



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

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31 May 2006

INITIAL ASSESSMENT REPORT

APPLICATION A532

RATIO OF LONG CHAIN POLYUNSATURATED FATTY ACIDS IN INFANT FORMULA PRODUCTS

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 12 July 2006
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED

(See 'Invitation for Public Submissions' for details)

For Information on matters relating to this Assessment Report or the assessment process generally, please refer to <http://www.foodstandards.gov.au/standardsdevelopment/>

EXECUTIVE SUMMARY

Food Standards Australia New Zealand (FSANZ) received a joint Application from the Infant Formula Manufacturers Association of Australia and the New Zealand Infant Formula Marketers' Association (the Applicant) on 27 February 2004. This Application seeks to amend Standard 2.9.1 – Infant Formula Products of the *Australia New Zealand Food Standards Code* (the Code), by removing the requirement for infant formula and follow-on formula¹ to contain omega 6 and omega 3 long chain polyunsaturated fatty acids (LCPUFAs) in a ratio of approximately two when added to these products.

The Applicant is seeking to remove the omega 6 to omega 3 LCPUFAs ratio for infant formula on the basis that the ratio is not supported by recent scientific evidence and that no other international legislation requires such a ratio. It is argued that the promotion of consistency between domestic and international food standards is important, where the inclusion of a ratio for products sold in Australia and New Zealand may pose a technical barrier to trade for Australian and New Zealand manufacturers and importers.

The Applicant also states that no potential infant formula ingredient provides a natural ratio of 2:1 for arachidonic acid (AA) and docosahexaenoic acid (DHA). Therefore, where DHA is added there is a need to manufacture, purify and add AA to ensure that the required ratio is met. Subsequently, the cost to manufacture products containing LCPUFAs is greater, and this cost is passed onto consumers.

The specific objectives for the assessment of this Application are therefore to:

- protect the public health and safety of formula-fed infants; and
- promote consistency between domestic and international food standards.

Reasons for Assessment

After considering the requirements for Initial Assessment as prescribed in section 13 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ has decided to accept the Application for the following reasons:

- The Application seeks approval to remove the omega 6 to omega 3 LCPUFA ratio for infant formula. Such an approval, if accepted, would warrant a variation to Standard 2.9.1 – Infant Formula Products.
- There is currently a requirement in the Code for infant formula and follow-on formula to contain omega 6 and omega 3 long chain polyunsaturated fatty acids (LCPUFA) in a ratio of approximately two when added to these products.
- The Application is not so similar to any previous application that it ought not be accepted.

¹ For the purpose of this report, the term 'infant formula' relates to both infant formula and follow-on formula.

- There are no other measures that would be more cost-effective than a variation to Standard 2.9.1 that could achieve the same end.
- At this stage no other relevant matters are apparent.

FSANZ has also identified two options that are available for Application A532:

1. Option 1 – Maintain *status quo*, or
2. Option 2 – Amend Standard 2.9.1 by removing the requirement for infant formula to contain omega 6 and omega 3 LCPUFA in a ratio of approximately two, when LCPUFA are added to these products.

FSANZ will undertake a full impact analysis at Draft Assessment, however has included preliminary consideration of impacts of these two options under Section 8 of this Initial Assessment Report.

Consultation

A number of questions have been posed in this Initial Assessment Report to facilitate consideration of Application A532. Public comment is invited on these questions, the proposed regulatory options, and the report as a whole.

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INVITATION FOR PUBLIC SUBMISSIONS

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

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

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

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

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Submissions need to be received by FSANZ by 6pm (Canberra time) 12 July 2006.

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

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

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

INTRODUCTION

Food Standards Australia New Zealand (FSANZ) received a joint Application from the Infant Formula Manufacturers Association of Australia and the New Zealand Infant Formula Marketers' Association (the Applicant) on 27 February 2004. The Application has requested an amendment to Standard 2.9.1 – Infant Formula Products of the *Australia New Zealand Food Standards Code* (the Code). This Initial Assessment Report discusses the issues involved in the proposed amendment and seeks comment from stakeholders, particularly in relation to expected regulatory impact(s), to assist FSANZ in making an assessment of this Application.

1. Nature of the Application

1.1 Basis of the Application

The Applicant has requested that Standard 2.9.1 of the Code be amended to remove subclause 23(d). This subclause requires long chain polyunsaturated fatty acids (LCPUFAs) voluntarily added to infant formula and follow-on formula to be present in a ratio of omega 6 to omega 3 LCPUFAs of approximately two. The Applicant contends that recent scientific evidence does not support the required ratio, and that subclause 23(d) could represent a technical barrier to trade because no proposed international legislation or existing overseas legislation requires such a ratio.

1.2 Scope of Application

This Application pertains solely to infant formula and follow-on formula. Infant formula and follow-on formula are defined in Standard 2.9.1 as follows:

Infant formula - means an infant formula product represented as a breast milk substitute for infants and which satisfies the nutritional requirements of infants aged up to four to six months.

Follow-on formula - means an infant formula product represented as either a breast milk substitute or replacement for infant formula and which constitutes the principal liquid source of nourishment in a progressively diversified diet for infants aged from six months.

This Application does not pertain to 'infant formulas for special dietary use' (e.g. formulas for premature infants and/or those with specific medical conditions). Clauses 25 and 27(1) of Standard 2.9.1 allow manufacturers to specifically formulate and modify the LCPUFA ratio of infant formula products for special dietary use. Therefore, the Applicant's request will not impact on the current requirements and manufacturing practices for infant formula products for special dietary use.

For the purpose of this report, the term 'infant formula' relates to both infant formula and follow-on formula.

2. Background

LCPUFAs are unsaturated fatty acids with a chain length greater than or equal to 20 carbon atoms², and include fatty acids with omega 6 and omega 3 chemical structures. LCPUFA are currently added to a variety of infant formula products, including some infant formula, follow-on formula and formula for special dietary use.

Arachidonic acid (C20:4 omega 6) (AA) and docosahexaenoic acid (C22:6 omega 3) (DHA) are the predominant LCPUFA added to infant formula. The ratio of omega 6 to omega 3 LCPUFAs is between 1.5-2:1 in currently available infant formula.

2.1 Current Standard

2.1.1 Domestic Infant Formula Regulations

Standard 2.9.1 of the Code regulates the compositional and labelling requirements for infant formula products^{3,4}. Subclause 23(d) of Division 2 – Infant Formula and Follow-on Formula of this Standard states:

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

- d) *have a ratio of total long chain omega 6 series fatty acids (C \geq 20) to total long chain omega 3 series fatty acids (C \geq 20) of approximately 2 in an infant formula or follow-on formula which contains those fatty acids.*

In addition, the Table to clause 23 prescribes maximum limits for omega 6 LCPUFA, omega 3 LCPUFA and AA of 2%, 1% and 1% of total fatty acids respectively.

The Applicant has requested that the requirement for an omega 6 to omega 3 LCPUFA ratio be removed, by deleting Clause 23(d) of Standard 2.9.1. This request does not affect the ability to add LCPUFA to infant formula, or the maximum prescribed limits in the Table to Clause 23.

2.1.2 Overseas and International Infant Formula Regulations

No overseas or international regulations specify a ratio between the omega 6 and omega 3 LCPUFAs content of infant formula. The United States (US Office of the Federal Register, 2006) and Canada (Health Canada, 1990) both place requirements on the total fat content and linoleic acid content (polyunsaturated fatty acid of 18 carbon lengths), however neither have any requirements specific to the LCPUFA contents of infant formula.

² Across the scientific literature, there is variation in the carbon chain length that is used to define ‘long chain polyunsaturated fatty acids’. Consistent with Standard 2.9.1 of the Code, LCPUFA are those fatty acids with a chain length of ≥ 20 carbon units.

³ Infant formula product (as defined in Standard 2.9.1) means a product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve as the principal liquid source of nourishment for infants.

⁴ ‘Infant formula products’ refers to all food regulated by Standard 2.9.1. Infant formula are a subset of this product category.

Codex Alimentarius currently has a draft infant formula standard (ALINORM 05/28/26 Appendix IV) under consideration by its Nutrition and Foods for Special Dietary Uses Committee, however the draft Standard does not include a ratio between omega 6 and omega 3 LCPUFA.

The European Commission is in the process of revising its infant formula directive (Commission of the European Communities, 2005). It is proposed in Clause 5.5 of the draft revised directive, that where LCPUFAs are added:

- the omega 3 LCPUFA content shall not exceed 1% of the total fat content, and the omega 6 LCPUFA content shall not exceed 2% of the total fat content;
- AA should not exceed 1% of the total fat content;
- the eicosapentaenoic acid (20:5 omega 3) (EPA) content shall not exceed the DHA content; and
- notwithstanding the omega 6 and omega 3 maximums above, the DHA content shall not exceed the omega 6 LCPUFA content.

These requirements are similar to those currently required by Clause 23 of Standard 2.9.1 of the Code with the exception of the final dot-point above relating to DHA content.

2.2 Current Market

2.2.1 Domestic Market

Infant formulas with added LCPUFAs suitable for formula-fed term infants are readily available from supermarkets in Australia and New Zealand. Four major brands supply the market, and all of these brands of infant formula are marketed with and without added LCPUFAs. Two of these brands are manufactured in New Zealand using locally produced milk powder, and subsequently sold in both Australia and New Zealand. The remaining two brands are manufactured overseas, likely from milk powders of mixed origin, and imported into Australia and New Zealand.

The word ‘gold’ in the product title of infant formulas suitable for term infants, as sold in Australia and New Zealand, is used to differentiate products that contain added LCPUFAs and, in some cases, other optional substances such as nucleotides. The cost of these infant formulas is greater than for formulas that do not contain LCPUFAs.

2.2.2 International Market

It is preferable for companies to manufacture one formulation for worldwide distribution, for cost advantage purposes. However, it appears that products made in or imported into Australia and New Zealand are sold only in these two countries. One reason for this manufacturing practice is the ratio requirement for added LCPUFAs. In addition, the increased cost of the product, partially related to compliance with the required ratio, may limit the sale of these products to countries outside of Australia and New Zealand.

2.3 Historical Background

Prior to the development of the Code, there was no regulation on the addition of LCPUFAs to infant formula in either of the separate Australian or New Zealand regulations. Any addition of LCPUFAs would have been permitted via the ability to add fish oil as an ingredient to infant formula.

A Proposal was raised to both harmonise and update the regulation of infant formula, titled Proposal P93 – Review of Infant Formula. At Preliminary Inquiry, the requirements for the addition of LCPUFAs were aligned with the maximum level requirements of the European Commission and the United Kingdom (these were the only infant formula regulations at that time with requirements specific to LCPUFAs). An omega 6 to omega 3 ratio was not included as part of the regulations in effect within these jurisdictions.

The decision to include a ratio was based primarily on the findings by the United States Life Sciences Research Office (LSRO) (Raiten *et al.*, 1998), which suggested that different omega 6 and omega 3 LCPUFA intakes interfere with the infant metabolism of these fatty acids to varying extents. A specific concern was that the addition of DHA alone to infant formula had been identified with a decrease in the serum levels of AA. Based on the results of studies in preterm infants and animals, the LSRO considered the addition of LCPUFAs at inappropriate levels could pose a safety risk for clinical outcomes, particularly in relation to growth. Therefore, the LSRO recommended against the addition of DHA and AA to infant formulas at that time (1998), but agreed that the decision should be reassessed within five years.

To accommodate perceived safety issues with the omega 6 and omega 3 LCPUFAs that were already permitted through addition of fish oil ingredients, the Proposal P93 Preliminary Inquiry Report proposed an additional measure of setting the omega 6 to omega 3 LCPUFAs content at a ratio of exactly two. This ratio was based on the level identified from human milk analyses (Forsyth, 1998). It was recognised at the time that this additional measure was inconsistent with other overseas and international regulations, but was considered necessary to manage a potential risk in a vulnerable population.

During public consultation, comments were received stating that the ratio of omega 6 to omega 3 LCPUFAs in human milk is not always exactly two. Consequently, the requirement for a ratio was retained, although the ratio was changed to ‘approximately 2’.

3. The Problem

Standard 2.9.1 of the Code prescribes that where LCPUFAs ($C \geq 20$) are voluntarily added to infant formula, they must be present in a ratio of omega 6 to omega 3 LCPUFAs of approximately two. The Applicant states that no potential infant formula ingredient provides a natural ratio of 2:1 for AA and DHA (including human breast milk). Therefore where DHA is added there is a need to manufacture, purify and add AA to ensure that the required ratio is met. Subsequently, the cost to manufacture LCPUFA-containing products is greater, and this cost is passed onto consumers.

The Applicant is seeking to remove this ratio requirement for infant formula, on the basis that the ratio is not supported by recent scientific evidence and that no other international legislation requires such a ratio.

Promoting consistency between domestic and international food standards is important, where the inclusion of a ratio for products sold in Australia and New Zealand may pose a technical barrier to trade for Australian and New Zealand manufacturers and importers.

4. Objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives that 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.

The specific objectives for the assessment of this Application are to:

- protect the public health and safety of formula-fed infants; and
- promote consistency between domestic and international food standards.

5. Key Assessment Questions

The following questions were developed within FSANZ to be considered at Initial Assessment, and to answer more comprehensively at Draft Assessment:

- What is the range of LCPUFA ratios naturally occurring in human milk, and how do these ratios compare to the omega 6 to omega 3 LCPUFA ratio prescribed in Standard 2.9.1?
- Are there any differences in the growth and development of infants fed formulas with varying ratios of omega 6 to omega 3 LCPUFA ratios?
- What are the risks associated with feeding infants formula containing the singular addition of DHA or AA?

RISK ASSESSMENT

6. Risk Assessment Issues

Essential fatty acids cannot be synthesised in the body and must be supplied in the diet to avoid deficiency. The essential fatty acid precursor to omega 6 LCPUFA is linoleic acid (C18:2) (LA), which the body can convert to a variety of omega 6 LCPUFA including AA. AA is also available preformed in food sources including eggs and plant based oils. The essential fatty acid precursor to omega 3 LCPUFA is alpha-linolenic acid (18:3) (ALA), which can be converted to EPA and DHA. Sources of preformed DHA and EPA include fish and fish products.

Humans cannot interconvert omega 6 and omega 3 fatty acids (including LCPUFAs), and a dietary imbalance in these fatty acids can thus potentially result in a state of nutritional insufficiency. A variety of ratios of omega 6 to omega 3 have therefore been proposed for optimal human intake (Mahan and Escott-Stump, 2000).

The following section summarises the relevant literature on the potential risks to term infants from infant formula with an omega 6 to omega 3 LCPUFA ratio that differs from approximately 2:1, and any risks from consuming an infant formula with only one of omega 6 or omega 3 LCPUFA.

There are three key literature reviews. The individual studies included in these reviews are detailed at Attachment 1.

Makrides et al. (2000a)

This literature review report was developed for the Infant Formula Manufacturers Association of Australia (IFMAA), and was supplied as part of the Application. Nine randomised controlled trials on term infants were reviewed, investigating the effects on growth from variations in the AA and DHA contents of infant formulas.

Makrides et al. (2005a)

This is a meta-analysis of 14 randomised controlled trials on term infants that have investigated LCPUFA intakes and their effect on infant growth. This meta-analysis is an extension of the Makrides et al. (2000a) review, although different study exclusion criteria were applied to the evidence base. The 14 trials have a combined sample size of 1846 infants.

Fleith and Clandinin (2005)

This study reviewed and made conclusions on infant formula as they relate to both preterm and term infants. However, a stand-alone systematic review of term infant literature was conducted as a subset of the wider review. The term infant review assessed 12 studies investigating the effects on biochemistry, visual and motor functions from variations in the AA and DHA contents of infant formulas.

6.1 Long-chain polyunsaturated fatty acid ratios in human milk

Although the prescribed ratio of approximately 2:1 was based on the assumption that the ratio of omega 6 to omega 3 LCPUFAs in breast milk remains relatively constant, more recent published data does not support that assumption.

It is suggested that whilst the AA content of human milk remains at a consistent level over the period of breastfeeding, the DHA levels in the milk vary with changes in the maternal diet (Makrides *et al.*, 2005a; Fleith and Clandinin, 2005). Makrides *et al.* (2005a) have also suggested that support for an omega 6 to omega 3 ratio of 2:1 as being the optimum for infant nutrition arose from studies using particular types of human milk samples (from mothers in developed countries), and that a wider range of breast milk ratios can occur with different maternal diets that are just as suitable for the growth of an infant.

6.2 The impact on infant growth from different omega 6 to omega 3 ratios

Many studies have been undertaken to determine the effects of varying the omega 6 to omega 3 ratio of LCPUFAs added to infant formula, by using preformed DHA and AA.

The literature review of LCPUFAs by Makrides *et al.* (2000a) indicates that variations in LCPUFA levels, including variations in the omega 6 to omega 3 ratio, do not have any significant effect on normal growth outcomes. This literature review dealt predominantly with variations in omega 6 to omega 3 LCPUFA contents, although several studies were included that investigated the addition of DHA alone.

The findings by Makrides *et al.* (2000a) are confirmed by the meta-analysis of omega 6 to omega 3 LCPUFA ratios conducted by Makrides *et al.* (2005a). The literature review on the effect of dietary polyunsaturated fatty acids in term infants by Fleith and Clandinin (2005) also supports the findings of Makrides *et al.* (2000a). Both of these reviews concluded that there is no effect on normal growth patterns with different omega 6 to omega 3 ratios.

6.3 Singular addition of long-chain polyunsaturated fatty acids to infant formula

FSANZ has not identified any scientific literature that assesses the singular addition of AA to infant formula. DHA has been shown to have particular benefits for visual acuity, and thus has been the topic of studies to assess the efficacy as well as the safety of adding DHA alone to infant formula.

The review paper supplied by the Applicant (Makrides *et al.*, 2000a) concludes from the then available evidence that infant formula with added DHA (and no added omega 6 LCPUFAs) decreases serum AA levels, but has no effect on normal infant growth. The Makrides *et al.* (2005a) meta analysis also shows a decrease in serum AA levels, but no significant difference in infant weight, length or head circumference when infant formula with added omega 3 LCPUFA were compared to standard infant formula (no LCPUFA). Fleith and Clandinin (2005) conclude that supplementation of DHA alone decreased serum AA levels but did not affect normal growth patterns in term infants.

The reduction in serum AA levels in infants is a concern that has been raised by Kuratko *et al.* (2005) in commentary on the Makrides *et al.* (2005a) review. Kuratko *et al.* mention that growth is a late indicator of nutrient deficiency, and that low serum AA levels may be an early sign of poor nutrition. A declaration was made by Kuratko *et al.* that they are employed by Martek Biosciences, which markets purified AA. The right of reply by Makrides *et al.* (2005b) states that growth is a measure used routinely by health professionals to assess nutritional status.

The decrease in AA levels identified by the three literature reviews is similar to findings by the European Scientific Committee on Food (ESCF) in their review of infant formula (European Scientific Committee on Food, 2003). The ESCF recommended that the omega 6 LCPUFA content of infant formula with added LCPUFA should not be lower than the DHA content, as a means of preventing a relative deficiency of AA, and to ensure an adequate balance between omega 6 and omega 3 LCPUFAs. This recommendation has been included in the draft revision of the European Directive on infant formula (see Section 2.1.2).

The European Scientific Committee on Food's recommendation was developed from two publications. One paper by Innis *et al.* (2002) detailed the effects of LCPUFA supplementation of pre-term infants. The other paper by Lauritzen *et al.* (2001) focused on omega 3 LCPUFAs and the development and function of the brain. Neither paper assessed the effect of LCPUFA supplementation on term infants.

FSANZ has also identified three individual studies that have compared formula containing DHA alone directly with formula containing DHA in combination with AA, and the impact on growth and developmental outcomes in term infants (Auestad *et al.*, 1997; Birch *et al.*, 2000; Makrides *et al.*, 2000b). Two of the three studies, each having more than 200 participants on a test diet for 12 months, did not find any difference in visual or neurological outcomes through to 2 years of age (Auestad *et al.*, 1997; Makrides *et al.*, 2000b). One study of 68 infants fed a test diet for 17 weeks reported a benefit of the DHA plus AA supplementation at a single age assessment (Birch *et al.*, 2000). It is suggested that this outcome could be due to the variation of amounts of LCPUFAs, in particular AA, per 100 grams of fatty acids in the formulas (Fleith and Clandinin 2005).

Questions:

- 1. What, if any, is the effect on infant growth and development associated with the addition of AA without DHA to infant formula? Are there any studies assessing the addition of AA without DHA to infant formula?**
- 2. Is there further information on the addition of DHA without AA to infant formula, and its effects on the growth and development of infants?**
- 3. Are there any risks from a reduction in serum AA levels of infants?**
- 4. Is there any additional evidence on the physical development of infants with an omega 6 to omega 3 LCPUFA ratio of approximately 2:1?**

RISK MANAGEMENT

No specific risk management issues have been identified at Initial Assessment. FSANZ will consider management of any identified risks at Draft Assessment. Submitter comments received during the public consultation period for this Initial Assessment Report will be considered at Draft Assessment.

7. Options

FSANZ is currently considering two options for addressing this Application:

7.1 Option 1 – Maintain *status quo*

Maintain *status quo* by not amending the Code, and thus retaining the requirement for omega 6 to omega 3 LCPUFAs to be present in a ratio of approximately two, when added to infant formula.

7.2 Option 2 – Amend Standard 2.9.1 by removing the requirement for infant formula to contain omega 6 and omega 3 LCPUFAs in a ratio of approximately two, when LCPUFAs are added to these products

This would allow the addition of one or more omega 6 or omega 3 LCPUFAs to infant formula up to the prescribed maximum percentage of total fatty acids, without the need for them to be present in a specific ratio.

8. Impact Analysis

8.1 Affected Parties

The parties affected by this Application are: **consumers** being formula-fed infants consuming infant formula with added LCPUFAs; **industry** being Australian and New Zealand manufacturers and importers of infant formula; and the **Governments** of Australia and New Zealand.

8.2 Cost-Benefit Analysis

This analysis assesses the immediate and tangible impacts of the current food standard under Option 1 and of the proposed amendment under Option 2.

8.2.1 Option 1 – Maintain Status Quo

8.2.1.1 Consumers

It is likely that maintaining the *status quo* will have minimal impact on consumers of infant formula. Infant formula with added LCPUFAs will continue to be available, thus formula-fed infants using these products may continue to benefit from consuming these fatty acids. In addition, the cost of these products for consumers is likely to remain higher than for infant formula without added LCPUFAs, due to the increased costs to manufacture products to the required LCPUFA ratio.

8.2.1.2 Industry

For industry, maintaining the *status quo* may lead to trade difficulties, due to the potential inconsistency with overseas and international legislation. Some infant formulas are manufactured for worldwide distribution, and Australia and New Zealand are minor consumers within this global trade. Therefore, trade difficulties may arise in the manufacture of products with added LCPUFAs that are suitable for both local and export markets. In addition, Australian and New Zealand importers may experience difficulties when seeking to import products that must comply with the Code. Consequently, the variety of infant formula with added LCPUFAs available in Australia and New Zealand may be reduced.

In addition, the increased costs to produce infant formula with added LCPUFAs in the required ratio will remain, where these costs are passed onto the consumer. Subsequently, industry note that if a product is not accepted by consumers because of the greater cost, then competition in the marketplace may reduce as these products may be withdrawn from the market.

8.2.1.3 Government

The impact of maintaining the *status quo* on the Australian and New Zealand governments is likely to be minimal, with respect to monitoring and enforcing the LCPUFA ratio for infant formula.

8.2.2 *Option 2 – Amend Standard 2.9.1 by removing the requirement for infant formula to contain omega 6 and omega 3 LCPUFAs in a ratio of approximately two, when LCPUFAs are added to these products.*

8.2.2.1 Consumers

Removing the LCPUFA ratio is unlikely to adversely affect the growth and development of formula-fed infants consuming these products. As Option 2 would potentially eliminate the compliance costs incurred by industry to meet the current LCPUFA ratio, it would be expected that this cost saving would be passed onto consumers.

8.2.2.2 Industry

An amendment to Standard 2.9.1 of the Code will have greatest benefit for industry, as manufacturing costs to comply with the current LCPUFA ratio are likely to be eliminated. Furthermore, the amendment may widen trade opportunities for manufacturers and importers through harmonisation with overseas and international food standards, and may also provide a cost advantage if only one formulation is manufactured for worldwide distribution.

In addition, Option 2 would allow the continued addition of LCPUFAs voluntarily to infant formula, and thus allows flexibility for product formulation.

8.2.2.3 Government

There is likely to be no impact on the Australian and New Zealand Governments as a result of removing the LCPUFA ratio for infant formula.

Questions:

- 5. What is the likelihood that manufacturers would add either DHA or AA alone to infant formula?**
- 6. What is the likely impact on consumers, industry and government agencies if the *status quo* were maintained?**
- 7. What is the likely impact on consumers, industry and government agencies if the LCPUFA ratio were removed from Standard 2.9.1?**

- | |
|---|
| <p>8. What impact would removal of the ratio requirement have on the cost and/or market value of infant formula and follow-on formula currently manufactured in and/or for the Australian and New Zealand markets?</p> <p>9. What trade barriers/issues currently exist for Australian and New Zealand manufacturers and importers of infant formula?</p> |
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9. Comparison of Options

At this Initial Assessment stage, no comparison of the identified regulatory options can be undertaken. Further information on the risk assessment and risk management aspects of this Application is required before such a comparison can be made. A comparison will therefore be provided at Draft Assessment.

COMMUNICATION

10. Communication and Consultation Strategy

At Initial Assessment, FSANZ does not intend to undertake specific communication and consultation work outside of the two statutory public consultation periods. FSANZ will review the nature of the feedback received from submitters to the Initial Assessment, and determine whether a more thorough communication strategy is required for Draft and Final Assessments.

11. Consultation

11.1 Public Consultation

This Initial Assessment Report is intended to seek early input on a range of specific issues known to be of interest to various stakeholders on the likely regulatory impact of this Application. At this stage FSANZ is seeking public comment to assist it in assessing this Application and is particularly interested in receiving further information on the questions asked throughout this Report, which are also presented at Attachment 2.

The first public consultation period will remain open for six weeks. Comments made by submitters during this period will be reviewed and reported in the Draft Assessment report.

11.2 World Trade Organization (WTO)

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

This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia and New Zealand's obligations under the WTO Technical Barrier to Trade or Sanitary and Phytosanitary Measure Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

CONCLUSION

12. Conclusion and Preferred Option

After considering the requirements for Initial Assessment as prescribed in section 13 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ has decided to accept the Application for the following reasons:

- The Application seeks approval to remove the omega 6 to omega 3 LCPUFA ratio for infant formula. Such an approval, if accepted, would warrant a variation to Standard 2.9.1 – Infant Formula Products.
- There is currently a requirement in the Code for infant formula and follow-on formula to contain omega 6 and omega 3 long chain polyunsaturated fatty acids in a ratio of approximately two when added to these products.
- The Application is not so similar to any previous application that it ought not be accepted.
- There are no other measures that would be more cost-effective than a variation to Standard 2.9.1 that could achieve the same end.
- At this stage no other relevant matters are apparent.

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ATTACHMENTS

1. Studies Cited in Literature Reviews
2. Initial Assessment Questions for Public Comment

Studies Cited in Literature Reviews

The following articles have been included in the literature reviews by either Makrides *et al.* (2000a), Makrides *et al.* (2005a), or Fleith and Clandinin (2005). All articles listed below are randomized, blinded, controlled, and enrolled infant subjects within 1 week of birth.

Study	n	Study period	Subject grouping				Results (weighted mean difference, LCPUFA vs. Standard)				
			Type Formula	Omega 6 LCPUFA % total fatty acids)	Omega 3 LCPUFA (% total fatty acids)	Omega 6: omega 3 LCPUFA ratio	Weight [95% CI]	Length [95% CI]	Head Circumference [95% CI]	Visual Evoked Potential	Cognitive Function
Agostoni <i>et al.</i> (1994)	34	4 months	Standard formula intake	-	-	-	-0.16 [-0.47, 0.15]	-0.97 [-2.06, 0.12]	-0.14 [-0.75, 0.47]	n/a	LCPUFA had a significantly (p<0.05) higher score than the standard formula.
	34		Standard formula + DHA + AA	0.44	0.35	1.3:1					
Auestad <i>et al.</i> (1997)	45	12 months	Standard formula intake	-	-	-	-0.17 [-0.6, 0.26]	-0.08 [-1.11, 0.95]	-0.18 [-0.63, 0.27]	No significant difference between the groups.	No significant difference between the groups.
	43		Standard formula + DHA	0	0.3	-					
	46		Standard formula + DHA + AA	0.43	0.12	3.6:1					
Auestad <i>et al.</i> (2001)	54	12 months	Standard formula intake	-	-	-	-0.11 [-0.44, 0.22]	-0.19 [-1.05, 0.67]	-0.01 [-0.4, 0.42]	No significant difference between the groups.	No significant difference between the groups.
	60		Standard formula + DHA + AA	0.46	0.16	2.9:1					
	63		Standard formula + DHA + AA	0.45	0.14	3.2:1					

Study	n	Study period	Subject grouping				Results (weighted mean difference, LCPUFA vs. Standard)				
			Type Formula	Omega 6 LCPUFA % total fatty acids)	Omega 3 LCPUFA (% total fatty acids)	Omega 6: omega 3 LCPUFA ratio	Weight [95% CI]	Length [95% CI]	Head Circumference [95% CI]	Visual Evoked Potential	Cognitive Function
Birch <i>et al.</i> (1998) and Birch <i>et al.</i> (2000)	23	4 months	Standard formula intake	-	-	-	-0.21 [-0.12, 0.54]	-0.49 [-1.51, 0.53]	-0.25 [-0.83, 0.33]	LCPUFA had a significantly (p<0.05) higher score than the standard formula.	LCPUFA had a significantly (p<0.05) higher score than the standard formula.
	22		Standard formula + DHA	0	0.35	-					
	23		Standard formula + DHA + AA	0.72	0.36	2:1					
Birch <i>et al.</i> (2002)	30	1 year	Standard formula intake	-	-	-	n/a	n/a	n/a	LCPUFA had a higher (p<0.05) score than the standard formula.	n/a
	28		Standard formula + DHA + AA	0.72	0.36	2:1					
Carlson <i>et al.</i> (1996)	22	4 months	Standard formula intake	-	-	-	-0.08 [-0.51, 0.35]	-0.05 [-1.13, 1.03]	-0.13 [-0.61, 0.35]	No significant difference between the groups.	n/a
	20		Standard formula + DHA + AA	0.43	0.1	4.3:1					
Carlson <i>et al.</i> (1999)	104	12 months	Standard formula intake	-	-	-	0.22 [-0.07, 0.51]	0.19 [-0.55, 0.93]	-0.01 [-0.44, 0.24]	n/a	n/a
	212		Standard formula + DHA + AA	0.6	0.3	2:1					

Study	n	Study period	Subject grouping				Results (weighted mean difference, LCPUFA vs. Standard)				
			Type Formula	Omega 6 LCPUFA % total fatty acids)	Omega 3 LCPUFA (% total fatty acids)	Omega 6: omega 3 LCPUFA ratio	Weight [95% CI]	Length [95% CI]	Head Circumference [95% CI]	Visual Evoked Potential	Cognitive Function
Decsi and Koletzko (1995)	7	4 months	Standard formula intake	-	-	-	0.21 [-0.36, 0.78]	-0.8 [-1.44, 3.04]	1.49 [0.44, 2.54]	n/a	n/a
	9		Standard formula + DHA + AA	0.4	0.33	1.2:1					
Innis <i>et al.</i> (1996)	37	4 months	Standard formula intake	-	-	-	0.06 [-0.3, 0.42]	-0.48 [-1.63, 0.67]	0.12 [-0.43, 0.67]	n/a	n/a
	68		Standard formula + DHA	0	0.12-0.24	-					
Lapillonne <i>et al.</i> (2000)	12	4 months	Standard formula intake	-	-	-	-0.28 [-0.95, 0.39]	1.10 [-0.82, 3.02]	-1.40 [-2.62, -0.18]	n/a	n/a
	12		Standard formula + DHA	0	0.39	-					
Lucas <i>et al.</i> (1999)	309	6 months	Standard formula intake	-	-	-	No values reported, however it was reported that there was no significant difference between groups.	No values reported, however it was reported that there was no significant difference between groups.	No values reported, however it was reported that there was no significant difference between groups.	n/a	No significant difference between the groups.
			Standard formula + DHA +AA	0.3	0.33	0.9:1					
Makrides <i>et al.</i> (1995)	19	7 months	Standard formula intake	-	-	-	-0.20 [-0.73, 0.33]	-0.46 [-1.99, 1.07]	-0.47 [-1.4, 0.46]	LCPUFA had a significantly (p<0.05) higher score than standard formula.	n/a
	13		Standard formula + DHA	0	1.0	-					

Study	n	Study period	Subject grouping				Results (weighted mean difference, LCPUFA vs. Standard)				
			Type Formula	Omega 6 LCPUFA % total fatty acids)	Omega 3 LCPUFA (% total fatty acids)	Omega 6: omega 3 LCPUFA ratio	Weight [95% CI]	Length [95% CI]	Head Circumference [95% CI]	Visual Evoked Potential	Cognitive Function
Makrides <i>et al.</i> (1999)	22	12 months	Standard formula intake	-	-	-	-0.38 [-0.97, 0.21]	-0.51 [-2.1, 1.08]	-0.22 [-0.44, 0.88]	No significant difference between the groups.	No significant difference between the groups.
	25		Standard formula + DHA	0	0.45	-					
	24		Standard formula + DHA + AA	0.34	0.34	1:1					
Morris <i>et al.</i> (2000)	140	3 months	Standard formula intake	-	-	-	-0.33 [-0.79, 0.13]	-0.18 [-1.28, 0.92]	-0.51 [-1.07, 0.05]	n/a	n/a
			Standard formula + DHA + AA	0.4	0.2	2:1					
Willatts <i>et al.</i> (1998)	58	4 months	Standard formula intake	-	-	-	No values reported, however it was reported that there was no significant difference between groups.	No values reported, however it was reported that there was no significant difference between groups.	No values reported, however it was reported that there was no significant difference between groups.	n/a	LCPUFA had a significantly (p<0.05) higher score than the standard formula.
			Standard formula + DHA + AA	0.35	0.2	1.8:1					

Initial Assessment Questions for Public Comment

Information on the Infant Formula Market in Australia and New Zealand

Risk Assessment

1. What, if any, is the effect on infant growth and development associated with the addition of AA without DHA to infant formula? Are there any studies assessing the addition of AA without DHA to infant formula?
2. Is there further information on the addition of DHA without AA to infant formula, and its effects on the growth and development of infants?
3. Are there any risks from a reduction in serum AA levels of infants?
4. Is there any additional evidence on the physical development of infants with an omega 6 to omega 3 LCPUFA ratio of approximately 2:1?

Risk Management

5. What is the likelihood that manufacturers would add either DHA or AA alone to infant formula?
6. What is the likely impact on consumers, industry and government agencies if the *status quo* were maintained?
7. What is the likely impact on consumers, industry and government agencies if the LCPUFA ratio were removed from Standard 2.9.1?
8. What impact would removal of the ratio requirement have on the cost and/or market value of infant formula and follow-on formula currently manufactured in and/or for the Australian and New Zealand markets?
9. What trade barriers/issues currently exist for Australian and New Zealand manufacturers and importers of infant formula?