.26% to 1.80% of the total fat content of infant formula. However, FSANZ also conducted the calculations based on the Applicant's proposed levels of use, and FSANZ's calculations indicated that MCTs would be present within the range of 0.00126% to 0.0018% of the total fatty acid content. The FSANZ calculations were supported by submissions from Unitech Industries Limited and Pyx Ltd.

### *5.4.3 Source of MCTs*

Unitech Industries Limited and Pyx Ltd requested that the definition of MCTs be expanded to include an additional source other than coconut and palm kernel oils. Both submissions proposed Babassu oil (*Orbignya spp.*) as an additional source of MCTs. Unitech Industries Limited highlighted that Babassu oil is recognised by Codex as another source of MCTs.

## **FSANZ consideration**

Babassu oil is recognised by Codex (Codex Standard for Named Vegetable Oils) as a vegetable oil, rather than being specifically recognised as a source of MCTs, as was implied by Unitech Industries Limited.

As discussed above in section 5.2 and in the Food Technology Report at Attachment 4, the Applicant states that the MCTs used in their micronutrient preparations are in compliance with the European Pharmacopoeia monograph for identity and purity of MCTs. This monograph does not include Babassu oil as a source of MCTs.

Standard 1.3.4 – Identity and Purity states that substances added to foods must comply with a relevant monograph in a list of primary and secondary sources, or with a specification included in the Schedule to Standard 1.3.4. Standard 1.3.4 recognises the European Pharmacopoeia as a secondary source of specifications for substances added to food. Therefore, the MCTs used by the Applicant may comply with Standard 1.3.4 if they in turn comply with the European Pharmacopoeia monograph for MCTs. Similarly, if MCTs derived from Babassu oil (or another source) comply with one of the primary or secondary sources listed in Standard 1.3.4, those MCTs may also comply with that standard and therefore be an appropriate source of MCTs for use as processing aids in regular infant formula and follow-on formula should this Application be approved.

If MCTs sourced from Babassu oil (or other sources) are not subject to a monograph in a primary or secondary source listed in Standard 1.3.4, a distinct specification may have to be created and added to the Schedule of Standard 1.3.4.

Note that MCTs are added to infant formula products for special dietary use (addressed in Division 3 of Standard 2.9.1) as an ingredient and are considered not to be subject to Standard 1.3.4. However, MCTs added as processing aids to regular infant formula and infant formula products would be required to comply with Standard 1.3.4.

#### *5.4.4 MCTs as processing aids or an ingredient?*

A number of submitters requested that MCTs be considered as an ingredient rather than as processing aids in subclause 23(a) of Standard 2.9.1. These submitters considered that this would be preferable to MCTs being considered as an ingredient in Division 3 of the Standard, whilst being considered as processing aids under subclause 23(a).

At Draft Assessment, the Food Technology Association of Victoria suggested that MCTs would actually be performing a technological function in the final food (as a dispersing agent for fat soluble vitamins), and that they should be designated as an added source of fat rather than a processing aid.

Nestlé Australia Limited suggested that, given there are no safety issues associated with the use of MCTs as processing aids for fat-soluble vitamins, MCTs should be permitted as a processing aid in infant formula products, not just for fat-soluble vitamins.

At Draft Assessment, the Food Technology Association of Victoria asked why there was not a draft amendment to Standard 1.3.3 – Processing Aids included in the Draft Assessment Report (to include MCTs in the Standard), and whether soy oil was specifically mentioned in Standard 1.3.3.

#### **FSANZ consideration**

The intention of the addition of MCTs proposed in this Application is distinctly different to the purpose of addition to infant formula products covered in Division 3 of Standard 2.9.1.



The MCTs permitted to be added in Division 3 are intended to serve a nutritive function, namely as a source of energy for infants. However, this Application requests MCTs be permitted only as processing aids for the delivery of fat-soluble vitamins in infant formula and follow-on formula. There is no nutritional requirement for the addition of MCTs in any significant quantity to infant formula and follow-on formula. Therefore, FSANZ considers it important to ensure MCTs are added to infant formula and follow-on formula as processing aids, rather than as an ingredient (other than when present as a natural constituent of a milk-based ingredient).

The Application is for MCTs to be approved as a processing aid in infant formula and follow-on formula. The intended use of MCTs is as a carrier for fat-soluble vitamins, which is a permitted function of processing aids. FSANZ considers that, in the context of this Application, the proposed use of MCTs in infant formula and follow-on formula is as a processing aid.

The Application specifically addressed the use of MCTs as processing aids for fat soluble vitamins, and the levels of use suggested in the Application were associated with that specific function. It is therefore appropriate to consider only the use of MCTs as a carrier for fat-soluble vitamins in infant formula and follow-on formula in this Application.

Foods are generally permitted as processing aids by virtue of subclause 3(a) of Standard 1.3.1. Whilst, MCTs could generally be added to foods as an ingredient, whilst also fulfilling a technological function, this is not the case with infant formula and follow-on formula. Subclause 23(a) of Standard 2.9.1 currently prohibits any addition of MCTs to infant formula and follow-on formula, unless present as a natural constituent of a milk-based ingredient. Therefore, a specific permission for the addition of MCTs to infant formula and follow-on formula is required. This permission is specific to subclause 23(a) of Standard 2.9.1 and does not require additional permission in Standard 1.3.3.

#### *5.4.5 Maximum limits for MCTs*

At Initial Assessment, Pyx Ltd suggested that MCTs be permitted to be added to a maximum level of 0.01% of total fat content. Alternatively, Dairy Goat Co-operative (NZ) Ltd suggested MCTs be permitted at a maximum level 3% of total fat, except for MCTs 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.

At Draft Assessment, the Department of Human Services, Victoria suggested that maximum limits should be set for MCT levels to ensure excessive amounts are not added unnecessarily. It was suggested that the draft variation to the standard would not be enforceable as it cannot be determined if a manufacturer has abided by the processing aid limits or added significantly higher levels.

#### **FSANZ consideration**

Analytical tests could not distinguish between MCTs added as processing aids and MCTs present as a constituent of a milk-based ingredient in an infant formula or follow-on formula. Unless there are test methods that can differentiate between the sources of these MCTs, the establishment of a maximum limit for addition as a processing aid would not be an enforceable limit.

MCTs are permitted to be added as an ingredient to infant formula products for special dietary use (addressed in Division 3 of Standard 2.9.1) at much higher levels than those proposed in this Application. The addition of MCTs as processing aids to regular infant formula and follow-on formula should be controlled by the amount required to fulfil the technological function of delivering fat-soluble vitamins; an amount that is likely to be less than 0.002% of the total fat content.

#### 5.4.6 *Breastfeeding rates*

Women's Health Action suggested that breastfeeding rates would decrease in direct relation to the increase in sales of new infant formula products containing MCTs as processing aids. The potential to develop and market new products and establish new markets was seen as a means of attracting breastfeeding mothers to infant formula. In the view of the Women's Health Action group, this would be seen as contrary to the New Zealand Ministry of Health's targets to increase breastfeeding rates and therefore, in serious violation of FSANZ's section 10 (of FSANZ Act) objective to protect public health and safety.

#### **FSANZ Consideration**

The intent of permitting MCTs as processing aids is not to establish new markets for infant formula per se, but rather to provide an alternative to existing infant formula and follow-on formula products containing soybean oil. Permission to add MCTs as processing aids to infant formula and infant formula products is not viewed by FSANZ, nor intended by the Applicant to be a means of attracting breastfeeding mothers to utilise infant formula in place of breast milk. FSANZ recognises and fully supports public health recommendations in support of breastfeeding as best for baby.

#### **5.5 Risk Management**

The risk assessment concluded from the available information that the use of MCTs as a processing aid in infant formula and follow-on formula would raise no public health and safety concerns under the proposed conditions of use.

It is appropriate to allow the addition of MCTs as processing aids in preparations for permitted fat-soluble vitamins, in infant formula and follow-on formula. FSANZ therefore proposes to include permission for the addition of MCTs as processing aids in preparations for permitted fat-soluble vitamins, in infant formula and follow-on formula in subclause 23(a) of Standard 2.9.1 – Infant Formula Products, as listed in the draft variation of **Attachment 1**.

### **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.

There are no options other than approving or not approving 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.

## **7. Impact Analysis**

### **7.1 Affected Parties**

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

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.

### **7.2 Impact Analysis**

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

#### 7.2.1.1 Industry

There is no benefit identified for industry if MCTs are not approved as processing aids in infant formula and follow-on formula. Manufacturers of nutrient preparations will not be able to supply preparations utilising MCTs to manufacturers of infant formula and follow-on formula (for products marketed in Australia or New Zealand).

Manufacturers of infant and follow-on formula will not be able to utilise nutrient preparations utilising MCTs in order to negate the requirement for labelling warning statements associated with soybean oil in particular.

#### 7.2.1.2 Formula fed infants and their carers

There is no benefit identified to formula fed infants and their carers by not permitting MCTs as processing aids in infant formula and follow-on formula. Consumers with concerns over allergenicity or with issues related to genetic modification of alternative oils will not have access to infant formula containing MCTs (as an alternative oil source that does not have the associated issues relating to allergenicity or genetic modification).

### 7.2.1.3 Government

There is no cost or benefit identified to government by not permitting MCTs as processing aids in infant formula and follow-on formula.

### *7.2.2 Option 2 – **Approve** MCTs as processing aids in infant formula and follow-on formula.*

#### 7.2.2.1 Industry

Infant formula manufacturers and importers are likely to benefit from permitting MCTs as processing aids in infant formula and follow-on formula as there will be potential to develop and market new products, which do not have the allergenicity, genetic modification and labelling issues associated with the use of oils derived from soybean and peanut. Manufacturers of nutrient preparations will benefit from sales to infant formula manufacturers.

#### 7.2.2.2 Formula fed infants and their carers

Formula fed infants and their carers may benefit from additional choice. As stated by the Applicant, the purpose of adding MCTs to infant formula is to provide infant formula without the labelling and potential allergenicity and GMO issues associated with the use of soybean and peanut oil. This will benefit carers of formula fed infants who may have concerns over GMO or potential allergenicity issues associated with soybean and peanut products. The Applicant has stated that the cost of using MCTs is comparable to other oils and therefore there should be no negative or positive price implications for consumers.

#### 7.2.2.3 Government

It is unlikely that there will be any significant costs or benefits to government agencies enforcing the food regulations. MCTs are already permitted in certain types of infant formula and there is no indication that this permission has had a significant impact on resources.

### *7.2.3 Assessment of Impacts*

On the basis of this Final Assessment there is likely to be a benefit to formula fed infants and their carers in the form of additional choice of infant formula products, without the potential concerns over allergenicity and GMO issues associated with soybean and peanut oil products. There will be a benefit to manufacturers of nutrient preparations and infant formula products to establish new markets in Australia and New Zealand.

## **8. Consultation**

### **8.1 Initial Assessment**

FSANZ received 12 submissions in response to the Initial Assessment Report. All submissions indicated support for the Application to progress to Draft Assessment, with no submissions supporting Option 1.

## **8.2 Draft Assessment**

FSANZ received 10 submissions in response to the Draft Assessment Report. Only one submission did not support the approval of the Application at the Final Assessment stage. A summary of submissions is at Attachment 5. Issues raised in submissions to the Initial and Draft Assessment reports have been addressed in section 5.4 of this Report.

## **8.3 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 relevant international standards for infant formula and amending the Code to allow the use of MCTs as processing aids is unlikely to have a significant effect on international trade. Codex, the EU and United States do not prohibit MCTs for use in infant formula products. For this reason FSANZ did not notify relevant agencies under either the Sanitary and Phytosanitary (SPS) or the Technical Barriers to Trade (TBT) Agreements.

## **9. Conclusion and Recommendation**

FSANZ recommends the approval of the use of MCTs in infant formula and follow-on formula as processing aids in preparations of permitted fat-soluble vitamins for the following reasons:

- The Safety Assessment Report concluded that the use of MCTs as a processing aid in food would not raise any public health and safety concerns.
- The Nutrition Assessment Report concluded that the use of MCTs as processing aids in infant formula and follow-on formula would not pose any significant nutrition related health risks for infant nutrition.
- The Food Technology Report indicates that the use of MCTs as processing aids in preparations of permitted fat-soluble vitamins in infant formula and follow-on formula is technologically justified, and represents an alternative source of oil without the associated mandatory label declaration and potential GMO concerns associated with the use of soybean and/or peanut products.
- The proposed changes to the Code are consistent with the section 10 objectives of the FSANZ Act.
- The Regulatory Impact Statement indicates that for the preferred option, namely, to approve the use of MCTs as processing aids in preparations of permitted fat-soluble vitamins in infant formula and follow-on formula, the benefits of the proposed amendment outweigh the costs.

## **11. Implementation and review**

Following this Final Assessment Report and consideration by the FSANZ Board, a notification will be made to the Ministerial Council. The amendments to the Code with respect to Standard 2.9.1 – Infant Formula Products, would come into effect shortly thereafter upon gazettal, subject to any request from the Ministerial Council for a review.

### **ATTACHMENTS**

1. Draft variation or standard to the *Australia New Zealand Food Standards Code*
2. Safety Assessment Report
3. Nutrition Assessment Report
4. Food Technology Report
5. Summary of Public Submissions

**DRAFT VARIATIONS TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE**

**To commence: On gazettal**

[1] *Standard 2.9.1 of the Australia New Zealand Food Standards Code is varied by omitting subclause 23(a) and substituting –*

- (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 –
  - (i) a natural constituent of a milk-based ingredient of that particular infant formula or follow-on formula or;
  - (ii) a processing aid used in preparations of permitted fat soluble vitamins of that particular infant formula or follow-on formula where the fat soluble vitamins have been specified in Schedule 1 to this Standard; and

## SAFETY ASSESSMENT REPORT

### MEDIUM CHAIN TRIGLYCERIDES (MCTs) IN INFANT FORMULA PRODUCTS

#### Executive Summary

Medium chain fatty acids (MCTs) are currently permitted in infant formula and follow-on formula when present as natural constituents of dairy ingredients, or in other specifically formulated infant formula products for special dietary use.

This Application requests permission for the use of MCTs in infant formula and follow-on formula as processing aids in preparations of permitted fat-soluble vitamins. More specifically, MCTs play a role in the micro-encapsulation process of lipophilic nutrients such as vitamins (A, D, E and K), carotenoids and polyunsaturated fatty acids, and act as a stabiliser as well as ensuring the production of appropriate particle size of the lipophilic phase. As such, MCTs provide an alternative to other oils such as partially hydrogenated soybean oil, which may be a cause for concern to consumers with allergies to soy products or those wishing to avoid genetically modified sources of oils.

The Applicant contends that the use of small amounts (no more than 2% of the total fat content) of MCTs as carriers or processing aids for vitamin dispersion should not significantly affect the composition of infant formula.

The safety assessment of MCTs concluded that:

- MCTs are sourced from a traditional food and have a safe history of use.
- The MCT micronutrient preparation complies with European Pharmacopoeia purity standards.
- MCTs and their component fatty acids have a very low acute toxicity in animals regardless of the route of administration. In acute oral toxicity studies, levels of 25 ml/kg and 36 ml/kg did not cause mortality in mice or rats respectively.
- Studies in both experimental animals and humans indicate that MCT-based diets do not cause significant adverse health effects.
- MCTs administered in the diet had no adverse effect on rat reproductive or developmental parameters or on terminal gestational development and postnatal survival of pigs.
- There was no evidence of carcinogenicity in the chronic studies with MCT tricaprylin.
- MCTs show little evidence of genotoxic or mutagenic potential in *in vitro* assays.

From the available information, it is concluded that the use of MCTs as a processing aid in food would not raise any public health and safety concerns.



## Introduction

Application A563 seeks approval for the use of medium chain triglycerides (MCTs) as a processing aid in infant formula products. MCTs consist of a mixture of triglycerides of saturated fatty acids, mainly caprylic acid (C<sub>8</sub>H<sub>16</sub>O<sub>2</sub>; 50 – 80%) and capric acid (C<sub>10</sub>H<sub>20</sub>O<sub>2</sub>; 20 – 50%) with a minor contribution of caproic (C<sub>6</sub>H<sub>12</sub>O<sub>2</sub>; 1 – 2%) and lauric (C<sub>12</sub>H<sub>24</sub>O<sub>2</sub>; 1 – 2%) fatty acids. They contain no less than 95 percent of saturated fatty acids with 8 and 10 carbon atoms.

MCTs are a component of many foods, with coconut and palm oils being the dietary sources with the highest concentration of MCTs. The MCTs in this Application are derived from the oil extracted from the hard, dried fraction of the endosperm of the coconut, *Cocos nucifera* L. MCTs are produced conventionally by splitting and distilling the extracted fatty acids, mixing them to the desired ratio and esterifying with glycerine to form a triglyceride.

Due to its unique absorption and metabolism characteristics, MCT oil has been used therapeutically since the 1950s in the treatment of fat malabsorption, cystic fibrosis, epilepsy, weight control, and to increase exercise performance. MCTs have also been used in an increasing number of food and nutrition applications as they offer a number of advantages over long-chain triglycerides, which are metabolised differently and absorbed less quickly. MCTs are also used primarily as emulsifiers in various human and veterinary pharmaceutical preparations and in cosmetics and are being used in an increasing number of food applications (Traul *et al.*, 2000).

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## Absorption, Distribution, Metabolism and Excretion (ADME)

Upon ingestion, MCTs are partially hydrolysed to medium chain fatty acids (MCFAs) by lingual lipase in the stomach and then completely broken down by pancreatic lipase inside the intestinal lumen. MCFAs are then absorbed via the portal vein to the liver rather than through the thoracic duct lymph system, the common route for the absorption of triglycerides containing long-chain fatty acids. A minor fraction of MCFAs by-pass the liver and are distributed to peripheral tissues via the general circulation (Babayan, 1988). The MCFAs are catabolised mainly in the liver hepatocytes to medium-chain fatty acyl CoA esters, or are used to synthesise longer-chain fatty acids. Medium-chain fatty acyl CoAs (mainly of caprylic and capric acids) are transported into mitochondria, where they are metabolised, initially by medium-chain acyl CoA dehydrogenase, to acetoacetate and betahydroxybutyrate. Acetoacetate and betahydroxybutyrate may be further metabolised in the liver to CO<sub>2</sub>, water and energy, and may enter other metabolic pathways in the liver or be transported by the systemic circulation to other tissues, where they are metabolised to produce CO<sub>2</sub>, water and energy. Studies with adult human volunteers have shown that little, if any, of the MCT is stored in adipose tissues (CTFA, 1980).

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In contrast to MCTs, long chain triglycerides are metabolised differently, and after hydrolysis are incorporated into chylomicrons and absorbed via the lymphatic system. In the presence of pancreatic lipase or bile salt deficiency, MCTs can still be absorbed whereas long chain triglycerides cannot (Bach and Babayan, 1982). MCTs also have a carnitine-independent entry into mitochondria and undergo rapid  $\beta$ -oxidation to provide energy of the cell (Babayan, 1987).

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Field Code Changed

For this reason, MCTs are used extensively in human nutrition as an energy source for individuals with malabsorption syndromes, for use in special purpose infant formulas and for total parenteral nutrition.

The hepatic mitochondrial metabolism of MCFAs such as caprylic and capric acid ultimately results in an excess of acetyl CoA which in turn results in the production of acetate, CO<sub>2</sub> and ketone bodies and a minor part allows the lengthening of endogenous fatty acids (Bach and Babayan 1982; Babayan 1987). It has been suggested though that MCT diets, when fed in excess of caloric requirements, might lead to enhanced *de novo* fatty acid synthesis and elongation activity in the liver (Hill *et al.*, 1990). Most of the MCFAs are catabolised within the liver with only a minor portion reaching the general circulation bound to albumin.

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Although it has been established that consumption of MCTs can lead to ketone production, it is generally accepted that there is no risk of ketoacidosis or ketonaemia with MCTs at levels associated with normal consumption levels. High circulating levels of caprylic acid can cause central nervous system toxicity (coma), however these concentrations are not achieved from consuming MCTs, even at levels higher than would normally be found in food products (e.g. about 10 – 15% in baked goods (Bach and Babayan 1982).

Field Code Changed

MCT-based diets have been shown to cause minor alterations in serum lipid profiles, and have infrequently produced slower rates of weight gain relative to long chain triglyceride (LCT)-based diets. Experimental studies in both animals and humans have shown that MCT-based diets do not cause significant toxicity, even when the diets have consisted of more than 5% MCTs (Traul *et al.*, 2000). In low birth-weight infants, MCTs have been shown to improve fat absorption without significantly changing body weight. Nutritional studies have concluded that (1) MCTs are calorically less dense than LCTs; (2) the energy retention of MCT-based diets is less than that of LCT-based diets; and (3) the thermic response to food is greater after an MCT-based meal. None of these attributes are considered clinically adverse. Clinical trials have indicated that normal dietary levels of MCTs have no significant effect on the absorption of vitamins A, D or E. Furthermore, there are no adverse effects on the absorption or retention of calcium, magnesium or phosphorus (Traul *et al.*, 2000).

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Field Code Changed

### Identity and purity of MCT

MCT is a colourless or slightly yellowish, oily liquid, practically insoluble in water, and is miscible with alcohol, methylene chloride, light petroleum and fatty oils.

The identity and purity of the MCT preparation was determined to be in compliance with the European Pharmacopoeia standard (Ph. Eur, 2002), and conforms to the following tests:

Test	Value	Comment
appearance	-	Colourless
relative density	0.93 – 0.96	-
refractive index	1.44 – 1.452	-
viscosity	25 – 33 mPas	-
acid value	≤ 0.2	-
hydroxyl value	≤ 10	-
iodine value	≤ 1.0	-
peroxide value	≤ 1.0	-
saponification value	310 – 360 (determined on 1g)	-
unsaponifiable matter	≤ 0.5% (determined on 5g)	-

Test	Value	Comment
fatty acid composition: caproic acid	≤ 2%	-
caprylic acid	50 – 80%	-
capric acid	20 – 50%	-
lauric acid	≤ 3%	-
myristic acid	≤ 1%	-
Heavy metals: chromium	≤ 0.05 ppm	-
copper	≤ 0.1 ppm	-
lead	≤ 0.1 ppm	-
nickel	≤ 0.1 ppm	-
tin	≤ 0.1 ppm	-

### Toxicological evaluation of MCTs

MCTs have been evaluated in acute and sub-chronic toxicity tests using oral, dermal, intraperitoneal, inhalation or intramuscular routes of administration. On the basis of these studies, products have been developed which are administered to humans by oral, topical and intravenous routes. Only oral administration studies are considered relevant for this Application and are summarised below.

#### Animal Studies

##### *Acute toxicity*

The acute oral toxicity of MCTs (caprylic/capric triglyceride) was evaluated in eight single dose mice and rat studies. In these studies, doses between 4.5 ml/kg and 36 ml/kg did not produce mortality. An LD<sub>50</sub> was not established, but was greater than 25 ml/kg for mice and greater than 36 ml/kg for rats.

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In two separate mouse studies, administration of 25 ml/kg MCTs caused transient ataxia, lethargy, dyspnoea and diuresis within 15 minutes, however all symptoms disappeared after 1 to 3 days; no necropsy observations were made (Poole, 1977).

Field Code Changed

During 10 days observation, MCTs did not elicit toxic effects in fasted Wistar male rats administered single doses from 4.5 to 36 ml/kg. Animals receiving higher doses consumed less feed and excreted softer faeces for the first two days (Klimmer, 1971). In each of four single dose acute studies, five male and five female Wistar rats were given approximately 5.24 ml/kg MCT preparations (Miglyol 812) and observed for 14 days. No deaths, adverse observations or abnormal gross pathology findings at necropsy were noted (Lewis and Palanker, 1977).

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##### *Acute study of component fatty acids*

A study carried out on groups of 10 young adult Osborne-Mendel rats established that the oral LD<sub>50</sub> for caprylic acid was approximately 10.57 ml/kg (Jenner *et al.*, 1964) and subsequent experiments with male and female rats fed a mixed preparation of caprylic/capric triglyceride indicated that the LD<sub>50</sub> was >5 ml/kg (Elder, 1980). Other acute oral toxicity studies with component fatty acids showed that within 10-15 minutes of administration, mice showed lethargy and ataxia, and dyspnoea within 1 hour, however these symptoms disappeared after 24 hours.

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Field Code Changed

The acute toxicity of MCTs has also been investigated through different routes of administration (dermal, intramuscular, intraperitoneal and inhalation) (summarised in (Traul *et al.*, 2000) and it can be concluded that MCTs and their component fatty acids have a very low acute toxicity in animals regardless of the route of administration. MCTs have also been found to have no effect on ocular and dermal irritation, light sensitivity and immune function (Traul *et al.*, 2000).

Field Code Changed

Field Code Changed

#### *Sub-chronic toxicity*

### **1. Roth, R. and Shapiro, R. (1981) Report No.T-1551. Chick oedema test. Miglyol 812: Neutralol. Unpublished report of the Product Safety Laboratory**

*Test material:* Miglyol® 812 (MCT preparation) incorporated into the diet at a level of 16%

*Test groups:* 12 seven day old Single comb White Leghorn male chicks

*Control:* received standard diet

*Dose:* incorporation into (daily) diet at 16% for 3 weeks

*GLP:* Not stated.

#### *Results*

Due to the reduced feed consumption by chicks receiving the high fat diet, the treated group showed reduced body weight gain and reduced muscle weight. All mortality was attributed to starvation and not the consumption of Miglyol 812.

Chick oedema factor was determined at autopsy by hydropericardium, hydroperitoneum and subcutaneous oedema. Apart from very slight subcutaneous oedema observed in three treated birds, there was no evidence of an oedematous condition and gross autopsy did not reveal any abnormal liver or kidney changes.

### **2. Klimmer, O. (1971) Report on the toxicological testing on Miglyol 812 neutral oils. Unpublished report of the Pharmacological Inst. Of the Rhenish Friedrich-Wilhelm University**

*Test material:* Miglyol® 812 (MCT preparation)

*Test groups:* two separate test groups of 10 male Wistar rats

*Control:* not stated

*Dose:* 3.58 to 7.56 ml/kg body weight/day and 10.8 to 21.3 ml/kg body weight/day by oral gavage for 30 days,

*GLP:* Not stated.

Deleted:

#### *Results*

Transitory reductions in food intake and other digestive disturbances were noted during the first 5 – 7 days of the trial. However, no toxic effects or adverse effects on weight gain or urinalysis values were noted.

**3. Klimmer, O. (1971) Report on the toxicological testing on Miglyol 812 neutral oils. Unpublished report of the Pharmacological Inst. Of the Rhenish Friedrich-Wilhelm University**

*Test material:* Miglyol® 812 (MCT preparation)

Test groups: 20 male and 20 female rats

Control: not stated

Dose: rats fed at 0, 10,000 or 50,000 ppm MCT in the diet (representing 0, 1% and 5% of the diet) for 3 months.

GLP: Not stated.

*Results*

No signs of toxicity or adverse effects on body weight, body weight gain, blood chemistry values (liver enzymes, non-esterified fatty acids and esterified fatty acids) or organ weights were noted. This study also showed that Miglyol 812 did not increase triglyceride levels or induce a hyperlipidaemic condition. Furthermore, at necropsy, the absolute and brain-weight-relative weights of the liver, kidney, adrenal gland, thyroid gland, gonads and brain of the rats fed the test material were the same control-fed rats. The no observed adverse effect level (NOAEL) for this study was determined to be greater than 5% (50,000 ppm) in the diet.

**4. Webb, D., Wood, F., Bertram, T. Fortier, N. (1993) A 91-day feeding study in rats with caprenin. Food and Chemical Toxicology 31: 935 – 946**

*Test material:* caprenin (a mixed chain MCT/LCT consisting of caprylic (23.2%), capric (26.6%) and behenic (C<sub>22</sub>, 45%) acids.

Test groups: 25 male and 25 female weanling Crl:CD BR Sprague-Dawley rats

Control: animals fed diets with corn oil (12.1%) or a mixture of corn oil and Captex 300, an MCT (3.1% and 11.21%, respectively).

Dose: rats fed at 0, 5.23, 10.23 or 15% in the diet for 91 days. \*

GLP: Not stated.

\* All diets contained at least 3% corn oil to provide essential fatty acids and were balanced at about 4000 kcal/kg and provided 26.8% of dietary calories as fat, 19% as protein and 52.4% as carbohydrate.

*Results*

The test groups showed no treatment-associated deaths and clinical observations revealed no significant differences in body weights or body weight gains across all groups. There were no gross or histopathological findings and no significant differences among groups in the total fat content of the hearts, livers or perirenal fat pads; however there was a trend to lower amounts of fat deposited in the animals fed caprenin-containing diets.

The NOAEL for caprenin was determined to be equal to or greater than 15% of the diet (approximately 13.84 and 15.3 ml/kg body weight/day for males and females, respectively) and for MCTs, in the corn oil/MCT diet, to be greater than 11.2 % of the diet (approximately 9.6 ml/ kg body weight/day).

## Developmental and reproductive toxicity studies

Three different experiments with Sherman albino rats (Kaunitz *et al.*, 1958), Wistar rats (Harkins and Sarett, 1968) and pigs (Azain, 1993) indicated that MCTs administered in the diet had no adverse effect on rat reproductive or developmental parameters or on terminal gestational development and postnatal survival of pigs.

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Field Code Changed

Field Code Changed

## Chronic toxicity/carcinogenicity studies

Chronic studies in F344/N rats via oral gavage of the MCT tricaprylin over a period of 2 years showed an increase in mortality when administered the highest dose of 10 ml/kg body weight/day (approximately 9.5 g/kg body weight/day). No carcinomas were observed at doses of 5 and 10 ml/kg, although there were increased incidences of pancreatic and forestomach hyperplasia and adenoma (NTP, 2006). In contrast, no significant toxic effects or effects on mortality were seen in Wistar rats (Harkins and Sarett 1968) or Sherman rats (Kaunitz *et al.*, 1958) fed mixed-chain MCT in the diet for one year at levels up to 20% of the diet (approximately 10.5 ml/kg body weight/day). None of the effects seen in the subchronic studies show a carcinogenic potential for MCTs.

Field Code Changed

Field Code Changed

## Genotoxicity/mutagenicity studies

Caprylic acid showed no mutagenic activity in microbial mutation assays (indicator organisms: *Saccharomyces cerevisiae* strain D4 and *Salmonella typhimurium* strains TA1535, TA1537 and TA1538) (Brusick, 1976).

Field Code Changed

Ames mutagenicity plate incorporation assays indicated that tricaprylin was mutagenic with, but not without S9, in strain TA1535. However, tricaprylin did not induce mutations in strains TA97, TA98 or TA100, with or without S9 (NTP, 2006).

Field Code Changed

In summary there is little evidence of MCT being genotoxic. Tricaprylin was not classified as a carcinogen in the chronic carcinogenicity study and caprylic acid was not mutagenic in yeast or bacteria. Despite one positive result with tricaprylin in the Ames test, there is insufficient evidence to classify it as a mutagen.

## Effects in humans

Traul et al. summarised four different studies reporting the effects of MCT in the human diet.

A 10-week crossover study was carried out with eight patients who were fed formula diets containing MCTs [77.7% C<sub>8</sub> (caprylic), 19.6% C<sub>10</sub> (capric), 1.9% C<sub>6</sub> and 0.8% C<sub>12</sub>], butter or corn oil as the only source of dietary fat. The only side-effect documented for the MCT formula was a transient period of nausea and abdominal fullness during the first 3 – 4 days (Hashim *et al.*, 1960).

Four human volunteers who had fasted overnight were fed 1.05 ml MCT/kg body weight (approximately 1 g MCT/kg body weight) where the MCT comprised 71% caprylic, 25% capric and 3% lauric fatty acids. Their serum-free fatty acids showed a high proportion of octanoic acid and a low proportion of long-chain acids for 4h after feeding the MCT preparation, however, no toxicological symptoms were observed (CTFA 1980).

This CTFA expert report also recounts a study with 10 human volunteers who ingested 100 ml (approximately 95 g) of synthetic fat (a triglyceride comprising 74% lauric, 17% lauric, 5% capric, 3% myristic and a trace of caproic). Eight of the participants had no chylomicrons in their sera, and none developed diarrhoea or had fat in their faeces. The levels of free fatty acids in the sera were raised for all the participants. These results confirm other data showing that MCTs are readily metabolised in the intestine and are absorbed mainly as free fatty acids without adverse effects.

In another study, 10 non-obese males were over-fed (150% of estimated energy requirements) two formula diets for 6 days each in a randomised crossover design. The fat components of the diets represented 40% of caloric energy either as MCT or LCT. Although no significant clinical toxicity was reported, unlike previous reports, a threefold increase in fasting serum triglyceride values was found for the MCT (but not the LCT) diet. It was suggested that MCT diets, when fed in excess of caloric needs, may stimulate fatty acid synthesis and enhanced fatty acid elongation activity in the liver (Hill *et al.*, 1990).

The effect of MCT ratios in infant formula has also been trialled in a randomised double-blind crossover clinical trial in which low birth-weight infants (n=15) were fed each of two formulas, which were of equal gross energy and protein content but differed in fat composition. The high MCT formula contained medium-and long-chain triglycerides at a ratio of 46:54 (w/w); in the low MCT formula, the ratio was 4:96 (w/w). There were no significant differences in coefficients of energy digestibility, metabolisability, coefficients of nitrogen digestibility or of nitrogen retention between the two diets. Furthermore, there were no significant differences in rates of gain in weight, and estimates of the energy, fat and protein composition of weight gained were similar between the groups (Whyte *et al.*, 1986). In conclusion, studies in both experimental animals and humans indicate that MCT-based diets do not cause significant adverse health effects.

#### *Sensitive populations*

Some individuals in the population suffer from an inherited autosomal recessive trait called Medium-chain Acyl CoA Dehydrogenase Deficiency (MCADD). This trait was first defined biochemically only 20 years ago in a patient with hypoketotic hypoglycaemia and is estimated to be as common in newborns as phenylketonuria, with an incidence rate of 1 in every 12,000 live births; in the U.S. the incidence has been shown to be as high as 1 in every 8500 live births (Roth, 2005). The pathophysiology of MCADD results from the inability to carry out the first step of beta-oxidation, this ultimately results in continued glucose consumption with a reduction or absence of corresponding increase in ketone body production. This is clinically manifested as severe hypoglycaemia and hypoketonuria with accumulation of monocarboxylic and dicarboxylic fatty acids, which ultimately appear with acyl-carnitine compounds in the urine.

Medical treatment of this disorder is a diet permitting adequate nutrition while avoiding fasting periods longer than 4-5 hours; carnitine may also be administered to prevent the excretion of toxic intermediates.

Expert advice indicates that there should be no problem for infants with MCADD to utilise infant formula or follow-on formula with MCTs at levels up to 2% in infant formula (NSW Health Department, public submission to the Initial Assessment Report for Application A563).

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## Nutrition Assessment

### 1. Introduction

The aim of this nutrition assessment is to consider the nutritional consequences for Australian and New Zealand infants from allowing infant formula products to contain added quantities of medium chain triglycerides (by virtue of the proposed processing aid permissions).

Two approaches can assist in achieving this aim: assessing the nutritional need for medium chain triglycerides in infants, and assessing the potential adverse nutritional consequences from an increase in medium chain triglyceride intake.

Therefore, this assessment will be conducted by reviewing the typical intake of medium chain triglycerides from human milk as a guide for their nutritional need in infant formula, and to assess the growth and development of infants at different levels of medium chain triglyceride intake.

### 2. Medium Chain Triglyceride Content of Human Milk

There is very little data on the medium chain triglyceride content of human milk. FSANZ has been able to identify three study that quantifies such levels – Jensen *et al.* (1992); Jensen (1996); and Koletzko *et al.* (1992). The details of these three studies are provided below:

Study	Origin of Human Milk	Medium Chain Triglyceride Content (% total fatty acids)			
		C8:0	C10:0	C12:0	Total
Jensen et al., 1992	Germany	-	0.71	4.41	5.12
	Gambia	-	0.92	6.99	7.91
	Caribbean	0.37	2.39	12.32	15.08
	United States	0.02	0.06	4.34	4.42
	United States	0.03	1.40	6.20	7.63
Jensen, 1996	Normalised data (5 studies) from mothers with western diets	0.17	1.01	4.94	6.12
	Normalised data (8 studies) from mothers with non-western Diets	0.37	1.63	8.12	10.12
Koletzko et al., 1992	Germany	0.0	0.71	4.41	5.12
	Nigeria	0.0	0.54	8.34	8.88

The best estimate that can be derived from the above information is that medium chain triglycerides of the 8:0, 10:0 and 12:0 series constitute approximately 5-15% of the fatty acids in human milk. The evidence indicates that the MCT content of human milk varies across different countries, most likely due to dietary differences. The variation in the levels of MCTs found in breast milk from various countries indicates that there is no tight physiological control required for the MCT content of breast milk.

### 3. Growth and Development with Increasing Medium Chain Triglyceride Intake

Medium chain triglycerides are composed of medium chain saturated fatty acids, and like all fats their primary nutritional role is to act as a source of energy. However, medium chain triglycerides have a lower energy density compared to longer chain triglycerides (European Scientific Committee on Food, 2003). Therefore, the growth and development at different medium chain triglyceride concentrations is a potential nutrition-related health risk that requires investigation.

During an investigation of this risk, FSANZ was unable to identify any growth/development research on full-term infants, with the only data available being confined to preterm infants (<37 weeks gestational age). Although less than ideal for assessing a general permission relating to medium chain triglycerides in infant formula, this data still allows for a growth and development comparison across medium chain triglyceride concentrations.

A key article on growth and development is a Cochrane Review authored by Klenoff-Brumberg and Genen (2002). This review assesses eight separate articles in a meta-analysis design, and excludes eleven studies. The reasons for exclusion were that four studies did not indicate whether they were randomised, three studies exposed their infant subjects to intakes of human milk, three studies did not use high enough medium chain triglyceride concentrations, and one study used too short a study duration (three days).

The details of the eight included studies are listed below.

Study	Endpoints	Design	Study Duration	Subjects	Subject Grouping*	Subject No.	Results
Hamosh et al. (1989)	Changes in weight gain.	Randomised Cross-over trial	1 week on each formula	12 Infants with a mean gestational age of 29 weeks	Control formula	12	There was no statistically significant difference ( $p>0.05$ ) in weight gain between the two formulas.
					MCT formula (39% TFA)	12	
Hamosh et al. (1991)	Changes in weight gain, length gain and head circumference.	Randomised Cross-over trial	1 week on each formula	9 Infants with a mean gestational age of 29 weeks	Control (term) formula (1.4% MCT)	10	There were no statistically significant differences ( $p>0.05$ ) between the different formulas for any of the study endpoints.
					High MCT formula (50% TFA)	7	
					Low MCT formula (14% TFA)	6	
Huston et al. (1983)	Changes in weight gain, length gain and head circumference.	Randomised controlled trial	1 week	20 Infants with a mean gestational age of 30.4 weeks	Control formula	10	There were no statistically significant differences ( $p>0.05$ ) between the groups for any of the study endpoints.
					MCT formula (50% TFA)	10	

Study	Endpoints	Design	Study Duration	Subjects	Subject Grouping*	Subject No.	Results
Okamoto et al. (1982)	Changes in weight gain, length, head circumference, and skin fold thickness.	Randomised controlled trial	Average 27 days	23 Infants with a mean gestational age of 31 weeks	Control formula	10	There were no statistically significant differences ( $p>0.05$ ) between the groups for any of the study endpoints.
					Low MCT (40% TFA)	7	
					High MCT (80% TFA)	6	
Sulkers et al. (1992)	Changes in weight gain.	Randomised controlled trial	2 weeks	28 Infants with a mean gestational age of 32 weeks	Low MCT (6% TFA)	15	There was no statistically significant difference ( $p>0.05$ ) in weight gain between the two groups.
					High MCT (40% TFA)	13	
Sulkers et al. (1993)	Changes in weight gain.	Randomised controlled trial	3 weeks	18 Infants with a mean gestational age of 32 weeks	Low MCT (6% TFA)	9	There was no statistically significant difference ( $p>0.05$ ) in weight gain between the two groups.
					High MCT (40% TFA)	9	
Whyte et al. (1986)	Changes in weight gain, length gain and head circumference.	Randomised Cross-over trial	1 week on each formula	15 Infants with a mean gestational age of 31 weeks	Low MCT (4% TFA)	15	There was no statistically significant difference ( $p>0.05$ ) in weight gain between the two formulas.
					High MCT (46% TFA)	15	
Wu et al. (1993)	Mean start and end values for weight, length and head circumference	Randomised controlled trial	3 weeks	58 Infants with a mean gestational age of 31 weeks	Control formula (No MCT)	16	There were no statistically significant ( $p>0.05$ ) changes in study variable across the groups.
					Low MCT formula (17% TFA)	15	
					Low MCT formula (34% TFA)	14	
					High MCT (50% TFA)	15	

\* All formulas used in each study had an identical total fat content. A change in medium chain triglyceride content therefore produces an inverse change in the content of longer chain triglycerides.

MCT = medium chain triglyceride

TFA = total fatty acids

The meta-analysis conducted by Klenoff-Brumberg and Genen (2002) determined that there is no statistical difference in short-term growth parameters between high (40-80% of total fatty acids), low (1-40% of total fatty acids) and nil medium chain triglyceride formula concentrations. The parameters considered in the meta-analysis included weight gain (g/day), length gain (cm/week), head circumference (cm/week), and skin-fold thickness gain (mm/week). The study durations were between 1-3 weeks of feeding.

On the basis of the above findings, it is concluded that increasing intakes of medium chain triglycerides have no impact on growth or development (either positive or negative) beyond that conferred with similar intakes of longer chain triglycerides. Therefore, a potential nutrition-related health risk to infant energy intakes has not been identified.

#### **4. Conclusion**

On the basis of the available evidence, it can be concluded that there is no nutritional justification for adding medium chain triglyceride oils to infant formula. The data on human milk concentrations also shows a high degree of variability, suggesting that there is no specific nutritional requirement for infants to consume medium chain triglycerides. However, there are also no significant nutrition-related health risks to infant nutrition that have been identified with the intake of medium chain triglycerides.

Therefore, it can be considered that an addition of medium chain triglycerides to infant formula in the form of a processing aid does not pose any significant nutritional concerns, given that the use of such a processing aid will likely increase the medium chain content of infant formula by a small percentage of total fatty acids.

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## FOOD TECHNOLOGY REPORT

### A563 – MEDIUM CHAIN TRIGLYCERIDES IN INFANT FORMULA PRODUCTS

#### Introduction

Food Standards Australia New Zealand has received an Application from DSM Nutritional Products seeking approval for the addition of medium chain triglycerides (MCTs) to infant formula and follow-on formula as a processing aid. MCTs are intended to act as carriers for permitted fat-soluble nutrients in infant formula and follow-on formula.

Other sources of plant oils currently used for this purpose, such as soybean and peanut oils, require the presence of these oils to be declared on the label of food products in accordance with Clause 4 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations. The Applicant states that the use of MCTs, as carriers for fat-soluble nutrients, provides an alternative oil source that will not require these warning statements.

MCTs are currently prohibited from being added to most infant formula and follow-on formula by subclause 23(a) of Standard 2.9.1 – Infant Formula Products, of the *Australia New Zealand Food Standards Code* (the Code). MCTs are only permitted in infant formula and follow-on formula if present as the result of being a natural constituent of a milk-based ingredient of that particular infant formula or follow-on formula.

#### Chemical Structure and Specification

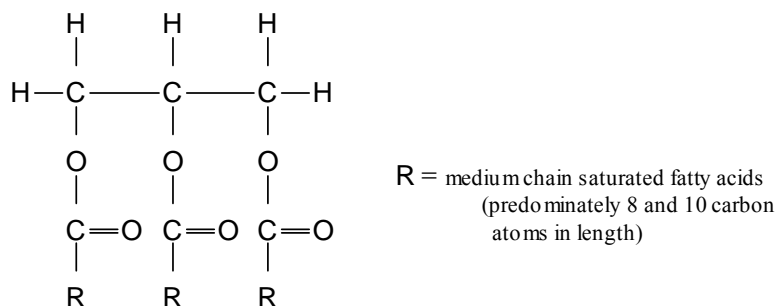
##### *Chemical Structure*

Subclause 1(2) of Standard 2.9.1 defines MCTs as:

*triacylglycerols which contain predominantly the saturated fatty acids designated by 8:0 and 10:0.*

The Applicant states that the MCTs used in their micronutrient preparations are in compliance with the definition of MCTs in the European Pharmacopoeia. This definition satisfies the definition of MCTs in Standard 2.9.1 of the Code. MCTs are defined in the European Pharmacopoeia 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, and consisting of a mixture of triglycerides of saturated fatty acids, mainly of caprylic acid (C<sub>8</sub>H<sub>16</sub>O<sub>2</sub>) and capric acid (C<sub>10</sub>H<sub>20</sub>O<sub>2</sub>) and containing not less than 95% of saturated fatty acids with 8 and 10 carbon atoms. In addition, MCTs typically contain saturated fatty acids of 6 carbon atoms (1.0 – 2.0 %) and 12 carbon atoms (1.0 – 2.0 %) (Bach & Babayan 1982).

The structural formula for MCTs is provided below.



Structural formula for MCTs

### Specification

As stated above, the Applicant states that the MCTs used in their micronutrient preparations are in compliance with the monograph for MCTs included in the European Pharmacopoeia.

Standard 1.3.4 – Identity and Purity of the Code has the following purpose:

*to ensure that substances added to food in accordance with the Code meet appropriate specifications for identity and purity of food additives, processing aids, vitamins and minerals and other added nutrients. In general, these specifications are those used by the international community.*

Clause 3(e) of Standard 1.3.4 – Identity and Purity recognises the European Pharmacopoeia as a secondary source of specifications for substances added to food. Therefore, it would appear that the MCTs proposed by the Applicant, for addition to infant formula and follow-on formula as processing aids, are in compliance with Standard 1.3.4.

### Technological justification

Fat-soluble nutrients can be difficult to incorporate into some food preparations, due to problems associated with the ability of fat-soluble nutrients to form an emulsion with hydrophilic components of the preparation and with some nutrients being susceptible to oxidation. Micro-encapsulation is a common technique for the incorporation of fat-soluble nutrients into food preparations, and provides a protective and stabilising environment for the nutrient in the food matrix.

MCT oil provides a suitable vehicle for the dissolution of fat-soluble nutrients in a micro-encapsulation matrix. It serves the same function as other oils that are already utilised for this purpose, such as partially hydrogenated soybean and peanut oil, but does not have the associated allergy and labelling concerns associated with these oils.

### Levels of use of MCTs

The Applicant indicates that the use of MCT containing oils as processing aids in preparations of fat-soluble nutrients will result in MCTs being added to infant formula and follow-on formula at less than 2% of the total fat content of such formulae.

Two submissions to the Initial Assessment Report suggested that the required level of MCT addition to infant formula and follow-on formula would be much less than 2% of total fat content.

To illustrate this, the Applicant provided a calculation using an example nutrient premix containing MCTs. The nutrient premix in the example contained 0.25% of Vitamin D3 (cholecalciferol) and 7.5% of MCTs (the remainder of the premix being made up of water soluble matrix materials such as gums and starch), and was added to infant formula to provide the maximum permitted amount of Vitamin D (0.63 µg/100 kJ under Standard 2.9.1).

The amount of the nutrient premix required to provide the maximum permitted amount of Vitamin D would be 252 µg (0.63 µg/0.25%). Therefore, the amount of MCT present in 252 µg of the premix would be 18.9 µg per 100 kJ (252 µg x 7.5%). The minimum and maximum amounts of fat permitted in infant formula according to Standard 2.9.1 are 1.05 g and 1.50 g per 100 kJ respectively. The Applicant calculated that MCTs would therefore be present at between 1.26% and 1.80% of the total fat content of infant formula.

However, when FSANZ calculated the content of MCT using the above example, the range of MCT present as a percentage of the total fat content of infant formula was 0.00126% (18.9 µg/1.5 g) to 0.00189% (18.9 µg/1.05 g). This is three orders of magnitude less than the Applicant's calculations and corresponds with the levels indicated in two submissions to the Initial Assessment Report. Unitech Industries Limited claimed that if MCTs made up 20% of a micro-encapsulation matrix, and all fat-soluble vitamins were added at maximum permitted levels, the amount of MCTs in infant formula would be no more than 0.005% of the total fat content. In addition, Pyx Ltd claimed that should all lipophilic vitamins be added at maximum permitted levels, using MCT oil as a carrier, the levels of MCTs added would be significantly less than 0.01% of the total fat content of infant formula.

## **Manufacture and Uses**

### *Production of MCTs*

The oil extracted from coconuts contains approximately 9.6 – 18.0 percent of C8:0 and C10:0 fatty acids, while the oil extracted from palm kernels contains approximately 5.0 – 11.2 percent of C:8 and C:10 fatty acids (Codex-Stan 210). These oils are hydrolysed to medium chain fatty acids and glycerol. The glycerol is removed and the fatty acids are fractionated by distillation. The fractionated fatty acids are then re-esterified with glycerol to form MCTs.

One submission to the Initial Assessment Report raised the question of the likelihood of trans fatty acids being introduced to infant formula products as a result of the addition of MCTs. MCTs contain saturated fatty acids and therefore do not undergo hydrogenation during the production process. It is the partial hydrogenation step for unsaturated fatty acids that can produce some trans fatty acids. Therefore there should not be any introduction of trans fatty acids from the addition of MCTs in a food product.

### *Micro-encapsulation process*

An example of a micro-encapsulation process for fat-soluble vitamins was summarised in the Application. Vitamin D3 is dissolved in MCT oil to form the lipophilic phase, which is stabilised with dl- $\alpha$ -tocopherol.



The lipophilic stage is mixed with an aqueous solution (for example, acacia and sucrose) to form an emulsion. The emulsion is sprayed into a bed of starch powder, then dried and separated from any excess starch, resulting in a free flowing non-hygroscopic powder of beadlets for incorporation into food preparations. The beadlets therefore, consist of micro-encapsulated Vitamin D3 in an MCT oil phase, mixed with a food gum and sugar, protected by a starch outer layer.

The Applicant indicated that partially hydrogenated soybean oil has been used for this micro-encapsulation process. However, customers of the Applicant have indicated a preference for an alternative source of the oil component, due to the requirement to include the presence of soybeans, and their products on their final labels in accordance with Clause 4 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations. Thus, MCT oil is to replace partially hydrogenated soybean oil in a new form of the vitamin D preparation produced by the Applicant.

#### *Uses*

MCTs are used extensively in infant formulas designed for pre-term infants and infant formulas for special dietary purposes. Clause 34 of the Standard 2.9.1 specifically permits the addition of MCTs to infant formula products for specific dietary use based upon protein substitutes. Infant and follow-on formulas in many international markets are not prohibited from containing added MCTs.

In addition to infant formula, MCTs are also used in a clinical setting in formulas for enteral and parenteral feeding and for people with malabsorption conditions. Various supplement type products aimed at weight loss and enhanced athletic performance, also contain added MCTs.

#### **Conclusion**

The use of MCTs in infant formula and follow-on formula as a processing aid in preparations of permitted fat-soluble vitamins is technologically justified. The use of MCTs provides an alternative source of oil that does not have concerns over allergenicity and subsequent label warning statement requirements. The levels of MCTs likely to be present in infant formula and follow-on formula as a result of being used as a processing aid in preparations of fat-soluble vitamins is significantly less than 2%.

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European Pharmacopoeia 3<sup>rd</sup> Edition, Council of Europe, Strassbourg (1996)

## Summary of Submissions

### Draft Assessment Report

Ten submissions were received on the Draft Assessment Report

Submitter Organisation	Name
South Australia Department of Health	Joanne Cammans
Food Technology Association of Victoria Inc.	David Gill
Women's Health Action	Louise James
New Zealand Food Safety Authority	Carole Inkster
Fonterra Co-operative Group Ltd	Roger Hall
NSW Food Authority	Jenine Ryle
Queensland Health	Gary Bielby
Department of Human Services Victoria	Victor Di Paola
Australian Food and Grocery Council	Kim Leighton
Nestle Australia Limited	Robyn Banks

Submitter	Position	Comments
South Australia Department of Health	Cautious support for the Application.	No additional comments.
Food Technology Association of Victoria Inc.	Supports Option 2 with some comments	<p>Questions why a draft amendment to Standard 1.3.3 was not included in Attachment 1 to the Draft Assessment Report.</p> <p>Believes that MCTs are performing a technological function in the final food (as a dispersing agent for fat-soluble vitamins) and therefore should more correctly be designated as an added source of fat, rather than a processing aid. This would require the MCTs to be declared in the ingredients list on the label.</p>
Women's Health Action (NZ)	Does not support Option 2.	<p>The potential for new markets (referred to in section 7.2.2.1 of the Draft Assessment Report) is viewed as a means of attracting breast feeding mothers, which is contrary to the New Zealand Ministry of Health targets to increase the breastfeeding rate and is therefore in serious violation of the section 10 objective of the FSANZ Act – protection of public health and safety.</p> <p>Believes that breastfeeding would decrease in direct relation to any increase in sales of the new product. Any reduction in breastfeeding rates will see a subsequent increase in health risks for both infant and mother.</p>
New Zealand Food Safety Authority	Supports Option 2.	No additional comments.
Fonterra Co-operative Group Ltd	Supports Option 2.	No additional comments.
NSW Food Authority	Supports Option 2.	Believes issues raised in submissions to the Initial Assessment Report have been addressed by the Draft Assessment Report.

<b>Submitter</b>	<b>Position</b>	<b>Comments</b>
Department of Human Services Victoria	Supports Option 2 with some further work required.	<p>Raised the question of the bioavailability of fat soluble vitamins when MCTs are a carrier. Varying the carrier can affect the absorption of substances. Provided the example of the drug, cyclosporine that has decreased absorption when MCTs are the carrier, compared to long chain triglycerides.</p> <p>Believes there should be maximum limits for total MCT levels to ensure excessive amounts are not added unnecessarily. Maximum limits should allow for natural variation of MCT present as a constituent of a milk based ingredient plus the amounts required as a processing aid. Believes the standard as it was drafted in the Draft Assessment Report is not enforceable. That is, it cannot be determined if a manufacturer has abided by the processing aid limits or added significantly higher levels.</p> <p>A maximum MCT level would prevent any potential long term adverse effects from unnecessarily high MCT concentrations, such as the possibility of increased blood triglycerides, inadequate provision of essential long chain fatty acids, or reduced energy provision.</p>
Queensland Health	Supports Option 2	No additional comments.
Australian Food & Grocery Council	Supports Option 2	No additional comments.
Nestle Australia Limited	Supports inclusion of MCT as a processing aid.	Given no safety concerns, MCTs should be permitted as a processing aid in infant formula products, not just for fat-soluble vitamins that are added to infant formula.

### Initial Assessment Report

Twelve submissions were received on the Initial Assessment Report.

#### Submitter Organisation

Food Technology Association of Victoria Inc.  
Dairy Goat Co-operative (NZ) Ltd  
Unitech Industries Limited  
New Zealand Food Safety Authority  
Fonterra Co-operative Group Ltd  
South Australia Department of Health  
Pyx Ltd  
NSW Health Department  
Department of Human Services Victoria  
Australian Food and Grocery Council  
Dietitians Association of Australia  
NSW Food Authority

#### Name

David Gill  
Dianne Lowry  
Philippa Remihana  
Carole Inkster  
Roger Hall  
Joanne Cammans  
Lynley Drummond  
Dr Denise Robinson  
Victor Di Paola  
Joan Cort  
Sue Cassidy  
Kelly Boulton

<b>Submitter</b>	<b>Position</b>	<b>Comments</b>
Food Technology Association of Victoria	Accepts Option 2	No additional comments.

Submitter	Position	Comments
Dairy Goat Co-operative (NZ) Ltd (DGC)	Supports the Application	<p>Believes the applicant has taken a proactive approach to food manufacturers concerns about the use of soy derived oils, with their associated allergy concerns.</p> <p>Based on infant formula products manufactured by DGC, supports the applicant's assertion that use of MCTs within compounded forms of fat soluble vitamins will not increase the MCT content in infant formula products by more than 2% of the total fat content.</p> <p>The DGC recommends consideration be given to permitting the use of MCT oils as an ingredient in infant and follow on formulas, (with a maximum level applied) rather than as a processing aid. They claim that this will improve harmonisation of international infant formula regulations.</p> <p>Believes the wording of subclause 23(a) of Standard 2.9.1 is confusing because:</p> <ul style="list-style-type: none"> <li>• Confusion arises between medium chain fatty acids (MCFAs) and MCTs (which are triglycerides containing three medium chain fatty acids);</li> <li>• Milk fats naturally contain MCFAs, but the levels of MCTs (which are much more difficult to measure) is substantially less than the total of the MCFAs present;</li> <li>• The distribution of MCFAs in different milk fats is not well documented.</li> </ul> <p>Suggested that a maximum level of MCT addition could be applied, and provided the following as an example, 'a maximum of 3% of total fat, excepting any MCTs present in a particular infant formula and 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'. The inclusion of the word 'any' in the above wording is proposed to avoid confusion regarding MCTs and MCFAs.</p>
Unitech Industries Limited	Supports the Application	<p>Acknowledges the technical need of MCTs as a processing aid for lipophilic vitamins.</p> <p>Acknowledges the identified labelling issues associated with using suitable alternative vegetable oils, including soybean oil and peanut oil, which have strong GMP and allergen issues associated with them.</p> <p>Also raised the following issues:</p> <ul style="list-style-type: none"> <li>• Would like to have MCTs approved as a product group for use as a processing aid in the preparation of fat-soluble vitamins and not restricted by the naming of particular MCT species. Section 6.2 of the Initial Assessment Report defined MCTs as being obtained from the oil extracted from <i>Cocos nucifera</i> L. or <i>Elaeis guineensis</i> Jacq. Submission states that Codex Alimentarius also recognises Babassu oil (<i>Orbignya spp.</i>) as another MCT oil.</li> </ul>

Submitter	Position	Comments
		<ul style="list-style-type: none"> <li>Queries the claim that the level of MCTs will be increased by no more than 2% of total fat content. Rather, they propose that assuming MCTs make up no more than 20% of the encapsulation matrix for permitted fat soluble vitamins, and that those vitamins were included in an infant formula at the maximum allowable levels permitted under Standard 2.9.1, then MCTs will contribute no more than 0.005% of the total fat content.</li> </ul>
New Zealand Food Safety Authority	Agrees that Application should go to Draft Assessment	<p>Notes that there are a number of issues regarding the safety and suitability of MCTs in infant formula products targeted at term infants that will be addressed in the Draft Assessment process.</p> <p>Specifically noted that any safety concerns associated with the potential increased consumption of coconut and/or palm kernel oil will be addressed in the Draft Assessment Report, including whether the level of trans fatty acids will be increased with the use of MCTs.</p> <p>Would be useful to know the levels of naturally occurring MCTs in term infant formula products.</p>
Fonterra Co-operative Group Ltd	Supports Option 2	No additional comments.
South Australia Department of Health	Cautious support to Application	Will await the results of the safety assessment before giving full support.
Pyx Ltd	Supports Application	<p>Milk based infant formula products manufactured in Australia and New Zealand are made from either bovine or goat milk. Bovine sources typically contain only very low residual quantities of bovine milk fat. In contrast, goat milk formulas may contain significant levels of goat milk fat.</p> <p>Provided some data on typical medium chain fatty acid composition in milk fat sources (NZ bovine, goat and human). Emphasised that the presence of medium chain fatty acids did not necessarily relate to the existence of MCTs.</p> <p>Believes the intent of subclause 23(a) in Standard 2.9.1 is to prohibit the specific addition of MCT oil ingredients to any large extent, as is common practice in formulas for premature infants and those with special metabolic needs.</p> <p>The levels of MCT oil ingredients that would be added, should all lipophilic vitamins be added at their maximum allowable levels using MCT oil as a carrier, were calculated to be significantly less than 0.01% of the total fat content.</p> <p>Clause 34 of Standard 2.9.1 specifically allows MCTs to be added as an ingredient. MCT oil ingredients should be treated as an ingredient throughout Standard 2.9.1, rather than as a processing aid and an ingredient in different parts of the Standard.</p> <p>The use of MCT oils is a more favourable option than the potential alternatives of soy and peanut oils, both of which have allergenicity issues, or partially hydrogenated oils, which introduce potentially elevated and unnecessary levels of <i>trans</i> fatty acids.</p>

Submitter	Position	Comments
		<p>Recommendations:</p> <ul style="list-style-type: none"> <li>• That MCT oils are defined as those being triglycerides predominately C8 and C10 fatty acids and derived from palm kernel, coconut and Babassu oils.</li> <li>• MCT oil ingredients are permitted for use as carriers for the manufacture of encapsulated lipophilic vitamin compounds in infant formula products.</li> <li>• The addition of MCT oil ingredients are permitted in Infant Formula and Follow-on Formula products up to a maximum percentage of 0.01% of the total fat content.</li> <li>• That clause 23(a) is replaced with a statement allowing the inclusion of MCT oil ingredients to a maximum of 0.01% of the total fat content, <u>or</u>:</li> <li>• Clause 23(a) is deleted and Schedule 1 of the standard is amended to recognise specific ingredients that may be used to assist with the preparation of vitamin compounds to provide stability.</li> </ul>
NSW Health Department	Supports Application	<p>Main public health concern appears to relate to a metabolic disorder called 'medium chain acyl CoA dehydrogenase deficiency' (MCAD). Expert advice indicates that there should be no problem with small amounts of MCTs up to 2% in infant formula.</p> <p>Prepared to accept the addition of MCTs in light of the benefits of better nutrient dispersion for some infants. However, NSW Health supports the overriding principle that the composition of infant formula should be close as possible to that of human milk.</p> <p>Makes comment that the Applicant's contention that human breast milk contains 8-10% MCTs is incorrect and that the actual percentage of MCTs in human breast milk is 1-2%. [The Applicant actually states that human breast milk contains 8-10% of medium chain fatty acids – the Initial Assessment Report incorrectly represented this information as 8-10% MCTs]</p>
Department of Human Services Victoria	Supports Option 2 at this stage	<p>Requested that, in the risk assessment, consideration be given to determining the purity of the compounds. Considered it necessary to know what percentage of MCTs is to be present in the final compounds.</p> <p>Also posed two questions:</p> <ul style="list-style-type: none"> <li>• Should a minimum percentage of MCTs be mandated?</li> <li>• Can we be assured that no other fatty acid groups are included in the compounds?</li> </ul>
Australian Food and Grocery Council	Supports Application	<p>Considers that the prohibition of MCTs in infant and follow-on formula is unnecessary and inconsistent with the permissions to use MCTs in specially formulated products for premature and low birth weight infants, as well as international best practice.</p> <p>Concerned that there is no clear scientific evidence that points to either a demonstrated safety risk at the concentrations intended for use, or that there is a need to control the fatty acid profile of infant formula to the extent that MCTs at low concentrations should be prohibited.</p>

Submitter	Position	Comments
		<p>Contends that the prohibition of use of MCTs was not due to a precautionary approach in regard to consistency with breast milk profile, but rather that there was no benefit for their inclusion. This Application changes this position in that it demonstrates a significant benefit in the microencapsulation of fat soluble vitamins A, D, E and K.</p> <p>AFGC advocates that the use of processing aids, providing the processing aid is safe and fulfils a technological function, should be available to the food industry for use in food processing.</p> <p>Supports the principle that MCTs should be safe when consumed as intended by the manufacturer.</p> <p>Approval for the use of MCTs as a processing aid in all infant formulations would benefit both manufacturers and consumers by reducing the safety risk associated with allergens from alternative oils such as partially hydrogenated soybean oil, and increased absorption of nutrients by infants.</p>
Dietitians Association of Australia	Agrees that Application should go to Draft Assessment	<p>DAA sees potential benefits in the use of MCT oils to minimise the use of soybean oil as a potential allergen for some infants and as an ingredient that may assist in enhancing the delivery of fat soluble vitamins to infants.</p> <p>Would like further information on the implications of these changes to infant formula, such as the impact the addition of MCT oils may have on the overall nutritional composition of infant formula.</p>
NSW Food Authority	Supports Application at IAR stage	Does not object to further consideration of the Application.