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

2-07
4 April 2007

INITIAL ASSESSMENT REPORT

APPLICATION A594

ADDITION OF LUTEIN AS A NUTRITIVE SUBSTANCE IN INFANT FORMULA

AND

APPLICATION A597

ADDITION OF LUTEIN TO FORMULATED SUPPLEMENTARY FOODS FOR YOUNG CHILDREN

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 16 May 2007
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

Two related Applications have been received from Wyeth Pty Ltd and are addressed in this report. The first is seeking the addition of lutein to the list of permitted nutritive substances in infant formula and follow-on formula. The second Application is seeking the addition of lutein to the list of permitted nutritive substances in formulated supplementary foods for young children (FSFYC), a category that includes products sometimes referred to as 'toddler milks'.

Background

Lutein is a carotenoid commonly found in dark green vegetables and fruits, as well as in corn and egg yolks. Lutein is also found in varying quantities in breast milk. The body is unable to synthesise lutein, and therefore relies on the diet as the source of lutein. Dietary lutein is absorbed and concentrated in part of the eye where it may protect eye health by filtering out harmful blue light and acting as an antioxidant. The Applicant argues that the addition of lutein to infant formula may help to protect eye health in formula-fed infants who would otherwise receive little or no dietary lutein. The Applicant also argues that the addition of lutein to formulated supplementary foods for young children may benefit eye health in those consuming such foods, especially where the rest of the diet is low in lutein rich foods for some reason.

Purpose

The purpose of this Initial Assessment Report is to provide relevant information, including that supplied by the Applicant, to assist in identifying the affected parties and to outline the relevant issues necessary to evaluate the Application.

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:

Application A594 – Infant Formula Products:

- The Application seeks approval to add lutein to the list of permitted nutritive substances in infant and follow-on formulas. Such an approval, if accepted, would warrant a variation to Standard 2.9.1 – Infant Formula Products in the *Australia New Zealand Food Standards Code* (the Code).

- There is currently no permission in the Code for infant formula and follow-on formula to contain lutein as a nutritive substance.

- 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 2.91 that could achieve the same end.

- At this stage no other relevant matters are apparent.

Application A597 – Formulated Supplementary Foods for Young Children:

- The Application seeks approval to add lutein to the list of permitted nutritive substances in formulated supplementary foods for young children. Such an approval, if accepted, would warrant a variation to Standard 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods of the Code.

- There is currently no permission in the Code for formulated supplementary foods for young children to contain lutein as a nutritive substance.

- 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 2.9.3 that could achieve the same end.

- At this stage no other relevant matters are apparent.

For Initial Assessment, both Application A594 and Application A597 are considered together, however, they remain separate Applications. This Initial Assessment Report presents information common to both Applications and also addresses specific issues relating to each Application.

Consultation

A number of questions have been posed in this Initial Assessment Report to facilitate consideration of Applications A594 and A597. Public comment is invited on these questions, the proposed regulatory options, and the report as a whole.

Responses to this Initial Assessment Report will be used to develop the next stage of the Application and the preparation of a Draft Assessment Report.

CONTENTS

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:

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

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

Submissions need to be received by FSANZ by 6pm (Canberra time) 16 MAY 2007.

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 an Application from Wyeth Pty Ltd on 13 November 2006. The Applicant has requested an amendment to Standard 2.9.1 – Infant Formula Products of the Code (Application A594) to allow the optional addition of lutein as a nutritive substance to infant formula and follow-on formula. Lutein is a normal constituent of breast milk and may be helpful in promoting eye health. The Applicant argues that the inclusion of lutein in infant formula products would extend any benefits of dietary lutein to formula fed infants.

The same Applicant has also submitted a second Application on 2 January 2007; requesting an amendment to Standard 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods (Application A597). The requested amendment would allow the optional addition of lutein as a nutritive substance to formulated supplementary foods for young children (FSFYC). Lutein is a normal constituent of many fruits and vegetables that may be consumed by young children. The Applicant argues that including lutein in FSFYC may be beneficial for eye health, especially in those young children not consuming other foods rich in lutein.

For Initial Assessment, both Application A594 and Application A597 are considered together, however, they remain separate Applications. This Initial Assessment Report presents information common to both Applications and also addresses specific issues relating to each Application.

This Initial Assessment Report discusses the issues involved in the proposed amendments and seeks comment from stakeholders, particularly in relation to expected regulatory impact(s), to assist FSANZ in making an assessment of these Applications.

1. Nature of the Application

1.1 Basis of the Applications

1.1.1 Application A594 – Infant Formula

The Applicant has requested lutein from marigold (*Tagetes erecta* L) be permitted as an optional nutritive substance for inclusion in the table to clause 7 of Standard 2.9.1 with a maximum concentration of 250 µg/L in infant formula and 500 µg/L in follow-on formula.

The Application is based on the role of lutein in supporting eye health and aims to provide formula-fed infants with lutein at levels comparable to breast-fed infants. Also, the Applicant considers lutein in follow-on formula would provide additional lutein to support eye health in infants over the age of 6 months, whose diets do not reliably contain lutein.

The Applicant also contends lutein is not a novel substance because it is found in breast milk and is approved for use in Listed medicines by the Therapeutic Goods Administration (TGA) in Australia.

1.1.2 Application A597 – Formulated Meal Replacements and Formulated Supplementary Foods

The Applicant has requested lutein from marigold (*Tagetes erecta* L) be permitted as an optional nutritive substance in FSFYC in Division 4 of Standard 2.9.3 at a maximum concentration of 500 µg/L.

This Application is also based on the role of lutein in supporting eye health with the aim of providing additional lutein in the diets of young children. The Applicant considers some of the richest food sources of lutein are some of the least preferred foods of toddlers and young children.

1.2 Scope of Application

1.2.1 Application A594 – Infant Formula

Application A594 pertains 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 composition 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.

1.2.2 Application A597 – FSFYC

Application A597 pertains to FSFYC. Formulated supplementary foods and FSFYC are defined in Standard 2.9.3 as follows:

> *Formulated supplementary food – means a food specifically designed as a supplement to a normal diet to address situations where intakes of energy and nutrients may not be adequate to meet an individuals requirements.*
>
> *Formulated supplementary food for young children – means a formulated supplementary food for children aged one to three years.*

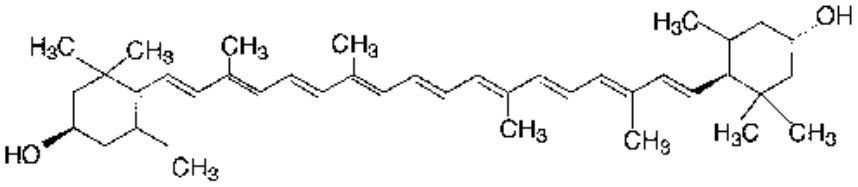
The Applicant has indicated that lutein, if permitted as a nutritive substance in the Code, will be added to cow's milk based FSFYC, both powdered and liquid. The majority of FSFYC available in Australia and New Zealand are milk-based supplementary drinks known as 'toddler formula'. However, under current definitions of FSFYC in the Code there is potential to include a broader range of foods as FSFYC are not restricted to cow's milk based products.

FSANZ is not aware of other products that are currently manufactured to the FSFYC provisions.

2. Background

2.1 Chemistry of Lutein

Lutein is a natural fat soluble xanthophyll carotenoid occurring as a pigment in some plants and algae (Alves-Rodrigues and Shao, 2004). Its chemical formula is: $C_{40}H_{56}O_2$:



2.2 Sources of Lutein

Food sources of lutein include breast milk, dark green and yellow vegetables and fruits such as broccoli, green beans, green peas, Brussels sprouts, cabbage, kale, spinach, lettuce, corn, kiwi fruit and honeydew melons, and egg yolks (USDA). Lutein is also found in nettles, algae and the petals of many yellow flowers. The source of lutein proposed by the Applicant is from the marigold flower (*Tagetes erecta* L).

2.3 Nutritional Role of Lutein

Lutein is not synthesised by humans. Body stores of lutein are derived from food containing lutein (Alves-Rodrigues and Shao, 2004). Dietary lutein is absorbed and subsequently concentrated in the retina of the eye, specifically the macula lutea. *In vitro* data suggest that lutein protects the macula lutea from ultraviolet light damage by reducing the formation of free radicals. This is achieved by absorbing the UV radiation and scavenging any free radicals which may form. (Alves-Rodrigues and Shao, 2004). Lutein is not regarded as a vitamin and is not covered by the *Nutrient Reference Values for Australia and New Zealand*[1], or other dietary recommendations.

Lutein is not regarded as a vitamin and is not covered by the *Nutrient Reference Values for Australia and New Zealand*[2], or other dietary recommendations.

Formatted: Bullets and Numbering

[1] This document is available online at http://www.nhmrc.gov.au/publications/synopses/n35syn.htm.
[2] This document is available online at http://www.nhmrc.gov.au/publications/synopses/n35syn.htm.

~~2.4~~2.4 Current Regulations

2.4.1 Domestic Regulations

2.4.1.1 Food Standards

Relevant Standards in the Code for both Applications include:

- Standard 1.1.1 – Preliminary Provisions, Division 1, clause 2 defines a nutritive substance to mean *a substance not normally consumed as a food in itself and not normally used as an ingredient of food, but which after extraction /or refinement, or synthesis, is intentionally added to a food to achieve a nutritional purpose, and includes vitamins, minerals, amino acids, electrolytes and nucleotides*.

  Division 2, clause 9 notes nutritive substances must not be added to food unless expressly permitted in the Code.

- Standard 2.9.1 – Infant Formula Products regulates the compositional and labelling requirements for infant formula products[3,4]. Division 1, clause 7 lists the permitted nutritive substances that may be voluntarily added to infant formula, the form(s) in which they may be added, the minimum amount per 100 kJ for a claim to be allowed, and the maximum amount permitted per 100 kJ when the substance is added. The maximum permitted amount applies to the sum of the naturally occurring and added nutritive substance.

- Standard 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods provides, compositional and labelling requirements for formulated meal replacements and formulated supplementary foods. In addition, clause 6 of this Standard, sets out the compositional and labelling requirements specifically for FSFYC. Table 3, in the Schedule to this Standard lists the vitamins and minerals currently permitted for addition to FSFYC including the maximum quantity permitted and the maximum claim per serving.

- Standard 1.3.1 – Food Additives, clause 3 permits the addition of lutein as a food colour under Schedule 3 in processed foods specified in Schedule 1. Under Schedule 1 lutein is not permitted to be added as a colour to infant formula products

2.4.1.2 Therapeutic Goods, Australia

Lutein is eligible for use in Listed medicines on the Australian Register of Therapeutic Goods for supply in Australia, with no substance specific restrictions noted[5].

---

[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.

[5] Substances that may be used in Listed medicines in Australia www.tga.gov.au/cm/listsubs.htm. Accessed 26 February 2007.

Preparations of *Tagetes erecta* that meet the definition of a herbal substance in Regulation 2 of the TGA regulations 1991 are approved for use in Listed medicines[6].

2.4.1.3 Medicines and Medical Devices Safety Authority (Medsafe), New Zealand

Lutein is not a scheduled medicine in New Zealand and is not contained in any medicines currently registered in New Zealand[7].

~~2.4.1.4~~2.4.1.4 Dietary Supplements Regulations, New Zealand

Formatted: Bullets and Numbering

The New Zealand *Dietary Supplements Regulations 1985* currently regulate food-type and therapeutic-type dietary supplements in New Zealand. As a substance normally derived from food, lutein products are permitted to be sold as nutritive supplements under the current Dietary Supplements Regulations, with products currently available on the market.

The Dietary Supplement Regulations are currently under review with a proposal to separate regulation of products into food-type dietary supplements and therapeutic-type dietary supplements[8].

2.4.2 Overseas and International Regulations

FSANZ is not currently aware of any overseas or international regulations that permit the addition of lutein as a nutritive substance to infant formula or FSFYC.

In the United States of America crystalline lutein is 'generally recognised as safe' (GRAS) for use as an ingredient in specified categories of foods and beverages, including 'infant and toddler foods', but not in infant formula.

FSANZ is aware that lutein is permitted for use as a food colour in several international regulations but not for addition to infant formula, for example European Council Directives[9].

The Applicant has indicated that in addition to making an application to FSANZ they making simultaneous applications to other regulatory agencies internationally to permit the addition of lutein to infant formula and FSFYC.

2.5 Ministerial Policy Guidelines

FSANZ must have regard to any written policy guidelines formulated by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) when developing and varying food standards (See section 4). The Ministerial Council is currently developing a policy guideline on the addition of substances other than vitamins and minerals to foods.

---

[6] Personal communication, Michele McLaughlin, Therapeutic Goods Administration, Australia, 14 March 2007
[7] Personal communication Carol Smith, Medsafe, Ministry of Health, New Zealand, 15 March 2007.
[8] New Zealand Food Safety Authority, discussion paper *Proposed Changes to the Regulation of Dietary Supplements,* Feb 2007.
[9] European Parliament and Council Directive 94/36/EC (1994). *Official Journal of the European Communities.* http://ec.europa.eu/food/fs/sfp/addit_flavor/flav08_en.pdf. Accessed on 26 February 2007.

It is expected that this policy guideline will not be adopted by the Ministerial Council until late 2007.

2.6 Current Market

2.6.1 Application A594 – Infant Formula

2.6.1.1 Domestic Market

Four major brands of infant and follow-on formula are available on the market in Australia and New Zealand. 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. However, as lutein is not a permitted nutritive substance in the Code, there are no infant formula products with added lutein available on the domestic market.

2.6.1.2 International Market

Given the global nature of the manufacture of infant formula, it is a cost advantage for companies to manufacture one formulation for worldwide distribution. Also, the composition of formula is more likely to reflect international standards to reduce any potential barriers to trade. FSANZ is not currently aware of infant formula or FSFYC produced internationally that contain lutein as a nutritive substance.

2.6.2 Application A597 – Formulated Supplementary Foods for Young Children

2.6.2.1 Domestic Market

The majority of FSFYC available in Australia and New Zealand are milk-based supplementary drinks known as 'toddler formula'. FSANZ is not aware of other products that are currently manufactured to the FSFYC provisions.

Toddler formula is generally promoted as a supplementary milk drink for children aged over 12 months of age and is recommended to be prepared in water. In addition toddler formulas are sometimes promoted as being suitable as a replacement for milk in other foods e.g. custards.

FSANZ is aware of only a small number of manufacturers/importers of FSFYC in Australia and New Zealand. On the whole, the market for these products is believed to be relatively small and discrete, although possibly growing. Generally the manufacturers of FSFYC are also manufacturers of infant formula.

2.6.2.2 International Market

FSANZ is not currently aware of FSFYC produced internationally containing lutein as a nutritive substance.

3. The Issue

3.1 Application A594 – Infant Formula

Lutein is found naturally in varying quantities in breast milk, and in some foods that might be consumed by infants after six months of age. There is a potential benefit from lutein for infants in supporting eye health. Lutein is not currently permitted as a nutritive substance in infant formula. Therefore, formula-fed infants do not potentially benefit from consuming optimal levels of lutein in their diet. The Applicant has requested that lutein be permitted as a nutritive substance in infant formula.

3.2 Application A597 – Formulated Supplementary Foods for Young Children

Lutein is found naturally in many fruits and vegetables that young children are likely to consume. There is a potential benefit from lutein for young children in supporting eye health. Currently there is no permission to add lutein as a nutritive substance to FYSFC. Therefore, those children who consume FYSFC as part of their diet do not potentially benefit from consuming optimal levels of lutein. The Applicant is requesting permission for lutein to be added as a nutritive substance to FSFYC.

4. Objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in *Food Standards Australia New Zealand Act 1991* (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.

5. Key Assessment Questions

1. What are the benefits for formula-fed infants (less than 12 months old) and/or young children (1-3 years old) of consuming infant formula or FSFYC that contains lutein?

- Is there an effect on growth and development including eye development?
- Is there an optimal intake/level of lutein for health?
- Is there a minimum effective level of lutein?
- Is there a level at which no more benefit can be derived?

2. What are the risks for formula-fed infants who consume infant formula and/or for young children who consume FSFYC, that contain lutein derived from marigold?

3. Is the proposed form of lutein bioavailable for formula-fed infants and young children?

4. Does the proposed form of lutein effectively deliver the benefits identified for formula-fed infants and young children who consume FSFYC?

5. What level of lutein is found in breast milk and how does this compare to the levels proposed for infant formula?

RISK/BENEFIT ASSESSMENT

5.1 Lutein in Infant Formula and Formulated Supplementary Foods for Young Children

The Applicant has submitted a number of published reports in support of the desirability of adding lutein to infant formula and FSFYC. These reports focus predominantly on the role lutein plays as a protective optical filter in the eye, the levels of lutein found in breast milk, and the bioavailability of lutein when supplied as part of infant formula.

An evaluation of the scientific data on the bioavailability of the proposed form of lutein from infant formula and FYSFC, and the role of lutein in eye health, particularly in infants and young children, will be presented in the Draft Assessment Report.

5.2 Safety of Lutein for Infants and for Young Children

The Applicant has submitted a number of published reports in support of the safety of lutein, including an evaluation of lutein by the Joint FAO/WHO Expert Committee on Food Additives and Contaminants (JECFA).

Lutein was evaluated by JECFA in 2004, when an Acceptable Daily Intake (ADI) of 0-2 mg/kg body weight/day was established. The ADI is based on a No Observed Effect Level of 200 mg/kg body weight/day (the highest dose tested) in a sub-chronic toxicity study in rats. A safety factor of 100 was applied.

All studies evaluated by JECFA, including a developmental toxicity study in rats and a 52-week study in monkeys to evaluate ocular effects, indicated no adverse toxicological effects attributable to lutein.

An evaluation of the safety data for lutein, particularly in regard to its safety for infants and young children, will be presented in the Draft Assessment Report.

To assist in the assessment of the potential risks and benefits of permitting the addition of lutein as a nutritive substance to infant formula products and/or formulated supplementary foods for young children, FSANZ seeks comment on the questions raised in Section 5 – Key Assessment Questions above.

RISK MANAGEMENT

6. Risk Management Issues

At Initial Assessment, two potential risk management issues have been identified. FSANZ will consider management of these risks and any other identified risks at Draft Assessment. Submitter comments received during the public consultation period will be considered at Draft Assessment.

6.1 Labelling, including nutrition, health and related claims

6.1.1 Application A594 – Infant Formula

Standard 2.9.1 of the Code prescribes the general labelling and packaging requirements for infant formula products. Clause 20 of Standard 2.9.1 prohibits claims on infant formula and follow-on formula in reference to the presence of any nutrient or nutritive substance. However, if an infant formula or follow-on formula contains an added nutrient or nutritive substance then this must be included in the statement of ingredients and the average quantity (added and naturally present) must be declared on the label.

FSANZ is currently considering a revised approach to nutrition, health and related claims. It is proposed in draft Standard 1.2.7 – Nutrition, Health and Related Claims that the above approach will be maintained. Therefore, claims on infant formula and follow-on formula that relate to the presence of any nutrient or nutritive substance will remain prohibited.

In addition, there are voluntary codes of practice that regulate the marketing of breast-milk substitutes in Australia (Department of Health and Ageing, 1992), and New Zealand (Ministry of Health, 1997, and New Zealand Infant Formula Marketers Association, 1997), which aim to ensure the appropriate marketing and distribution of these products.

6.1.2 Application A597 – Formulated Supplementary Foods for Young Children

Standard 2.9.3 of the Code currently prescribes specific labelling requirements for vitamins and minerals (added and naturally occurring) in FSFYC. Labelling of nutritive substances other than vitamins and minerals must comply with the generic labelling requirements outlined in Standard 1.2.4 – Labelling of Ingredients and Standard 1.2.8 – Nutrition Information Requirements of the Code.

These Standards require, among other things, that the presence of a nutritive substance be declared on the label in the statement of ingredients, and in a nutrition information panel if a claim is made in relation to the food.

Draft Standard 1.2.7, which will regulate the use of nutrition content claims and health claims, will apply to FSFYC, unless claims are otherwise prescribed or prohibited under Standard 2.9.3. The need for specific labelling requirements for FSFYC with added nutritive substances will be considered at Draft Assessment.

Question:
1. Should FSFYC with added lutein be permitted to make nutrition content claims and/or health claims in relation to the presence of lutein?

6.2 Levels of Addition

6.2.1 Application A594 – Infant Formula

The Applicant is seeking permission to add lutein at a maximum concentration of 250 µg/L in infant formula and 500 µg/L in follow-on formula. The Applicant has requested a greater concentration of lutein in follow-on formula to reflect that follow-on formula will comprise a smaller proportion of the progressively diversified diet of infants aged from six months.

The appropriate level of addition of lutein to infant formula and follow-on formula will be considered at Draft Assessment. The request to permit twice the concentration of lutein in follow-on formula compared with infant formula will be assessed, and take into account lutein obtained from other foods by infants aged from six months.

In addition to a maximum concentration of lutein, a minimum concentration of lutein will also need to be considered based on the minimum amount of lutein shown to provide benefit to the consumer.

6.2.2 Application A597 – Formulated Supplementary Foods for Young Children

Similarly to follow-on formula, the Applicant is seeking permission to add lutein to FSFYC at a maximum concentration of 500 µg/L. The Applicant notes that some of the richest sources of lutein are some of the least preferred foods of young children and that FSFYC comprise only a portion of the progressively diversified diet of young children.

The appropriate level of addition of lutein to FSFYC will be considered at Draft Assessment. In determining an appropriate level of addition of lutein to FSFYC, the amount of lutein contributed by other foods in the diet of young children will need to be considered. Also, the level of addition will need to take into account the potentially broader range of foods that may comprise FSFYC.

Question:
2. If permitted, what levels (i.e. minimum and maximum) of lutein are appropriate to add to infant formula, follow-on formula and/or FSFYC?

7. Regulatory Options

7.1 Application A594 – Infant Formula

FSANZ is currently considering two regulatory options for Application A594:

- Option 1 – Maintain *status quo* by not amending the Code to permit the addition of lutein as a nutritive substance in infant formula and follow-on formula; and

- Option 2 – Amend Standard 2.9.1 to permit the addition of lutein as a nutritive substance at a maximum concentration of 250 µg/L in infant formula and 500 µg/L in follow-on formula.

7.2 Application A597 – Formulated Supplementary Foods for Young Children

FSANZ is currently considering two regulatory options for Application A597:

- Option 1 – Maintain *status quo* by not amending the Code to permit the addition of lutein as a nutritive substance in FSFYC; and

- Option 2 – Amend Standard 2.9.3 to permit the addition of lutein as a nutritive substance at a maximum concentration of 500 µg/L in FSFYC.

8. Impact Analysis

8.1 Affected Parties

The parties affected by these Applications are: **consumers** being formula-fed infants and young children consuming FSFYC and their **carers**; **industry** being Australian and New Zealand manufacturers and importers of infant formula and FSFYC; and the **Governments** of Australia and New Zealand.

8.2 Cost-Benefit Analysis

This analysis provides a preliminary assessment of the potential impacts of the regulatory options on the affected parties for both Application A594 and Application A597. A full cost benefit analysis will be undertaken at Draft Assessment and will identify impacts that are specific to each Application.

8.2.1 Consumers

It is likely that maintaining the *status quo* will have minimal impact on consumers of infant formula and FSFYC, as these products will continue to be available for their caregivers to purchase. Adding lutein to infant formula and FSFYC would provide formula-fed infants and young children consuming FSFYC with an additional source of lutein in their diet. In addition, it would provide caregivers with increased choice as products with and without added lutein would be available for purchase. It is unknown what costs would be added by the manufacturers of these products however any costs are expected to be passed on to caregivers who choose to purchase infant formula and FSFYC with added lutein.

Assessment of the efficacy and safety of adding lutein to infant formula and FSFYC, to be undertaken at Draft Assessment, will identify any potential nutritional benefits and risks for consumers if lutein is present in these products.

8.2.2 Industry

There are no additional benefits for industry of maintaining the *status quo.* A permission to allow the voluntary addition of lutein to infant formula and/or FSFYC allows industry to be innovative and produce new products for the Australian and New Zealand markets, and potentially international markets. As the addition of lutein to infant formula and/or FSFYC would be a voluntary permission, there should not be additional barriers to trade. While there would be a cost to manufacturers to add lutein to infant formula and/or FSFYC, it is expected that this cost will be passed on to consumers at the point of sale.

8.2.3 Government

It is expected that there would be minimal impact for Government for either regulatory option.

Question:
3. What is the likely impact on consumers, industry and government from maintaining the *status quo* and of permitting the addition of lutein as a nutritive substance to infant formula and/or FSFYC?

8.3 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 these Applications is required before such a comparison can be made. A comparison of options will therefore be provided at Draft Assessment for both applications.

COMMUNICATION

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 additional communication strategies are required for Draft and Final Assessments.

9. Communication and Consultation Strategy

9.1 Public Consultation

This Initial Assessment Report is intended to seek early input on the likely regulatory impact of both Application A594 and Application A597. At this stage FSANZ is seeking public comment to assist it in assessing these Applications and is particularly interested in receiving further information on the questions asked throughout this Report.

Although the two Applications have been presented together in this Initial Assessment Report, feedback on specific issues relevant to each Application would be useful.

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.

9.2 World Trade Organization

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's and New Zealand's obligations under the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures 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

After considering the requirements for Initial Assessment as prescribed in section 13 of the FSANZ Act, FSANZ has decided to accept the Application for the following reasons:

Application A594 – Infant Formula Products:

- The Application seeks approval to add lutein to the list of permitted nutritive substances in infant and follow-on formulas. Such an approval, if accepted, would warrant a variation to Standard 2.9.1 of the Code.

- There is currently no permission in the Code for infant formula and follow-on formula to contain lutein as a nutritive substance.

- 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 2.91 that could achieve the same end.

- At this stage no other relevant matters are apparent.

Application A597 – Formulated Supplementary Foods for Young Children:

- The Application seeks approval to add lutein to the list of permitted nutritive substances in formulated supplementary foods for young children. Such an approval, if accepted, would warrant a variation to Standard 2.9.3 of the Code.

- There is currently no permission in the Code for formulated supplementary foods for young children to contain lutein as a nutritive substance.

- 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 2.9.3 that could achieve the same end.

- At this stage no other relevant matters are apparent.

References

Alves-Rodrigues A, and Shao A (2004). The science behind lutein. *Tox Letters* 150:57-83.

Department of Health and Ageing, Australian Government (1992). Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement. http://www.health.gov.au/internet/wcms/publishing.nsf/content/health-pubhlth-publicat-document-brfeed-maif_agreement.htm/$FILE/maif_agreement.pdf. Accessed on 21 February 2007.

Ministry of Health, New Zealand (1997). Infant Feeding: Guidelines for New Zealand Health Workers. http://www.moh.govt.nz/moh.nsf/ea6005dc347e7bd44c2566a40079ae6f/9313e0a0ecc2d8644c256671000e563b/$FILE/infant1.pdf. Accessed on 21 February 2007.

New Zealand Infant Formula Marketers' Association (1997). Code of Practice for the Marketing of Infant Formula. http://www.nzifma.org.nz/NZIFMA/Codeofpractice.html. Accessed on 21 February 2007.

USDA (United States Department of Agriculture. National Nutrient Database for Standard Reference), Release 19: Lutein + zeaxanthin common Measure, sorted by nutrient content. http://www.nal.usda.gov/fnic/foodcomp/Data/SR19/nutrlist/sr19a338.pdf Accessed 6/03/2007.