



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

6 August 2008
[13-08]

PRELIMINARY FINAL ASSESSMENT REPORT

PROPOSAL P274

REVIEW OF MINIMUM AGE LABELLING OF FOODS FOR INFANTS

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 17 September 2008
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

In April 2003, the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) requested that FSANZ review the minimum age labelling requirements for infant foods, to resolve an apparent inconsistency with the revised Australian National Health and Medical Research Council (NHMRC) *Dietary Guidelines for Children and Adolescents* (incorporating *Infant Feeding Guidelines for Health Workers*), subsequently released in June 2003. The NHMRC guidelines recommend exclusive breastfeeding for the first six months of life and the introduction of solid foods at around six months. The review was to also consider and accommodate New Zealand infant feeding guidelines.

Standard 2.9.2 of the *Australia New Zealand Food Standards Code* (the Code) permits infant foods to be labelled as suitable ‘from four months’, which is inconsistent with the recommended age for the introduction of solids in the NHMRC infant feeding guidelines. The inconsistency between the current minimum age labelling on infant foods (from four months) and infant feeding recommendations (around six months) has the potential to create confusion for consumers (i.e. parents/carers) as to the appropriate timing for the introduction of solids to infants.

This Proposal was initiated in 2003, but after the release of the Draft Assessment in October 2004, work on this Proposal was delayed due to other Ministerial Council priorities.

Two recent developments provided an impetus for recommencing work on the Proposal in August 2007: the publication in June 2007 of the draft New Zealand *Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2 years)*¹ revising the previous recommended age for the introduction of complementary solid foods from ‘around four to six months’ to ‘around six months’ and the recommendation of the 2007 Australia Parliamentary Inquiry into the health benefits of breastfeeding² which recommended that FSANZ amend the labelling requirements for foods for infants to align with the NHMRC Dietary Guidelines.

FSANZ released a targeted consultation paper on 5 October 2007 which provided interested parties with an opportunity to comment on the proposed regulatory approach and the key recommendations being considered, prior to the Final Assessment.

In May 2008, the New Zealand Ministry of Health released the finalised *Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2 years)*³ recommending the age for the introduction of complementary solid foods be ‘around six months’. The revised Guidelines also recommend that appropriate complementary solid foods should be introduced when an infant is at the appropriate stage of development, which will vary from infant to infant.

Also in 2008, in response to issues raised in the consultation paper, additional targeted consultation was undertaken with key stakeholders.

¹ New Zealand Ministry of Health, *Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2): A Background Paper*, Draft for consultation (2007).

² House of Representatives Standing Committee on Health and Ageing, *The Best Start, Report on the inquiry into the health benefits of breastfeeding*, Canberra, Commonwealth of Australia 2007

³ New Zealand Ministry of Health, *Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2): A Background Paper*, (2008).

On the basis of issues raised through consultation, plus the recent release of the New Zealand Guidelines, updated cost information provided by industry, and the revision of FSANZ's risk assessment to consider more recent scientific evidence, particularly with regard to allergies, FSANZ decided in June 2008 to undertake a Preliminary Final Assessment.

This Preliminary Final Assessment Report provides an opportunity for consultation on FSANZ's consideration of the issues raised in consultation, the proposed regulatory approach and the key recommendations being considered, prior to the Final Assessment.

In particular, FSANZ will seek comment on the:

- proposed amendments to Table 2 to Clause 8 regarding the reference recommended dietary intake (RDI) value for iron for labelling purposes;
- revised risk assessment and updated costs analysis;
- proposed transition period; and
- proposed approach to age and / or stage labelling of first complementary foods.

Regulatory Options

Two options have been identified for this Proposal:

1. Reject the proposal thus maintaining the *status quo* i.e. retaining the minimum reference age of four months for infant food labelling; or
2. Amend Standard 2.9.2 by varying the minimum reference age on infant food labelling to 'around six months'.

Preferred Approach

To amend the minimum age labelling permitted on infant foods in Standard 2.9.2 from '4 months' to 'around 6 months' in accordance with the infant feeding recommendations of Australia and New Zealand (Option 2).

In addition, amend the warning statement under current paragraph 5(3) (c) to 'not for infants under the age of 4 months' and appear in a new paragraph 5(5) (b).

Minor amendments consequential to the minimum age labelling of 'around 6 months', and a change in the reference RDI for iron are also proposed.

The preferred approach is Option 2 because it:

- provides consistency with the infant feeding recommendations in Australia and New Zealand thereby reinforcing parent/carer education and infant health promotion;
- continues to protect the health and safety of infants;

- provides parents/carers with sufficient information in relation to the timing and consistency of infant foods so they can make appropriate choices;
- permits flexibility and recognition of the natural variation of individual infants and their developmental needs in relation to infant food choices;
- maintains the harmonisation of regulations for Australia and New Zealand; and
- provides net benefits to affected parties and is in line with minimum effective regulation.

Consultation and Communication

The Initial Assessment Report for this Proposal was released in July 2003. A total of 34 submissions were received, with the majority of submitters supporting an amendment to the current Standard; however views differed between age referencing and a ‘stages of development’ approach to the labelling of infant foods.

In October 2004, FSANZ released the Draft Assessment Report which proposed amending the minimum age labelling requirement of foods for infants to ‘around 6 months’. Of the 12 submissions received in response to the Draft Assessment, almost all supported amending the minimum reference age to ‘around six months’ with one industry submitter supporting the *status quo*. Some submitters supported a modified ‘stages of development’ approach.

In August 2007, FSANZ recommenced work on the Proposal, releasing a consultation paper on 5 October 2007 which provided interested parties with an opportunity to comment on the proposed regulatory approach and the key recommendations being considered prior to Final Assessment. Of the 20 responses received, more than half supported the proposed regulatory approach; the New Zealand government supported ‘first stage’ labelling in addition to the proposed minimum age labelling and eight submissions supported the *status quo*. Among the submitters supporting the *status quo* were several medical specialists who suggested FSANZ delay any regulatory changes until the completion of allergy research currently underway. Submissions from Australian jurisdictions, infant health and breastfeeding organisations supported the regulatory approach, while industry submitters were divided in their support.

In December 2007, FSANZ convened the Infant and Child Health Scientific Advisory Group (ICSAG)⁴ to provide scientific advice on risk assessment issues relating to infants and young children, including issues related to this Proposal. ICSAG members generally agreed that the evidence supported the introduction of solid foods ‘at around six months of age’. However, this should not extend to more than seven months as this increases nutritional risk (e.g. iron and zinc deficiencies) and risk of developmental problems. ICSAG members also discussed the age of introduction of solid foods in relation to risk of immune-related diseases and concluded that breastfeeding should be continued for several months after the introduction of solids ‘at around six months of age’.

⁴ ICSAG is a scientific advisory group comprised of experts in gastroenterology, pediatrics and child health. Refer to Section 5.3

They also noted that it was not yet possible to provide advice to parents of certain children at high risk of developing allergy as the appropriate intervention studies have not been undertaken to date.

FSANZ has prepared an education and communication strategy aimed at informing target audiences of the proposed regulatory changes. The audiences identified are health professionals providing parent/carer education and advice on infant feeding, government bodies responsible for infant feeding recommendations, jurisdictions responsible for the enforcement of food regulations, infant food manufacturers and parents/carers of infants. FSANZ will be collaborating with government agencies and health organisations responsible for parent/carer education on infant feeding to ensure consistent key messages are delivered to the target audiences.

Implementation

Following the consultation period for this Preliminary Final Assessment, a Final Assessment Report including the draft variations to the Code will be prepared for consideration by the FSANZ Board. Notification of the Board's approval of the draft variations will be made to the Ministerial Council for consideration. Subject to any request from the Ministerial Council for a review, the variations will be gazetted, taking effect on the date of gazettal..

The existing transition provisions in Standard 1.1.1 allow a period of 12 months from gazettal for industry to comply with new labelling requirements. However, at Preliminary Final Assessment of this Proposal, FSANZ is recommending an 18-month transition period for the implementation of the proposed labelling changes. This extended transition period is based on the longer (up to two years) shelf life of infant foods, the scale of the costs associated with a 12-month period (see Section 8.1), and the impost on a relatively small number of companies.

INVITATION FOR PUBLIC SUBMISSIONS

FSANZ invites public comment on this Preliminary Final Assessment Report based on regulation impact principles and the draft variation/s to the Code 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 Final Assessment of this Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 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, separate it from your submission and provide justification for treating it as confidential commercial material. Section 114 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. 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. Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au. There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

Submissions need to be received by FSANZ by 6pm (Canberra time) 17 September 2008.

Submissions received after this date will only be considered if 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.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, hard copy 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

CONTENTS

INTRODUCTION	2
1. BACKGROUND	3
1.1 <i>Infant Feeding Recommendations</i>	3
1.2 <i>Current Standard</i>	5
1.3 <i>International Regulation of Minimum Age Labelling</i>	5
1.4 <i>Current labelling of Infant Foods</i>	6
2. THE ISSUE / PROBLEM	7
3. OBJECTIVES	7
4. KEY ASSESSMENT QUESTIONS	7
RISK ASSESSMENT	8
5. RISK ASSESSMENT ISSUES	8
5.1 <i>Nutrition assessment</i>	8
5.2 <i>Risk of allergy and other immune-mediated diseases</i>	9
5.3 <i>Advice from the Infant and Child Health Scientific Advisory Group</i>	10
5.4 <i>Risk Assessment Summary</i>	11
RISK MANAGEMENT	11
6. RISK MANAGEMENT ISSUES	11
6.1 <i>Consumer research conducted on the role of labelling on infant foods</i>	11
6.2 <i>Consistency with Australia and New Zealand policy</i>	14
6.3 <i>Role of labelling in consumer education</i>	15
6.4 <i>Other issues raised in submissions</i>	21
7. REGULATORY OPTIONS	26
7.1 <i>Option 1 – Reject Proposal thus maintaining the Status Quo</i>	26
7.2 <i>Option 2 – Amend the minimum age labelling requirements in Standard 2.9.2 by varying the minimum reference age to ‘around six months’</i>	26
8. IMPACT ANALYSIS	26
8.1 <i>Affected Parties</i>	26
8.2 <i>Benefit Cost Analysis</i>	27
8.3 <i>Comparison of Options</i>	30
COMMUNICATION AND CONSULTATION STRATEGY	31
9. COMMUNICATION	31
10. CONSULTATION	31
10.1 <i>Public consultation</i>	31
10.2 <i>External Advisory Group</i>	33
10.3 <i>Infant and Child Health Scientific Advisory Group (ICSAG)</i>	33
10.4 <i>World Trade Organization (WTO)</i>	34
11. CONCLUSION AND PREFERRED APPROACH.....	34
12. IMPLEMENTATION AND REVIEW	35
ATTACHMENTS	35
ATTACHMENT 1 - DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE	36
ATTACHMENT 2 - NUTRITION ASSESSMENT.....	38
ATTACHMENT 3 - RISK OF ALLERGY AND OTHER IMMUNE-MEDIATED DISEASES	50
ATTACHMENT 4 - TERMS OF REFERENCE: INFANT AND YOUNG CHILD SCIENTIFIC ADVISORY GROUP	53
ATTACHMENT 5 - SUMMARY OF RESEARCH WITH AUSTRALIAN HEALTH PROFESSIONALS	56
ATTACHMENT 6 - SUMMARY OF SUBMISSIONS TO THE DRAFT ASSESSMENT REPORT	58
ATTACHMENT 7 - SUMMARY OF COMMENTS TO THE CONSULTATION PAPER 5 OCTOBER 2007	70

INTRODUCTION

In April 2003, Food Standards Australia New Zealand (FSANZ) was requested by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) to review the minimum age labelling requirements for infant foods in Standard 2.9.2 – Foods for Infants, of the *Australia New Zealand Food Standards Code* (the Code). This was to resolve an apparent inconsistency with the revised National Health and Medical Research Council (NHMRC) *Dietary Guidelines for Children and Adolescents* (incorporating *Infant Feeding Guidelines for Health Workers*)⁵. The NHMRC guidelines recommend exclusive breastfeeding for the first six months of life and the introduction of solid foods at ‘around six months’. In addition, Ministers asked that a review of minimum age labelling also consider and accommodate New Zealand infant feeding guidelines.

In response, FSANZ prepared a Proposal in July 2003. Following the release of the Draft Assessment in October 2004, however, work on this Proposal was unfortunately delayed due to other Ministerial Council priorities.

Two recent developments provided an impetus for recommencing work on the Proposal: the publication in June 2007 of the draft New Zealand *Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2 years)*⁶ revising the previous recommended age for the introduction of complementary solid foods from ‘around four to six months’ to ‘around six months’ and the recommendation of the 2007 Australian Parliamentary Inquiry into the health benefits of breastfeeding⁷ which recommended that FSANZ amend the labelling requirements for foods for infants to align with the NHMRC Dietary Guidelines.

FSANZ released a targeted consultation paper on 5 October 2007 which provided interested parties with an opportunity to comment on the proposed regulatory approach and the key recommendations being considered, prior to the Final Assessment.

In May 2008, the New Zealand Ministry of Health released the finalised New Zealand *Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2 years)*⁸. These guidelines recommend exclusive breastfeeding for the first six months of life and the introduction of complementary solid foods at ‘around six months’. These guidelines also recommend that appropriate complementary solid foods should be introduced when an infant is at the appropriate stage of development, which will vary from infant to infant.

Also in 2008, in response to issues raised in the consultation paper, additional targeted consultation was undertaken with key stakeholders.

⁵ NHMRC Dietary Guidelines for Children and Adolescents (incorporating Infant Feeding Guidelines for Health Workers) (2003)

⁶ New Zealand Ministry of Health, *Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2): A Background Paper*, Draft for consultation (2007).

⁷ House of Representatives Standing Committee on Health and Ageing, *The Best Start, Report on the inquiry into the health benefits of breastfeeding*, Canberra, Commonwealth of Australia 2007

⁸ New Zealand Ministry of Health, *Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2): A Background Paper* (2008).

On the basis of issues raised through consultation, plus the recent release of the New Zealand Guidelines, updated cost information provided by industry and revision of the risk assessment to incorporate recent research, particularly with regard to allergies FSANZ decided in June 2008 to provide a Preliminary Final Assessment.

This Preliminary Final Assessment Report presents a preferred regulatory approach amending and discusses issues raised through consultation following the Draft Assessment, the consultation paper, and the recent targeted consultation. The Preliminary Final Assessment provides a further opportunity to comment on the proposed regulatory approach and the key recommendations being considered, prior to Final Assessment.

1. Background

1.1 Infant Feeding Recommendations

1.1.1 International

In March 2001, the World Health Organization (WHO) conducted an expert consultation on the optimal duration of exclusive breastfeeding⁹. The outcome of this consultation was a recommendation, applying to populations, of *exclusive breastfeeding for 6 months, with introduction of complementary foods and continued breastfeeding thereafter*. This revised the WHO's previous recommendation of exclusive breastfeeding for the first four to six months of life¹⁰. Subsequently, the 54th World Health Assembly (WHA) in May 2001 adopted a comprehensive resolution¹¹ on infant and young child feeding, which called on WHO Member States (including Australia and New Zealand):

to strengthen activities and develop new approaches to protect, promote and support exclusive breastfeeding for six months as a global public health recommendation, taking into account the findings of the WHO expert consultation on the optimal duration of exclusive breastfeeding, and to provide safe and appropriate complementary foods, with continued breastfeeding, for up to two years of age or beyond, emphasizing channels of social dissemination of these concepts in order to lead communities to adhere to these practices.

The Global Strategy for Infant and Young Child Feeding¹² was endorsed by the 55th WHA in May 2002 and encompasses the comprehensive resolution outlined above. The aim of the Strategy is to renew efforts to promote, protect and support appropriate infant and young child feeding. It builds upon past initiatives and addresses the needs of all children. The Strategy specifies the responsibilities of governments, international and non-governmental organisations and other concerned parties. It engages all relevant stakeholders and provides a framework for accelerated action.

⁹ World Health Organization (2002) The Optimal Duration of Exclusive Breastfeeding - Report of an Expert Consultation, Geneva, Switzerland, 28-30 March 2001

¹⁰ WHO Infant Feeding Recommendation. Wkly Epidemiol Rec. 1995; 70:119-120

¹¹ WHA 54.2 Infant and Young Child Nutrition

¹² World Health Organization (2003) Global Strategy for Infant and Young Child Feeding, Geneva, Switzerland

1.1.2 Australia

The Australian NHMRC *Dietary Guidelines for Children and Adolescents* (incorporating *Infant Feeding Guidelines for Health Workers*) reflect the WHO recommendations. The Guidelines recommend exclusive breastfeeding for the first six months of life and the introduction of solid foods at around six months, to meet the infant's increasing nutritional and developmental needs. In recognising the requirements of individual infants, the guidelines also state *infants' needs differ, and a small number may benefit from the introduction of solids before the age of six months, but not before four months*. Previously, NHMRC recommendations¹³ encouraged breastfeeding for the first four to six months of life and introduction of solids thereafter.

The importance of the NHMRC recommendations was further recognised by the 2007 Australian Parliamentary Inquiry into the health benefits of breastfeeding¹⁴. The Inquiry Report included a number of recommendations aimed at increasing breastfeeding rates in Australia. One of the recommendations was that FSANZ amend the labelling requirements for foods for infants to align with the NHMRC Dietary Guidelines, which recommend babies be exclusively breastfed for the first six months.

FSANZ notes that the Australian NHMRC *Dietary Guidelines for Children and Adolescents* (incorporating *Infant Feeding Guidelines for Health Workers*), released in June 2003 are due for review in 2008. The timeframe for the completion of this review and the consequences of this review in relation to the infant feeding guidelines are not known at this time.

1.1.3 New Zealand

In June 2007, the New Zealand Ministry of Health revised the *Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2 years)*¹⁵ and published a draft for consultation.

The final revised *Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2 years)* were released by the Ministry of Health in May 2008.

The Guidelines revised the recommended age for the introduction of complementary solid foods to 'around six months' of age. Previously the New Zealand *Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2 years)*¹⁶ recommended infants be fed exclusively on breast milk from birth to four-six months of age and preferably until at least 12 months, with appropriate complementary solid foods being introduced at around four to six months.

The revised New Zealand Guidelines also reflect the WHO recommendations that infants be fed exclusively on breast milk for six months, *with the introduction of complementary foods and continued breastfeeding thereafter*¹⁷.

¹³ NHMRC Dietary Guidelines for Children and Adolescents (1995)

¹⁴ Standing Committee on Health and Ageing, House of Representatives, Canberra, *The Best Start: Report on Health Benefits of Breastfeeding*. (2007).

¹⁵ New Zealand Ministry of Health, *Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2): A Background Paper*, Draft for consultation (2007).

¹⁶ New Zealand Ministry of Health, *Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2): A Background Paper*. (1999)

¹⁷ World Health Organization (2002) *The Optimal Duration of Exclusive Breastfeeding - Report of an Expert Consultation*, Geneva, Switzerland, 28-30 March 2001

The revised New Zealand guidelines also recommend that appropriate complementary solid foods should be introduced when an infant is at the appropriate stage of development, which will vary from infant to infant.

1.2 Current Standard

Standard 2.9.2 – Foods for Infants, provides the compositional and labelling requirements of foods intended and/or represented for use as foods for infants, excluding infant formula products, which are regulated by Standard 2.9.1 – Infant Formula Products. An infant is defined in the Code as a person up to the age of 12 months. In relation to minimum age labelling, subclause 5(3) of Standard 2.9.2 currently requires the label of an infant food to contain:

- a statement indicating the consistency of the food and the minimum age, expressed in numbers, of the infants for whom the food is recommended; and
- where the food is recommended for infants between the age of four-six months, in association with the statement required above, the words – *Not recommended for infants under the age of 4 months.*

In addition the label of an infant food must not include a recommendation, express or implied, that the food is suitable for infants less than four months of age (subclause 5(2)).

1.3 International Regulation of Minimum Age Labelling

1.3.1 Codex Alimentarius

Codex standards exist for Processed Cereal-Based Foods for Infants and Children (CODEX STAN 74-1981, revised 2006) and Canned Baby Foods (CODEX STAN 73-1981) and provide guidance on the labelling of infant foods. While the Codex standard for canned baby foods does not have a minimum age labelling requirement, the Codex standard for cereal-based foods includes the requirement for *the label to indicate clearly from which age the product is recommended for use. This age shall not be less than six months for any product.*

1.3.2 Other International Standards

1.3.2.1 European Commission (EC)

The EC Directive on processed cereal-based foods and baby foods for infants and young children (2006/125/EC) requires the mandatory labelling of infant food with:

a statement as to the appropriate age from which the product may be used, regard being had to its composition, texture or other particular properties. The stated age shall not be less than four months for any product.

1.3.2.2 United States of America (USA)

The *Code Of Federal Regulations* from the US Food and Drug Administration (FDA) on food labelling prescribes no specific regulation for the labelling of infant foods other than different nutrition information labelling (21CFR101.9(J)(5)) and ingredient labelling (21CFR105.65).

1.3.2.3 Canada

Division 25 of the Canadian *Food and Drug Regulations 1954* sets out the requirements for infant foods and allows the naming of foods to reflect their consistency. In addition, the Regulations do not allow labelling of an infant food that implies that the food is suitable for consumption by infants less than six months of age (B25.061 (1)).

1.4 Current labelling of Infant Foods

There are three major manufacturers of infant foods in Australia and New Zealand. Currently manufacturers label their products with the minimum age for which the food is recommended in accordance with Standard 2.9.2. There are a range of ages chosen by manufacturers for labelling including '4 months and up', '4-6 months onwards', 'from 6 months', '6 months and up', '6-7 months onwards', 'from 8 months' and '8-9 months onwards' depending on the manufacturer and product.

Manufacturers also provide additional labelling information to assist parents/carers in making appropriate infant food choices. This includes the uniform use of three stage colour coding, in association with reference age labelling, to differentiate products corresponding to these reference ages. Some manufacturers also label infant foods with 'stages' (1st, 2nd, and 3rd Foods or Stage 1, 2 and 3) as an indication of developmental timing (beginner/starter) and combine these with age references.

The 'age' reference helps distinguish between different textures of infant foods, which change to meet the developmental requirements of infants as they grow. Infant foods labelled as suitable 'from 4 months' are a smooth, pureed texture with no lumps. The texture of infant food when labelled 'from 6 months' may still be a smooth puree or may change to a puree or mashed consistency with soft pieces which encourage the acts of biting and chewing. From about nine months molar teeth may have erupted, allowing infants to grind their teeth and bite and chew soft lumpy textures. As infants are also able to sit unsupported and their fine motor co-ordination is developing, self-feeding is encouraged. Infant foods labelled suitable for infants over nine month old are of a soft texture but include chunks to meet changing developmental requirements.

Internationally 'stage' and 'phase' approaches are used to label for the consistency of infant foods. A 'stages' approach may be used in conjunction with age labelling or, as in the case of a leading infant food company in the USA, a 'stages' approach to labelling is used with no mention of age¹⁸ e.g. 1st Foods, 2nd Foods etc.

¹⁸ The Gerber Feeding Plan, www.gerber.com Accessed 1 July 2008

2. The Issue / Problem

The minimum age labelling required by Standard 2.9.2 is not consistent with infant feeding recommendations in Australia and New Zealand. Similarly, the labelling may be inconsistent with WHO recommendations on exclusive breastfeeding. This situation has the potential to create confusion for consumers (i.e. parents/carers), as the labelling of infant foods will conflict with the recommended timing for the introduction of solids to infants.

3. Objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 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 of this Proposal are to ensure that the regulatory requirements for the minimum age labelling of foods for infants:

- protect the health and safety of infants;
- provide adequate information for parents/carers to make appropriate choices for infant feeding; and
- are consistent with infant feeding guidelines in Australia and New Zealand;

4. Key Assessment Questions

The Risk Assessment addresses the following questions:

1. Are there nutritional and/or developmental advantages or disadvantages in delaying the introduction of solids to infants to around six months?

2. What are the health risks associated with the early (close to four months) and late (close to six months) introduction of solids to infants?

RISK ASSESSMENT

5. Risk assessment issues

The following section summarises the risk assessment undertaken by FSANZ. The full details of the risk assessment can be found at Attachment 2 – Nutrition Assessment and Attachment 3 – Assessment of Risk of Allergy and Other Immune-mediated Diseases

5.1 Nutrition assessment

The nutrition assessment examines the introduction of solid foods between the ages of 4-6 months, to determine whether delaying solid food introduction to around six months of age will have an adverse impact on the nutritional and developmental outcomes for infants.

The following issues are considered:

- the potential for displacement of human breast milk and/or infant formula, any changes in energy intake, and whether growth outcomes are adversely affected;
- the capacity of infant kidneys to deal with the higher solute load of solid foods prior to six months of age;
- the impact on iron and zinc status, particularly in pre-term infants; and
- the influence of feeding practices during infancy on later food preferences.

If solids are introduced earlier in an infant's life, then this may displace intake of breastmilk or infant formula which in turn may affect nutrient and energy intake and potentially growth and development. The evidence from three intervention studies consistently showed that the introduction of solids at three-four months of age reduced breast milk intake. However, the evidence from these studies, as well as seven observational studies, indicates that the timing of solid food introduction does not significantly affect the rate of increase in weight and length of the infant.

A further concern in relation to the timing of solid food introduction is the ability of the infant kidney to concentrate soluble waste. Human breast milk and infant formula have a potential renal solute load (RSL) that is suitable for the developing kidney whereas most solid foods have a higher potential RSL; potentially increasing the risk of dehydration. While FSANZ was unable to identify any studies that directly assessed changes in RSL or water balance with the introduction of solid food during infancy, the greatest risk of negative water balance is during times of illness. However, the self-limiting capacity of infants to reduce their intake of solid foods during illness is likely to mitigate the potential risk.

Between the ages of four to six months, human breast milk or infant formula is generally considered sufficient to meet the iron and zinc needs of infants to six months of age.

By contrast, there is a view that a delay in the introduction of solid foods to around six months, as opposed to their earlier introduction, could place infants at risk of inadequate iron and zinc at a later age. FSANZ has not been able to identify any direct evidence addressing these issues. Evidence from two studies provides some indication that exclusive breastfeeding to six months of age does not increase the risk of iron deficiency at a later age. From this, it could be inferred that delaying the introduction of solids to six months does not have a detrimental effect on iron status biomarkers. It is expected that the outcomes on zinc status would be similar to, and certainly no worse than those for iron, as infants have a better storage of zinc compared to iron in the first six months of life.

There is emerging evidence suggesting that the timing of solid food introduction can influence later dietary outcomes and food preferences, however it is too early to draw conclusions about the impact this might have on recommended infant feeding practices.

It has also been suggested that pre-term infants may be at greater risk of iron and zinc deficiencies than full-term infants as a result of delaying the introduction of solids. FSANZ has been unable to identify any studies that confirm or refute this view.

Thus, based on the available evidence, delaying the introduction of solid foods to around six months of age is unlikely to have any discernible positive or negative effect on the nutritional or developmental outcomes of infants.

5.2 Risk of allergy and other immune-mediated diseases

Allergic diseases are caused by abnormal immune responses to otherwise harmless substances including food. Prevention of food allergy in infants and children continues to be an active area of scientific investigation. Debate has recently entered into this field based on studies suggesting that delayed introduction of solid foods to the infant's diet can increase the risk of allergy as well as other immune-mediated diseases such as coeliac disease and Type 1 diabetes mellitus. Submissions made to FSANZ, in response to a consultation paper released in 2007, have raised this as an issue that needs to be considered in light of the widely-held view that childhood allergies are rising. A number of the submitters are currently taking part in a project to review the relevant scientific literature in this area.

There is general agreement in the medical literature that the introduction of solid food before three months of age can increase the risk of allergy. However, there is no clear consensus on the optimal age to introduce solid food beyond that age. For infants at risk of developing allergic disease, the medical literature until recently has suggested that delaying the introduction of known food allergens is at least harmless and may be beneficial. This view is now challenged by emerging evidence which suggests that delaying the first exposure to food may, in fact, increase the risk of developing allergy. This is based on the argument that immune tolerance to food allergens is driven by regular, early exposure to these allergens during a critical window of time in the early stages of infant development. Although the exact timing of this window is uncertain, some evidence suggests it is likely to be between four and six months of age.

It should be noted that the WHO recommendations on exclusive breastfeeding, and subsequent Australian Government advice, have not been set in the context of any potential role the timing of introducing solid food to infants may have on the development of such diseases.

The 4th edition of the New Zealand Food and Nutrition Guidelines for Healthy Infants and Toddlers, published in 2008, does address this issue and recommends delaying introduction until ‘around 6 months’, but was unable to include a reference to the 2008 discussion paper by Australasian authors (Prescott *et al.*, 2008) in Paediatric Allergy and Immunology Online. The discussion paper concludes that there is a growing case for further revising the recommended age for the introduction of complementary foods to ‘4 months’ while breastfeeding is maintained for at least 6 months where possible.

FSANZ considers that, at this stage, scientific information is inadequate to reach a firm conclusion on this issue. Preliminary information suggests that delay in the introduction of solid food to infants’ diet may contribute to the risk of developing allergy and other immune-mediated diseases. However, this is an emerging area of research and the potential role of the various factors, including infant feeding practices, in the development of allergy and other immune-mediated diseases, requires further investigation.

5.3 Advice from the Infant and Child Health Scientific Advisory Group

In December 2007, FSANZ convened the Infant and Child Health Scientific Advisory Group (ICSAG)^{19,20}. FSANZ convened this group to provide scientific advice on risk assessment issues relating to infants and young children. Terms of reference for ICSAG are provided in Attachment 4.

In relation to the recommended age to introduce solids, ICSAG members generally agreed that the evidence supported the introduction of solids ‘at around six months of age’. They also noted that this was a simpler message for parents and health care workers and accommodated the variability between infants and their nutritional needs compared with the previous message of ‘between four-six months’. However, members noted that delaying the introduction of solids (to as late as six months) in preterm infants potentially places them at greater risk of iron and zinc deficiencies. Similarly, it was not recommended to delay the introduction of solids to more than seven months in full-term infants as this increases nutritional risk (e.g. iron deficiency) and risk of development problems. In the light of these discussions, members concluded that the stage of an infant’s development was more important with regard to the introduction of solids, than ‘age’.

ICSAG members also discussed the implications of introducing solids at a certain age and risk of immune-related diseases. Members noted that continuing breastfeeding after the introduction of solids was associated with reduced rates of allergy, whereas exclusive breastfeeding beyond seven months may increase the risk of allergy and asthma. They noted that there was emerging evidence indicating the early introduction of certain food types such as eggs and peanuts reduced the risk but little evidence to support delaying their introduction. Members concluded that breastfeeding should be continued for several months after the introduction of solids ‘at around six months of age’. They also noted that it was not yet possible to provide advice to parents of certain ‘high risk’ (i.e. of developing allergy) children as the appropriate intervention studies have not been done to date.

¹⁹ ICSAG is a scientific advisory group comprised of experts in gastroenterology, pediatrics and child health.

²⁰ See Section 10.3 for current membership of the ICSAG.

5.4 Risk Assessment Summary

The available evidence on the relationship between the timing of solid food introduction and infant growth, kidney function and iron/zinc status shows that there are unlikely to be any adverse health effects from a delay in the introduction of solid foods to six months of age. While ICSAG members noted that a delay in the introduction of solids (to as late as six months) in pre-term infants potentially places them at greater risk of iron and zinc deficiencies, FSANZ has not been able to identify any studies confirming or refuting this opinion.

The evidence regarding the timing of the introduction of solids and risk of allergy and other immune-mediated diseases, such as coeliac disease and Type 1 diabetes, is emerging and no firm conclusions can be drawn at this time. However, preliminary indications are that the risk of allergy may be minimised if breastfeeding is maintained throughout the period of introducing solids, whereas the risk may increase if the introduction of solids is delayed beyond seven months. ICSAG members supported these preliminary findings.

RISK MANAGEMENT

FSANZ's risk assessment has highlighted the importance of appropriate timing of the introduction of solids to the individual development of an infant. In addition, potential risks to infants from the early or late introduction of solids have been identified. It is therefore important that these risks are appropriately managed and that parents/carers have sufficient information to make informed choices in feeding their infant.

6. Risk management issues

6.1. Consumer research conducted on the role of labelling on infant foods

In 2004, in the absence of published literature on the role of labelling in the education of and decision-making by parent/carers around infant feeding, FSANZ commissioned research²¹ with consumers and consulted with health professionals to help determine the most appropriate regulatory approach to the minimum age labelling of infant foods.

6.1.1 *Qualitative Consumer Research*

In January 2004, FSANZ commissioned surveys in both Australia and New Zealand to assist in the assessment of Proposal P274. Specifically, the purpose of the study was to:

- collect information to determine how primary caregivers made decisions around the weaning of infants;
- determine the influence of current labelling on these decisions; and
- assess alternate labelling options for minimum age suitability of infant foods.

²¹ A copy of the full report *A Qualitative Consumer Study Related to Food Labelling of Infant Foods* is available at <http://www.foodstandards.gov.au/newsroom/publications/foodlabellingofinfantfoodsapril2004/index.cfm>

The study found that the decision of ‘when’ and ‘how’ to introduce solids was, for most participants, formed over a period of time, and via a number of (solicited and unsolicited) sources. The three most important sources reported were: the child health nurse, reference materials including books and magazines, and informal mothers’/coffee groups.

Most participants relied on two main cues to indicate a baby’s readiness for solids: a strong interest in food (indicated by following food with eyes or reaching for food when others are eating) and disturbed sleep patterns. These were seen more as signs of hunger rather than developmental readiness. Although other physiological cues were mentioned, most participants did not understand that a number of cues, rather than one or two alone, are a better indication of readiness for solids.

The majority of New Zealand participants introduced solids at four months or just before, compared to about a quarter of Australian participants, with half introducing solids at five months. Australian participants were generally aware that six months was the recommended target age for introducing solids, irrespective of whether their own behaviour emulated this. In New Zealand, participants tended to refer to the target as an age range of four-six months, yet acknowledged that six rather than four was recommended.

Participants regarded food labels as helpful in the selection of foods once solids have been introduced, but labels had little if any influence on the decision to start introducing solid foods.

There was considerable and consistent self-reported evidence from the groups in both countries that ‘4 months’, ‘from 4 months’ or ‘from 4-6 months’ on a food label encourages the introduction of solids closer to four months, rather than closer to six months.

Participants also considered that in the future, when a first-time parent is exposed to an ‘around six months’ label on first foods, and receives no conflicting advice from trusted sources, it is highly likely that she or he would resist introducing solids until as close as possible to six months, depending on their child’s physiological cues.

First-time mothers placed greater importance on the age and texture information on labels, using the age recommendation as a guide to be used in conjunction with advice from a child health nurse, and often their own mother. Second-time mothers were much more likely to rely on their own experiences, instinct and with what worked or didn’t with their first child.

Texture and age were seen as the most important elements for decision-making about what foods to purchase between the time solids are introduced and 12 months. Most participants tended to be guided more by one than the other, although some used one in conjunction with the other to confirm a purchase decision. There was however no consistent preference for one over the other.

Labels that provide the following three core elements received universal endorsement:

- an easy to find texture descriptor;
- a consistent age recommendation, that offers flexibility through an age range; and
- colour coding.

However, there was no agreement on the usefulness of the word ‘stage’ relative to the age and texture information in the label concepts.

Over the whole study, there was no clear preference for keeping or excluding the 1st, 2nd, 3rd Stage reference. Generally first-time parents did not view the stage reference as being as useful or important as the age and texture information. However, some did consider it would be useful and provide indirect benefits to mothers, such as being an easy way to direct husbands and relatives to shop for the right food for their baby, as well as assisting sleep and time deprived mothers to quickly select products from the supermarket shelf.

While the stage information was useful for some parents, most participants found the clarity and structure of the age and texture information more useful.

Overall:

- most participants used signs of hunger to indicate an infant’s readiness for solids;
- labels had little if any influence on the decision to start introducing solid foods;
- those who did use labels found the age and texture information the most useful;
- the use of ‘around 6 months’ was considered likely to move the introduction of solids closer to 6 months; and
- labelling of ‘stages’ was generally considered of little additional benefit, although some participants did consider this could be of some use.

Overall, this consumer research suggests that mandating age and texture on a label would provide adequate information to enable an informed choice and protect the health and safety of infants. This approach would also be in line with minimum effective regulation.

Section 6.3.1 refers to further more recent consumer research provided by food industry with regard to age and stage labelling of first complimentary foods.

6.1.2 Public health professional interviews

In addition to the qualitative consumer research, FSANZ conducted telephone interviews on infant feeding with a number of health professionals or policy officers from all Australian jurisdictions in late November 2003. Details of participants and the discussion outcomes are provided at Attachment 5.

The results indicated that whilst all interviewees were aware of the revised NHMRC recommendation, the statement ‘around six months’ was being interpreted in several different ways; for example, ‘five-six months’, ‘ around six months depending on individual infant’ and ‘six months but earlier if the signs are there’. Generally the interpretations were centred on the age of six months, while allowing for individual variation in readiness for the introduction of solids.

In terms of labelling, a ‘stages with ages’ was the approach most preferred by health professionals.

A 'stage' approach was considered to be less prescriptive but an 'age' approach was considered somewhat clearer. Some interviewees also voiced concerns that parents who considered their infants to be developed may in fact misinterpret cues.

6.2 Consistency with Australia and New Zealand policy

Until recently, the NHMRC infant feeding guidelines and the New Zealand guidelines differed in their recommendations on the timing of introduction of solids (recommending at 'around six months', and 'from four-six months' respectively). This inconsistency was widely acknowledged in submissions to the Initial and Draft Assessment. However, with the recent (May 2008) release of the revised New Zealand *Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2 years)*, infant feeding guidelines for New Zealand are now consistent with the NHMRC infant feeding recommendations (both recommending 'around six months').

On a population level, the revised New Zealand guidelines recommend that infants be fed exclusively on breast milk to around six months of age, at which time complementary foods can be introduced with continued breastfeeding until the infant is at least one year of age, or beyond. The revised guidelines note the growth and development of the child, including the child's developmental stages and skills will ideally guide decisions on the duration of breastfeeding and the age for introducing complementary foods. The Guidelines note that the developmental stages and skills of the infant that signal readiness for complementary foods will vary from infant to infant, but that the ideal is to wait until the infant is around six months of age.

NHMRC recommendations also note that the age of introducing solids may vary on an individual basis and underpin the population health recommendation of exclusive breastfeeding until six months with the following:

Although exclusive breast-feeding to 6 months of age is recommended, more experience is needed to identify any subgroups that require earlier introduction of solids (but never before 4 months). Six months should be regarded as a group recommendation²².

Thus, it can be concluded that an age reference to 'around six months' on an infant food label supports the policies of both Australia and New Zealand. Further evidence for this conclusion was obtained from the interviews with health professionals (see Section 6.1.2) where a number of respondents considered that the term 'around six months' allows for the introduction of solids prior to six months, to meet individual need as required.

6.2.1 Consistency of labelling with infant feeding recommendations

The majority of submitters to the Draft and Initial Assessment supported labelling which is consistent with infant feeding guidelines and accommodates the individual variation of infants. This was seen as important to reaffirm the education messages and advice provided by health professionals to parents/carers.

²² NHMRC Dietary Guidelines for Children and Adolescents (incorporating Infant Feeding Guidelines for Health Workers) (2002), page 48

Consumer research suggests that having infant foods labelled ‘from 4 months’ encourages consumers to perhaps inappropriately start their child on solid foods at four months, when they may not be ready developmentally. Conversely, there is concern that a change in labelling could also mislead parents, who may inappropriately delay giving their ‘developmentally ready’ infant solid foods.

Some industry responses to the Consultation Paper expressed the view that infant feeding guidelines failed to take into account the nutritional and developmental needs of individual infants. They noted that some infants required the introduction of solids between four to six months to meet their nutritional needs. Some responders also felt the current age reference four-six months was much clearer for consumers than ‘around six months’ when coupled with ‘not recommended for infants under the age of four months’.

Findings from FSANZ’s consumer research study²³ highlighted considerable and consistent self-reported evidence from participants in both Australia and New Zealand that either a ‘4 months’, ‘from 4 months’ or ‘from 4-6 months’ label encourages the introduction of solids closer to four months (see Section 6.1). Many of the participants, upon reflection, indicated that had first stage (‘blue foods’) foods been labelled from ‘6 months’ they would have reconsidered and consequently delayed the introduction of solids for a few weeks to a month or more.

However, research participants did indicate that they interpreted ‘around six months’ to mean aiming for six months with two-three weeks leeway either side. In the context of this term being the first age on infant food labels, introducing solids closer to four months was viewed as highly inappropriate.

The proposed regulatory option to amend Standard 2.9.2 by varying the minimum reference age to ‘around 6 months’, reflects the policy guidelines in both Australia and New Zealand and of the World Health Organization. Also, it may indirectly minimise the potential adverse effects associated with the early introduction of solids.

6.3 Role of labelling in consumer education

Traditionally infant food manufacturers have labelled infant foods to indicate the suitability of their products for different infant ages by including colour coding. Parents/carers may use this information to choose products suitable for their infant. In addition parents/carers also receive information and advice on infant feeding from health professionals e.g. maternal and child health nurses, doctors, dietitians and nutritionists.

There was general consensus among submitters that the primary role of labelling is to enable parents/carers to make informed choices when purchasing infant foods appropriate for their infant’s developmental stage. Labelling was not seen as a key educational tool but rather a supportive one, to provide information that is consistent with the policy guidelines and advice provided by government and health professionals.

²³ TNS Social Research report *A Qualitative Consumer Study Related to Food Labelling of Infant Foods*.

This was confirmed by FSANZ's consumer research (see Section 6.1.1) which found the decision of when and how to introduce solids was informed over a period of time, and via a number of solicited and unsolicited sources, with the most important source of information and advice being the child health nurse.

Similarly, anecdotal evidence provided by several health professionals indicated that labelling was not an influential factor on the timing of introducing solids compared to the influence of health workers, family members and friends. This view was supported by the consumer research which concluded that food labels had little if any influence on the decision to start solids.

As noted above, the consumer research concluded that label information becomes much more useful and important in guiding the transition on to more textured foods when parents/carers begin regularly buying infant foods. Minimum age labelling information was also considered of use to first-time mothers when faced with pressure from parents or friends to provide solids much earlier than is recommended.

6.3.1 Age versus stage

In the Draft Assessment Report, FSANZ discussed possible options for minimum age labelling, including raising the minimum reference age, and /or replacing the reference to 'age' with an alternate scheme e.g. phases or stages.

There were divergent views amongst submitters as to whether 'age', 'stage' or a modified version of these label elements such as both age and stage, were required. Submitters tended to support 'age', or 'age' and 'stage', rather than a 'stage' only approach. Industry supported the use of 'age', with one manufacturer supporting both age and stage referencing.

In response to the October 2007 Consultation Paper, the majority of responders supported the proposed regulatory approach of mandatory age reference labelling, in conjunction with mandatory labelling of food consistency. This approach allows for additional voluntary labelling of stages by food manufacturers. However, the New Zealand Government indicated support for the stages of development approach to infant food labelling and proposed a modified approach. This approach would require the labelling statement 'around 6 months' to also have a mandatory requirement for words to the effect that the food is intended as a first complementary food for the infant. Several other respondents also noted the importance of physiological cues of readiness in the decision to introduce solids, but considered that 'stage' labelling rather than 'age' labelling could be confusing to consumers.

In proposing this additional labelling requirement, the New Zealand Government expressed concern that there are risks associated with using an 'age' only approach for infant food labelling as this does not take into account the physiological 'readiness' of the infant and could lead to inappropriate infant food choices. In particular, they consider that foods labelled as suitable for infants aged 'around 6 months' should be clearly identified as intended to be the first complementary foods.

FSANZ's consumer research found that food labels had little if any influence on the decision to start solids. First-time mothers placed greater importance on the age and texture information on labels, using the age recommendation as a guide in conjunction with advice from a child health nurse, and often their own mother.

In addition to an age reference, infant food manufacturers are currently required to label infant foods with a statement indicating the consistency of the food. FSANZ is proposing that this requirement continue. This ensures that the label provides sufficient information to parents/carers on both the timing and consistency of infant foods to allow them to make safe and appropriate choices.

FSANZ recognises that physiological ‘readiness’ rather than age alone, is the preferred basis for introducing solids. However, a stage-only approach would be a difficult message to convey on a label due to the amount of supporting information that would need to be provided to consumers to assist their decision making. FSANZ is therefore of the view that the age reference, in conjunction with consistency information is appropriate to the support role that labelling plays in the education of parents/carers. This approach also aligns with consumer preferences (see Consumer Research Section 6.1), and does not preclude infant food manufacturers from voluntarily adding a reference to stage.

Prescribing ‘age’, rather than ‘age’ and ‘stage’ is also in line with the FSANZ objective of ‘minimum effective regulation’ and aims to simplify enforcement processes. It also allows for industry innovation in using developmental variation in the labelling of infant foods. Current industry practice demonstrates the effectiveness of this approach with the provision of additional consumer information, such as ‘stages’ and colour coding, on infant food labels on a voluntary basis. FSANZ has no evidence that consumers are being misled by the provision of information in this format. It is also noted that all three major infant food manufacturers in New Zealand have voluntarily incorporated stage labelling and colour coding in addition to age labelling on infant foods. One of the two largest infant food companies in New Zealand (estimated market share of 78%, Section 8.2) has chosen to incorporate stage labelling on its labels. FSANZ considers it unlikely that new entrants to the infant food market would not follow this established market practice.

Targeted consultation with key manufacturers of infant food in Australia and New Zealand, and child health professionals in New Zealand was undertaken during preparation of this Preliminary Final Assessment particularly around the reference to age and/or stage on labels for first complementary foods for infants.

New Zealand infant food manufacturers with a significant market share currently include stage and colour coding in infant food labels on a voluntary basis, so were generally supportive of mandatory ‘first stage’ labelling in addition to age, if required. However key Australian infant food manufacturers were not supportive of mandating a ‘first stage’ approach. One Australian infant food manufacturer provided consumer research²⁴ that indicates either ‘around 6 months’, ‘4-6 months’ and ‘4+ months’ all achieved similar results with regard to the age descriptor that best described their babies readiness for solids. ‘Stage 1’ was the age indicator that was least selected by mothers as the best description of their babies readiness for solids.

A key New Zealand child health professional group supported the concept in principle of providing as much information as possible on infant food labels, including stages, to guide caregivers.

²⁴ Research into Mothers with Babies, Australia, Veda Advantage Solutions Group, March 2008.

However, they also considered that a minimum effective regulation approach of mandating age and consistency, along with the proposed revised warning statement (Section 6.3.3), was a sensible approach. It was noted that the proposed amendment to the Code would continue to allow manufacturers to voluntarily add extra information including stages and/or the use of colour coding.

In addition, FSANZ considers the mandatory requirement for a ‘first stage’ labelling statement could cause confusion for parents/carers. Parents/carers may expect to see subsequent labelling for other stages e.g. ‘stage two and three’ and may be confused by the labelling of ‘first stage’ only on infant foods.

Therefore, FSANZ’s preferred regulatory approach is to retain a mandatory age reference in conjunction with a mandatory requirement for a statement indicating the food consistency on infant food labels. FSANZ considers parents/carers are provided with adequate information on both the timing and consistency of infant foods to make safe and appropriate choices. Also, this recommendation is in line with minimal effective regulation and consumer research.

6.3.2 *Advisory statement*

At Draft Assessment, FSANZ sought comment on a proposed advisory statement, to be required on infant foods labelled ‘around 6 months’, which encourages parents/carers to consult a health professional for advice when introducing solids. This requirement recognised the importance of the decision to introduce solids and the developmental cues underpinning this decision. It also anticipated that the advisory statement would be seen as a positive, educative message, which would serve as a prompt for parents/carers to actively seek assistance (rather than relying on food labelling) when considering introducing solids.

Submitters at Draft Assessment generally did not believe this proposed advisory statement was justified, or that it would be particularly helpful to parents/carers. Some submitters expressed concerns that the presence of this advisory statement could be seen as medicalisation of infant foods. Industry submissions also highlighted the issue of available label space for accommodating such a statement in addition to other labelling requirements such as the mandatory warning statement.

Two respondents to the consultation paper supported the inclusion of the proposed advisory statement as they saw health professionals as appropriate sources of information on infant feeding.

However, FSANZ considers there is not sufficient justification for the mandatory inclusion of the advisory statement on the labelling of infant foods.

6.3.3 *Warning statement ‘Not recommended for infants under the age of 4 months’*

Current regulations require the warning statement *not recommended for infants under the age of four months* to be included on the label of infant food recommended for infants between four and six months. Furthermore, it is not permissible to include a recommendation, expressed or implied, that an infant food is suitable for infants less than four months.

Despite public health initiatives to encourage mothers to breastfeed longer and delay the introduction of solids, as mentioned in Section 5, there is evidence that infants younger than four months of age in both Australia and New Zealand are continuing to be fed solid foods. The Australian Institute of Family Studies recently released a report²⁵ indicating that at three months old, 11% of infants were fed solids. The percentage of infants on solids rose to 38% at four months and 62% at five months. At six months, 91% of infants had started solids.

The retention of the warning statement was strongly supported by submitters in consultations. Several alternative versions of the statement were suggested by industry and breast feeding advocacy groups in response to the consultation paper. Three infant food manufacturers recommended shortening the statement by omitting the word ‘recommended’. One breast feeding advocacy organisation considered the word ‘suitable’ should be used instead of ‘recommended’ as it better reflected the NHMRC dietary guidelines statement *there is almost universal agreement that solids should not be started before the age of 4 months*²⁶. Another breast feeding advocacy organisation recommended increasing the warning statement from infants under the age of four months to at least five months to be consistent with WHO guidelines.

The FSANZ consumer research indicated that only a minority of participants were aware of the warning statement ‘not recommended for infants under the age of 4 months’, until their attention was drawn to it. Most participants did not regard the co-existence of the warning statement and the ‘around 6 months’ recommendation on the label to be a problem, given they typically checked feeding decisions via a health professional or reference materials. A small number of participants, particularly in New Zealand, saw the potential for the dual advice to be confusing and considered they would have needed to seek clarification on this issue from their health professional.

The purpose of the warning statement is to protect infant health and safety by discouraging the early introduction of solid foods. As the concerns around the early introduction of solid foods remain valid, FSANZ is of the opinion that the warning statement should be retained.

After consideration of the alternative versions of the warning statement suggested by submitters, FSANZ supports omitting ‘recommended’ from the warning statement as this simplifies the warning statement without altering the meaning and is more consistent with infant feeding recommendations. In addition, given that the small size of infant food containers is a constraint for labelling requirements, the reduced text requirement of the mandatory warning statement is an advantage for manufacturers.

Therefore, FSANZ proposes that the warning statement be retained and amended to *not for infants under the age of 4 months* on the labels of those foods promoted as suitable from ‘around 6 months’.

²⁵ Australian Institute of Family Studies, 2006-2007 Annual Report, Growing Up in Australia -The Longitudinal Study of Australia Children, (2008),

²⁶ NHMRC Dietary Guidelines for Children and Adolescents (incorporating Infant Feeding Guidelines for Health Workers) (2003)

6.3.4 *Consistency that minimises the risk of choking*

Currently, subclause 2(4) of Standard 2.9.2 requires food intended for infants under the age of six months to be formulated and manufactured to a consistency that minimises the risk of choking. The corresponding editorial note explains the intent of subclause 2(4) and describes the required consistency as being ‘soft and free of lumps’.

In addition to the above requirement, paragraph 5(3)(a) of Standard 2.9.2 requires manufacturers to include a statement on the label of foods for infants which indicates the consistency of the food.

At Draft Assessment, FSANZ proposed removing subclause 2(4) on the grounds that it was considered redundant given the ‘consistency’ declaration requirement of paragraph 5(3)(a), a mandatory warning and the proposed advisory statement. FSANZ considered that these provisions were sufficient to enable parents/carers to select suitable products for their infants and thereby minimise the risk of choking. The enforceability of this clause was also questioned during stakeholder consultation on the Proposal.

While industry submissions in response to the Draft Assessment Report favoured the removal of subclause 2(4), the New Zealand government supported the retention of the clause as it provided an extra assurance for carers that first solids for infants would be of an appropriate consistency, independent of labelling.

Public health organisations and jurisdictions responding to the consultation paper supported the retention of the amended subclause 2(4) although a breast feeding organisation was concerned that all foods suitable for infants around 6 months could be unnecessarily finely pureed as a consequence. In response, FSANZ notes that all infant foods must be labelled with a consistency statement to assist parents in making appropriate food choices for their infants.

In response to New Zealand Government concerns and noting the decision not to proceed with the mandatory advisory statement (as discussed in Section 6.3.2), FSANZ proposes that subclause 2(4) be retained. In addition FSANZ recommends subclause 2(4) be amended to incorporate the related editorial note which notes the intent is that the food should have a texture that is soft and free of lumps. This would clarify the requirements with regard to consistency and therefore assist enforcement.

6.3.5 *Additional compositional provisions for cereal-based foods*

Clause 3 of Standard 2.9.2 currently permits cereal-based food containing more than 70% cereal and promoted as being suitable for infants over the age of six months, to contain thiamin, niacin, vitamin B6, vitamin C, folate and magnesium²⁷ added to restoration levels, and mandates a minimum amount of iron (20 mg/100 g). In contrast, subclause 3(2) permits cereal-based food containing more than 70% cereal manufactured and marketed as suitable for infants from four months of age the voluntary addition of iron and vitamin C only. There is no mandatory requirement for the addition of iron.

²⁷ The addition of the listed vitamins and minerals are permitted in accordance with the permitted forms in Schedule 1 of Standard 2.9.1 - Infant Formula Products

As the preferred approach is to amend the minimum age labelling of infant foods to ‘around six months’, the subclause 3(2) referring to cereal-based foods as suitable for infants from four months of age is no longer relevant.

Therefore FSANZ is proposing that clause 3 of Standard 2.9.2 be amended to omit subclause 3(2) (see Attachment 1).

6.4 Other issues raised in submissions

6.4.1 International trade barriers

In developing and varying standards, FSANZ must also have regard to the promotion of consistency between domestic and international food standards and the desirability of an efficient and internationally competitive food industry.

Submissions received from industry expressed concern that differing labelling requirements to those required in Europe and USA would create trade barriers for international infant nutrition companies if they chose to import infant foods produced overseas.

As noted in Section 6.2, the proposed draft variations to Standard 2.9.2 support the infant feeding guidelines of both Australia and New Zealand, and maintains consistency of standards for trade purposes between the two countries. The proposed amendments to Standard 2.9.2 align with the Codex standard for cereal-based foods²⁸ which includes the requirement for *the label to indicate clearly from which age the product is recommended for use, and that this age shall not be less than six months for any product.*

Also the proposed amendment does not introduce a new requirement to requirement for labelling on infant foods, including those that may be imported into Australia or New Zealand, but is a revision of existing labelling requirements. While companies may need to re-label products for import, this is the current situation and therefore does not create additional trade barriers.

FSANZ considers it unlikely that this Proposal will create trade barriers and have an effect on international trade.

6.4.2 Transitional arrangements

Subclause 1(2) of Standard 1.1.1. provides for a transition period of 12 months after the commencement of a variation to the Code, to allow manufacturers and importers of foods time to comply with new regulations.

However, industry submitters to the Draft Assessment of this Proposal requested a longer transition period (two years) to facilitate an economical changeover of labels for infant foods, with an extended stock-in-trade provision of two years, to avoid added expense and possible stock destruction.

²⁸ Processed Cereal-Based Foods for Infants and Children (CODEX STAN 74-1981, revised 2006)

Industry submitters noted many infant foods manufactured in jars and tins are long shelf life products (up to two years) and that extra time is required to take account of seasonal production schedules, the long shelf life, the number of stock keeping units (SKUs) requiring label changes, and consumer research as well as label re-design and production.

In targeted consultation with industry it was noted that a transition period of 12 months would increase the number of items that would need to be written off within their shelf life, and an 18-month transition period was considered to be a minimum to minimise write-off costs.

Section 8.2.2.1 refers to cost estimates provided recently by an infant food manufacturer with approximately 78% market share. Estimated additional costs of retaining a 12-month transition period, rather than a 24-month period, are around \$AUD75,000-\$AUD110,000 based on product and label write-off and costs of managing the change e.g. employment of additional resources.

However, FSANZ notes that there is potential for consumer confusion due to the inconsistency between infant food labelling and infant feeding recommendations which would be prolonged if the transition time were to be extended beyond the standard period. Also, there is potential for a variety of age labels to be on infant foods on the market at any one time during the transition period. However, as noted in Section 1.4, there are already products with a variety of age labelling currently on the market, including some products that are using the proposed approach. It is likely that the variety of age labels would decrease over the transition period as manufacturers gradually change to comply with the new proposed requirements.

Therefore, at Preliminary Final Assessment, based on the shelf life of infant foods, the scale of the additional costs of a 12-month transition period (see Section 8.2.2.1) and the impost distributed across a relatively small number of companies, FSANZ is recommending an 18-month transition period for the implementation of the proposed labelling changes. This extended transition period is expected to reduce the additional costs to infant food manufacturers that would result from a 12 month transition period (see Section 8.2.2.1).

6.4.3 Issues raised in response to the Consultation Paper to the Final Assessment

6.4.3.1 Risk of allergy and age of introduction of solids

Submissions made in response to the October 2007 consultation paper referred to studies suggesting a potential to increase the risk of allergy through the delayed introduction of solid food to an infant's diet. Some submitters suggested Proposal P274 be delayed until the completion of studies currently under way to address the role of early exposure to allergic foods to prevent allergic disease.

The risk of allergy in relation to the age at which infants are introduced to solid foods is discussed in Section 5.2 and Attachment 3. It is noted that food allergy in infants and children continues to be an active area of scientific investigation especially given the view that childhood allergies are rising.

Preliminary information suggests that delay in the introduction of solid food to infants' diet may contribute to the risk of developing allergy.

However, this is an emerging area of research and FSANZ considers that the potential role of the various factors in the development of allergy, including infant feeding practices, requires further investigation. The Risk Assessment has concluded that, at this stage, scientific information is inadequate to reach a firm conclusion on this issue.

Therefore, given the advice of the Australian and New Zealand infant feeding guidelines that currently recommend the introduction of solids at around six months plus the inconclusive evidence around the relationship between the timing of the introduction of solids and allergic disease in infants, FSANZ is proposing to amend the proposed minimum age infant food labelling to ‘around 6 months’.

6.4.3.2 Proposed amendment to Standard 2.9.2 to vary the minimum reference age to ‘around 6 months’

At Draft Assessment, the draft variation of Standard 2.9.2 proposed that the minimum reference age ‘around 6 months’ must be included on the label of food for infants where the food was suitable for infants aged between four and six months. The labelling of infant foods as suitable for infants between four and six months was not expressly prohibited under this proposed drafting.

Two jurisdictional respondents to the consultation paper noted the proposed draft amendments to Standard 2.9.2 did not specifically prohibit the labelling of infant foods as suitable for infants between the age of four and six months. They recommended that any reference on a label implying the foods is suitable for infants before the age of six months should be prohibited.

FSANZ has further considered the proposed drafting of minimum age labelling under Standard 2.9.2 and revised the draft variations to ensure that the minimum age labelling permitted for infant foods is ‘around 6 months’ and also that the labelling of infant foods as suitable for infants between the age of four and six months is clearly not permitted (refer to Attachment 1).

It should be noted that Australian and New Zealand infant feeding guidelines acknowledge that while infants will probably be ready for the introduction of complementary solids at around six months of age, the developmental stages and skills that signal readiness vary from infant to infant, and some individual infants may be ready sooner.

The labelling of infant foods with the words ‘around 6 months’ provides a general recommendation and is not intended to preclude individual infants commencing solid foods prior to six months, if appropriate, but not before four months. This interpretation of ‘around six months’ was supported by interviews with health professionals, as noted in Section 6.1.2.

6.4.3.3 Definition of infant formula in Standard 2.9.1.

Standard 2.9.1 provides for the compositional, and labelling requirements for foods intended or represented for use as a substitute for breast milk, referred to as ‘infant formula products’. Infant formula is defined in Standard 2.9.1 as ‘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’. This Standard applies to all infant formula products whether in powder, liquid concentrate or ‘ready to drink’ forms.

Two jurisdictions suggested that the definition of infant formula in Standard 2.9.1 should omit the reference to four months to be consistent with infant feeding guidelines that recommend the introduction of solids at around six months. This would also align with the proposed minimum age labelling of ‘around 6 months’ under Standard 2.9.2.

FSANZ acknowledges this issue. However, proposing amendments to Standard Std 2.9.1 is not within the scope of this Proposal and this issue will be considered during a future review of Standard 2.9.1. This review will be undertaken after FSANZ receives policy guidelines on the intent of Part 2.9 of the Code and on infant formula which are currently under development. The timeline for development of these policy guidelines is not known at this time.

6.4.3.4 Warning statement package and print requirements for infant foods in Standard 2.9.2 and infant formula products in Standard 2.9.1.

Legibility requirements for warning statements prescribed in clause 3 of Standard 1.2.9 apply to infant foods regulated in Standard 2.9.2. Standard 1.2.9 requires a minimum print size for warning statements of 3 mm (with the exception of small packages which have a minimum print size of 1.5 mm). Standard 2.9.1 contains an exemption for infant formula products with a net weight of 500 g or less; these products must comply with the minimum legibility requirement of 1.5 mm. However, the majority of infant formula products sold have a net weight of greater than 500 g and therefore must comply with the 3 mm print size for warning statements.

Two industry submitters requested that infant foods be permitted to use a minimum print size of 1.5 mm for warning statements, as is the case for smaller packages (less than 500 g) regulated under Standard 2.9.1.

FSANZ has considered this suggestion and maintains that the minimum print size of 3 mm for warning statements is appropriate for infant foods. The smaller print size requirement for infant formula packages less than 500 g is permitted because of the detailed warnings, directions and statement requirements on these labels. Standard 2.9.2 does not require the same degree of prescriptive text on infant foods, therefore it is reasonable that these products continue to meet general legibility requirements set out in the Code.

6.4.3.5 Iron declaration on infant cereals

Currently Table 2 to clause 8 in Standard 2.9.2 provides the Recommended Dietary Intakes (RDIs) for permitted claims on vitamins and minerals. The table contains two values for iron – one for *under 6 months* (3 mg/day), and one for *from 6 months* (9 mg/day). The proposed amendment to the minimum age labelling of infant foods, to ‘around 6 months’ requires consideration of which RDI is appropriate to use for labelling of these foods.

In 1999, as part of the development of the joint *Australia New Zealand Food Standards Code*, Proposal P215²⁹ undertook development of Standard 2.9.2. In general, the RDI values for 6-12 months were included in the tables as most representative of infants who would be consuming these foods.

²⁹ Proposal P215 – Food for Infants (Review), Gazetted 2000.

However for iron, Proposal P215 notes that health authorities at that time recommended the use of iron fortified cereals for some infants over four months of age. Therefore iron fortification of cereal-based foods for infants from four months of age was permitted in the Standard. It was recommended that the RDI value for iron for younger infants (3 mg/day) also be included in Standard 2.9.2, in addition to the RDI value for older infants (9 mg/day). This allowed for claims for a good source of iron to be made on foods intended for infants from 4 months of age. This approach supported the health recommendations of that time, as well as the education of care-givers, that infants be fed iron rich foods, in particular iron fortified cereals.

However, FSANZ considers this previous rationale is no longer appropriate or necessary given the current revised infant feeding guidelines which encourage the introduction of solids closer to six months of age. Also, foods intended for infants ‘around six months’ must contain a minimum amount of iron.

Therefore in line with the current infant feeding guidelines of Australia and New Zealand that recommend the introduction of solids at ‘around six months’, FSANZ proposes the iron RDI for infants under six months be removed from Table 2 to clause 8. This approach is consistent with the approach taken for other vitamins and minerals listed in Table 2 to clause 8.

These amendments to the Code would provide clarity to industry at this time by providing only one iron RDI to be used for the purposes of labelling and making claims on infant foods. In addition, paragraph 2(3)(a) Standard 2.9.2 sets a maximum level of iron permitted in cereal-based food thus protecting the safety of infants.

FSANZ also notes that new Nutrient Reference Values (NRVs)³⁰ for Australia and New Zealand were released in 2006 and that FSANZ expects to undertake a review of the Code to incorporate these revised NRVs in the future. FSANZ considers that it is appropriate to further consider the issue of RDIs for infant foods within the context of this broader review of NRV values within the Code.

Therefore, at Preliminary Assessment FSANZ proposes to amend Table 2 to clause 8 to remove the words ‘in the case of infants from 6 months’ in relation to the iron RDI for older infants, and also remove the iron RDI for infants under 6 months. The Table would therefore include only one RDI value (9 mg) for iron for infants.

FSANZ acknowledges that the proposed amendment to the Table 2 to clause 8 may affect the ability of infant food manufacturers to make a good source claim on products currently formulated for infants from four-six months of age, and using the current RDI of 3 mg for the purposes of labelling and making claims.

Question for submitters:

What are the likely impacts, including financial impacts to affected parties of amending Table 2 to clause 8 Standard 2.9.2 as proposed? Please provide evidence.

³⁰ The NHMRC document *Nutrient Reference Values for Australia and New Zealand including recommended dietary intakes* is available online at <http://www.nhmrc.gov.au/publications/synopses/n35syn.htm>

7. Regulatory Options

FSANZ has identified two regulatory options at Preliminary Final Assessment:

7.1 Option 1 – Reject Proposal thus maintaining the *Status Quo*

Under this Option, there would be no change to the current regulatory arrangements for the minimum age labelling of infant foods. Consequently, infant foods would continue to require labelling using an ‘age’ reference and be permitted to label as ‘from 4 months’.

7.2 Option 2 – Amend the minimum age labelling requirements in Standard 2.9.2 by varying the minimum reference age to ‘around six months’

- With this Option, the requirement to label an infant food with an age reference would remain although the minimum reference age permitted would be varied to ‘around 6 months’. In addition other consequential amendments to Standard 2.9.2 would occur to reflect the variation of the minimum age reference.
- Under Option 2, the existing warning statement will be retained but amended by the omission of the word ‘recommended’ to ‘not for infants under the age of 4 months’.

Also, the current requirement to label infant foods with a statement indicating the consistency of the food would remain.

8. Impact Analysis

FSANZ is required, in the course of developing or varying food standards, to consider the impact of the proposed options on affected parties.

The regulatory impact assessment identifies and evaluates the advantages and disadvantages of proposed amendments, and their health and economic impacts.

8.1 Affected Parties

Those parties who are potentially affected by this Proposal include, but are not limited to:

- **consumers**, particularly the parents/ carers of infants who rely on food labels to provide information to make informed choices in feeding their infants;
- the manufacturers and/or importers of infant food (**industry**) that supply the Australian and New Zealand markets; and.
- the **Governments** of New Zealand, the States and Territories and Australia, including enforcement agencies and the health advisors.

8.2 Benefit Cost Analysis

8.2.1 Consumers

Option 1 will maintain the current approach to labelling and consumers will continue to receive information on the suitability of infant food products.

However, maintaining the current labelling may confuse parents/carers who receive advice from health professionals based on current infant feeding guidelines that recommend the introduction of solids at ‘around six months’. There is a risk, in this case, that some may disregard both the labelling and guidelines and make inappropriate and potentially harmful decisions for their infant on the introduction of solid foods.

Similarly, some parents/carers may be influenced by the labelling on infant foods (e.g. ‘from 4 months’) when making a decision to introduce foods to their infants and may prematurely commence their infant on solids at four months. Again, infant health may be compromised.

Under **Option 2**, if labelling was changed as proposed, parents/carers will continue to be provided with information on the suitability of infant food products but in a manner that is consistent with, and will therefore reinforce, infant feeding recommendations in both Australia and New Zealand. Option 2 is more likely to minimise any potential consumer confusion as infant feeding advice from health professionals and infant food labelling would be more consistent. Consistent information with regard to the recommended age for introducing solid foods would support appropriate infant feeding practices and contribute to the health and safety of infants.

8.2.2 Industry

Maintaining the *status quo* in **Option 1** could present an inherent risk to industry. Consumers may perceive industry as acting irresponsibly and undermining infant feeding recommendations if labelling is not adjusted to reflect current nutrition guidelines. Caregivers may consider product labels to be misleading which may lead to lack of confidence in manufacturers and a distrust of their products, and consequently a reduction in sales with negative financial implications for industry.

Option 2 would mean that industry will incur additional costs in re-labelling their infant foods. These costs have been broadly estimated at \$AUD355,000 using cost estimates provided by industry (see Section 8.2.2.1). Labelling changes could include complete label redesign and production, with revision of advertising and educational materials as additional costs. It is noted that some companies have already adopted infant feeding age references in their educational material and on some products which reflect the proposed approach. However the proposed requirements to use the specific wording ‘around 6 months’ on labels may incur additional costs.

As noted in Section 6.4.3.5, additional proposed amendments to Table 2 to clause 8 with regard to the RDI for iron, would provide clarity for industry for the purposes of labelling and making claims. However the proposed amendment may affect the ability of infant food manufacturers to make ‘good source’ claims in some instances. Additionally should infant food manufacturers chose to reformulate some products to enable ‘good source’ claims, additional costs may be incurred.

However, by changing labelling to be more consistent with infant feeding recommendations, there is likely to be a benefit to industry from increased consumer confidence and therefore the level of sales of infant foods is likely to be maintained.

A further advantage for industry under Option 2 is the reduced text requirement of the mandatory warning statement given the restraints on space for labelling requirements for infant foods.

8.2.2.1 Industry cost estimate for Option 2

In June 2008, FSANZ conducted targeted consultations with key infant food manufacturers to update cost estimates provided in submissions at Initial or Draft Assessment.

One large infant food manufacturer provided information that estimated direct costs of the changes to products requiring new labels due to regulatory requirements would be \$AUD185,000³¹ i.e. for label design and printing costs. In addition, the impact of retaining a 12 month transition period (compared to a 24 month transition period) was estimated to be an additional \$AUD75,000-\$AUD110,000. This estimate was based on product and label write off and costs of managing the change e.g. employment of additional resources³². This manufacturer also indicated they hold around 78% average market share in the Australia and New Zealand infant foods market and that 63 Stock Keeping Units (SKUs) would be affected by the proposed amendment to the Code. Assuming a mean additional cost associated with a 12 month transition period to be \$AUD92,500, the total cost to this manufacturer amounts to approximately \$AUD277,000.

On the basis of current and updated data provided, these are the direct monetary impacts that industry has identified to meet the regulatory requirements of the proposed change in the minimum age labelling of infant foods from 4-6 months to 'around 6 months'.

FSANZ has compared this information to a separate set of generic cost estimates based on recent information provided by the food industry in relation to the cost of labelling changes across a range of generic product categories. This information indicates that direct costs for the proposed changes could amount to between \$AUD3,498 and \$AUD3,811 per SKU, depending on how the products are packaged i.e. in glass jar or steel can respectively. Based on a total of 63 SKUs affected, FSANZ has estimated total costs to be in the range of \$AUD220,000-\$AUD240,000 depending on whether a glass jar or steel can is used to package the products. Using this approach, total costs could be around \$AUD230,000 for label design and manufacture. Other costs such as any label or product write-offs would be additional.

FSANZ estimates are similar to the costs provided by this manufacturer. The aggregate estimates reported by the manufacturer indicate they will incur costs of around \$AUD277,000, whereas FSANZ's estimate suggests costs of \$AUD230,000 with potentially some additional costs such as write off. Therefore the two estimates are consistent and provide a reliable index of the costs to the relevant food industry.

³¹ Where New Zealand dollars are included they have been converted to Australian dollars.

³² Personal communication with Judy Wood, Food Standards Australia New Zealand, 11 June 2008

In the absence of additional current quantitative information, FSANZ concludes that if this company represents approximately 78% of the market and is likely to incur costs of around \$AUD277,000 a total indicative cost for the relevant food industry could be extrapolated to around \$AUD355,000.

This estimate includes the additional costs provided by the manufacturer associated with retaining a 12 month transition period. It is expected that a longer transition period would reduce this cost. However the potential reduction in costs of a longer transition period has not been included in these estimates at Preliminary Final Assessment but will be further reviewed at Final Assessment when additional information is available.

In summary, the following table illustrates the methodology and computation of costs.

Item	Estimated Costs * \$AUD	Comment
Direct labelling costs from manufacturer	\$AUD185,000	Cost includes label design and production. Manufacturer has 78% market share.
Additional costs provided by manufacturer for 12 month transition period.	\$AUD92,500 (mean) Estimate provided = \$AUD75,000 - \$AUD110,000	Based on product and label write off and managing the change (including employment of additional resources). Includes the extra costs for a 12 month period as compared to a 24 month period.
Manufacturers total	\$AUD277,500	
FSANZ internal cost estimate	\$AUD230,000 (mean)	Based on 63 SKU at \$AUD3498-\$AUD3811 per SKU. Other costs such as any label or product write offs would be additional.
Total business compliance costs	<u>\$AUD355,000*</u>	Extrapolated total indicative cost for the relevant food industry based on manufacturer's estimates and 78% market share.

* Where New Zealand dollars are included they have been converted to Australian dollars.

8.2.3 Government

Option 1 presents an inconsistency with the national infant feeding guidelines of Australia and New Zealand. Maintaining current labelling would not support Government health agencies efforts to educate health professionals and consumers on the infant feeding recommendations, and possibly lead to inappropriate use of infant foods. This could potentially reduce the public health gain desired from implementation of the infant feeding guidelines.

Under **Option 2**, changes to the labelling of infant foods would reinforce and support Government infant feeding recommendations and infant health promotion.

Changes to the labelling of infant foods may need to be incorporated into Government education strategies to ensure parents/carers understand the meaning of the new labelling in the context of the infant feeding guidelines.

Option 2 will also maintain the harmonisation of food regulations between Australia and New Zealand. This would ensure consistency of regulatory approaches between trading partners, and provide regulatory clarity for the respective Governments.

8.3 Comparison of Options

The options being put forward for this Proposal are Option 1, rejection of the Proposal thus maintaining the *status quo*, and Option 2, amending the minimum age labelling to ‘around six months’.

A comparison of the two Options presented at Preliminary Final Assessment indicates that maintaining the *status quo* will present a number of disadvantages for parents/carers, infants, industry and Government. These disadvantages would result from the inconsistency between infant feeding recommendations for the age of introduction of solids and the minimum age labelling on infant foods.

- Parents/carers may be confused by labelling information that is contrary to infant feeding recommendations and as a consequence make inappropriate, and potentially harmful, decisions on the introduction of solids for their infant. The inconsistency between infant feeding recommendations and the minimum age labelling on infant foods may also cause a loss of consumer confidence in manufacturers and their products, with consequential effects on sales for infant food manufacturers.
- The effectiveness of government education efforts in promoting infant feeding recommendations may also be affected by the inconsistency between recommendations and the current minimum age labelling on infant foods. This could reduce the desired public health gains from implementation of infant feeding guidelines.
- In comparison, **Option 2** is consistent with FSANZ’s objectives and benefits parents/carers, governments and industry by ensuring infant food regulations are consistent with national infant feeding recommendations.
- Option 2 will minimise customer confusion by amending infant food labelling to ‘around 6 months’ which reflects infant feeding recommendations. Parents/carers will be provided with sufficient information in relation to the timing and consistency of infant foods to facilitate appropriate choices and to allow for variations in the development needs of individual infants.
- Option 2 will also support and reinforce Government health authorities’ infant feeding recommendations and parent education and therefore contribute to the promotion and protection of infant health and safety. Incorporating the changes in the labelling of infant foods into government education strategies would ensure parents/carers understand the meaning of the new labelling.

Under Option 2, industry is likely to benefit from increased consumer confidence by providing information on infant food labels which is consistent with infant feeding recommendations, thus sales of infant foods are likely to be maintained.

Option 2 also continues to allow for industry innovation in the provision of additional information on infant food labels; and the harmonisation of regulations for Australia and New Zealand is maintained. A further advantage for industry under Option 2 is the reduced text requirement of the mandatory warning statement given the restraints on space for labelling requirements for infant foods.

However, under Option 2 industry would incur additional costs due to the labelling changes required. As noted above some companies have already adopted infant feeding age references on some products and in some educational material reflecting the new approach. This initiative indicates a sentiment to provide uniform, consistent and accurate messages to the consumer by industry.

The analysis of potential impacts of the two regulatory options presented indicates that an overall net-benefit is achieved through Option 2 with advantages for consumers/carers, infants, government and industry.

COMMUNICATION AND CONSULTATION STRATEGY

9. Communication

FSANZ's communication and education strategy for Proposal P274 aims to increase awareness among target groups of the proposed changes to the minimum age labelling of infant foods and the infant feeding recommendations which support these changes. Target audiences identified are health professionals providing parent/carer education and advice on infant feeding, government bodies responsible for infant feeding recommendations, jurisdictions responsible for the enforcement of food regulations, infant food manufacturers and parents/carers of infants.

The importance of education strategies for health workers and parents/carers to support the labelling changes was raised by a number of submitters. FSANZ will develop and implement a communication strategy which will include consistent key messages and the best means to distribute those messages. We will do this in collaboration with government and health organisations responsible for infant feeding advice and education to parents/carers.

10. Consultation

10.1 Public consultation

10.1.1 Initial Assessment

The Initial Assessment of this Proposal was released for public comment from 16 July to 9 September 2003 (six weeks). A total of 34 submissions were received from consumer and public health groups and individuals, industry and government. The majority (30 submitters) supported an amendment to the current standard. However, views differed in the approach. Fourteen submitters supported an increase in the minimum reference age, compared to nine submitters who opted for an alternate phases/stages scheme.

10.1.2 Draft Assessment

FSANZ received a total of 12 submissions from key stakeholders representing maternal, infant and child health and welfare, jurisdictions, public health and industry groups in response to the Draft Assessment Report during the six week public consultation period from 20 October 2004 to 1 December 2004.

A summary of submissions is at Attachment 6. Almost all submitters, with the exception of two industry submitters, supported amending the minimum reference age to 'around six months' and recognised the importance of consistency between the labelling of infant foods and infant feeding guidelines. With regard to the issue of 'age' or 'stage' labelling on infant foods, submitters tended to support 'age' or 'age' and 'stage' rather than a 'stage' only approach. The New Zealand Government supported a modification to the proposed regulatory approach to include stages of development labelling. One industry submitter supported the status quo but generally industry supported amending minimum age labelling.

Submitters strongly supported the retention of the warning statement 'not recommended for infants under the age of 4 months' on labels of foods promoted as suitable from 'around six months'. Submitters were generally not in favour of the inclusion of an advisory statement on labels encouraging parents/carers to consult a health professional when introducing solids and did not see this statement as particularly helpful to parents/carers.

The proposed removal of subclause 2(4) from Standard 2.9.2 requiring food intended for infants under the age of six months to be of a consistency that minimises the risk of choking was supported by industry, but opposed by the New Zealand Government.

10.1.3 Consultation Paper Prior to Preliminary Final Assessment

A consultation paper on the proposed regulatory approach for Final Assessment and reflecting key issues from the Draft Assessment was released for targeted consultation. A summary of responses is at Attachment 7.

FSANZ received 20 responses to the consultation paper in the two week consultation period from 5 October 2007 to 19 October 2007. This included responses from government (5), industry (4), infant health organisations (3), health professional associations (2), health professionals and academics (5), and one individual breast feeding advocate.

The proposed regulatory approach was supported by all government, health professional associations, infant health organisations and one health professional. Two industry responses supported the proposed regulatory approach but one peak industry group and two infant food manufacturer supported the *status quo*. Several medical specialists also expressed reservations at raising the minimum age labelling at this time. The specialists were part of a group of international experts reviewing the role of exposure to allergenic foods in the prevention of allergic disease and supported the *status quo* until studies under way were completed. In addition, the New Zealand Government response recommended 'first stage' labelling for the first infant complementary foods, in conjunction with minimum age labelling, to reflect their preference for a stages of development approach to labelling.

10.1.4 Targeted Consultation During Final Assessment

In October 2007, FSANZ met with officials from New Zealand Ministry of Health and New Zealand Food Safety Authority to discuss their recommendation that stage labelling be mandated for ‘first foods’ for infants, along with the proposed age and consistency labelling. Also, during preparation of the Preliminary Final Assessment Report, additional targeted consultation was undertaken with some key manufacturers of infant foods in Australia and New Zealand, and with a key New Zealand child health provider, including discussion around the suggested stage labelling of ‘first foods’. There was mixed support for this approach. Section 6.3.1 provides comment on these discussions.

Issues raised in response to the consultation paper that have been raised in earlier rounds of public comment are addressed in the body of this Report. Newly identified issues and responses to these are outlined in Section 6.4.3.

10.2 External Advisory Group

FSANZ established an External Advisory Group (EAG) in January 2004 to provide expert technical advice specifically in relation to the consumer qualitative research undertaken at Draft Assessment. The membership of the EAG comprised the following public health professionals and industry representatives:

- Ms Angela Baldwin, Royal New Zealand Plunket Society (Inc.), New Zealand
- Ms Kay Gibbons, Royal Children’s Hospital, Melbourne, Australia
- Ms Anne Hillis, Heinz Watties Australasia
- Mrs Winsome Parnell, Nutrition Expert, Otago University, Dunedin, New Zealand
- Ms Judith Wilcox, Royal Women’s Hospital, Brisbane, Australia

The EAG met on three occasions and continued working with FSANZ to progress the Draft Assessment Report including the variation to Standard 2.9.2.

10.3 Infant and Child Health Scientific Advisory Group (ICSAG)

In December 2007, FSANZ convened the Infant and Child Health Scientific Advisory Group (ICSAG)³³. FSANZ convened this group to provide scientific advice on risk assessment issues relating to infants and young children.

The membership of the group attending the inaugural meeting of ICSAG comprises:

Dr Bob Boyd – Chief Medical Advisor – FSANZ, CHAIR ICSAG
Dr Pat Tuohy – Chief Advisor - Child and Youth Health, Ministry of Health, New Zealand
Assoc. Prof Peter Davies - Director – Children’s Nutrition Research Centre, University of Queensland, Royal Children’s Hospital, Australia
Dr Clare Wall – Senior Lecturer – Faculty of Medical and Health Sciences, the University of Auckland, New Zealand
Assoc. Prof Maria Makrides – Deputy Director - Women's & Children's Health Research Institute, North Adelaide, Australia

³³ ICSAG is a scientific advisory group comprised of experts in gastroenterology, pediatrics and child health.

Assoc. Prof Tony Catto-Smith – Director – Department of Gastroenterology & Clinical Nutrition, Royal Children’s Hospital, Melbourne, Australia

Professor Paul Mitchell – Director – Centre for Vision Research, Westmead Hospital, Sydney, Australia - attended via teleconference.

A summary of the ICSAG consideration of Proposal P274 is provided at Section 5.8.

10.4 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.

Industry has expressed concern that the proposed regulatory approach will mean infant feeding labelling in Australia and New Zealand will be inconsistent with European and USA requirements and this may impact on future importation of infant foods. While recognising that international standards may differ from the proposed labelling requirements for infant foods, amending the minimum age labelling requirements for infant foods is not expected to have a significant effect on international trade as the vast majority of infant foods are locally manufactured. Also, this is a proposed amendment to an existing requirement. Therefore, notification was not made to the WTO under the Technical Barriers to Trade (TBT) Agreement (see Section 6.4.1).

11. Conclusion and Preferred Approach

As requested by the Ministerial Council, FSANZ has reviewed the minimum age labeling requirements for infant foods to resolve an apparent inconsistency with the NHMRC, and now the recently revised New Zealand Ministry of Health infant feeding guidelines, which both recommend exclusive breastfeeding for the first six months of life and the introduction of solid foods at around six months. FSANZ’s preferred approach is Option 2, as amending the minimum age labelling requirements in Standard 2.9.2 by varying the minimum reference age to ‘around six months’ has net benefits for affected parties.

Preferred Approach

To amend the minimum age labelling permitted on infant foods in Standard 2.9.2 from ‘4 months’ to ‘around 6 months’ in accordance with the infant feeding recommendations of Australia and New Zealand (Option 2).

In addition, amend the warning statement under current paragraph 5(3) (c) to ‘not for infants under the age of 4 months’ and appear in a new paragraph 5(5) (b).

Minor amendments consequential to the minimum age labelling of ‘around 6 months’ and a change in the reference RDI for iron, are also proposed.

The preferred approach is Option 2 because it:

- provides consistency with the infant feeding recommendations in Australia and New Zealand thereby reinforcing parent/carer education and infant health promotion;
- continues to protect the health and safety of infants;
- provides parents/carers with sufficient information in relation to the timing and consistency of infant foods so they can make appropriate choices;
- permits flexibility and recognition of the natural variation of individual infants and their developmental needs in relation to infant food choices;
- maintains the harmonisation of regulations for Australia and New Zealand; and
- provides net benefits to affected parties and is in line with minimum effective regulation.

12. Implementation and Review

Following the consultation period for this Preliminary Final Assessment, a Final Assessment Report including the draft variation to the Code will be prepared for consideration by the FSANZ Board. Notification of the Board's approval of the draft variations will be made to the Ministerial Council for consideration. Subject to any request from the Ministerial Council for a review, the variations will be gazetted taking effect on the date of gazettal.

The existing transition provisions in Standard 1.1.1 allow a period of 12 months from gazettal for industry to comply with the new labelling requirements. However, at Preliminary Final Assessment of this Proposal, FSANZ is recommending an 18 month transition period for the implementation of the proposed labelling changes as it is expected this will reduce the cost to infant food manufacturers. This extended transition period is based on the longer (up to two years) shelf life of infant foods, the scale of the additional costs of a 12 month transition period (see Section 8.2.21) and the impost on a relatively small number of companies (Section 6.4.2).

ATTACHMENTS

1. Draft variations to the *Australia New Zealand Food Standards Code*
2. Nutrition Assessment
3. Assessment of Risk of Allergies and Other Immune-mediated Diseases
4. Infant and Child Scientific Advisory Group: Terms of Reference
5. Summary of Research with Australian Health Professionals
6. Summary of Submissions to the Draft Assessment Report
7. Summary of Comments to the Consultation Paper

Draft variation to the *Australia New Zealand Food Standards Code*

Standards or variations to standards are considered to be legislative instruments for the purposes of the Legislative Instruments Act (2003) and are not subject to disallowance or sunseting

To commence: 18 months from gazettal

[1] *Standard 1.1.1 of the Australia New Zealand Food Standards Code is varied by omitting paragraph (d) in the definition of warning statement, substituting –*

(d) paragraph 5(5)(b) and subclause 6(2) of Standard 2.9.2; and

[2] *Standard 2.9.2 of the Australia New Zealand Food Standards Code is varied by –*

[2.1] *omitting subclause 2(4), substituting –*

(4) Food suitable for infants around the age of 6 months, except for rusks, must be formulated and manufactured to a consistency that is soft and free of lumps.

[2.2] *omitting the Editorial note immediately following subclause 2(4)*

[2.3] *omitting subclause 3(1), substituting –*

(1) Cereal-based food for infants which contains more than 70% cereal, on a moisture free basis –

(a) must contain no less than 20 mg iron/100 g on a moisture free basis; and
(b) may contain added iron in the following forms –

- (i) electrolytic iron; or
- (ii) reduced iron; or
- (iii) in the permitted forms set out in Schedule 1 of Standard 2.9.1; and

(c) may contain added thiamin, niacin, vitamin B₆, vitamin C, folate, magnesium in the forms permitted in Schedule 1 of Standard 2.9.1; and
(d) may contain added vitamin C to a maximum level of 90 mg/100 g on a moisture-free basis.

[2.4] *omitting subclause 3(2)*

[2.5] *omitting clause 5, substituting –*

5 Labelling

(1) This clause does not apply to packaged water.

- (2) The label on a package of food for infants must not include a recommendation, whether express or implied that the food is suitable for infants less than 4 months old.
- (3) The label on a package of food for infants must include –
- (a) a statement indicating the consistency of the food; and
 - (b) a statement indicating from which age, expressed in numbers, the food is suitable; and
 - (c) where the added sugars content of the food for infants exceeds 4 g/100 g, the word –
‘sweetened’; and
 - (d) where honey has been used as an ingredient, the words –
‘sterilised honey’.
- (4) For paragraph 5(3)(b) the age must not be expressed in numbers less than 6 months.
- (5) In addition to the requirements in paragraphs 5(3)(a), (c) and (d), where the food is suitable for infants aged around 6 months the label on a package of food for infants must include the following statements –
- (a) ‘Around 6 months’; and
 - (b) ‘Not for infants under the age of 4 months’.

Editorial note:

This Standard does not place limits on the use of sugars except in the case of a vegetable juice, fruit drink and non-alcoholic beverage.

Claims such as ‘no added sugar’, ‘sweetened’ or words of similar import are subject to the general labelling provisions.

[2.5] *omitting from the Table 2 to clause 8 both entries for Iron, substituting –*

Iron	9 mg
------	------

Nutrition Assessment

Summary

The available evidence on the relationship between solid food introduction and infant growth, kidney function and iron/zinc status shows that there are unlikely to be any adverse health effects from a delay in the introduction of solid foods to six months of age.

Therefore, FSANZ concludes that the nutrition and developmental outcomes of infants will not be adversely affected by a delay in the introduction of solid foods to around six months of age.

1. Introduction

The timing of the transition from a purely liquid (breast milk or infant formula) diet to one that includes a range of other (solid) foods varies between infants and is dependent on achieving developmental milestones which indicate that an infant is 'ready' for solid foods. At around six months of age, infant nutritional needs increase to such an extent that human breast milk or infant formula alone can no longer meet these requirements.

It is recommended that infants should not begin receiving solid foods prior to the age of four months (NHMRC, 2003). Therefore, this nutrition assessment will examine the introduction of solid foods approximately between the ages of four to six months, to determine whether delaying solid food introduction to around six months of age will have an adverse impact on the nutritional and developmental outcomes for infants.

This nutrition assessment will examine the following issues as a means of reaching an overall conclusion on the timing of the introduction of solids:

- the potential for displacement of human breast milk and/or infant formula, any changes in energy intake, and whether growth outcomes are adversely affected;
- the capacity of infant kidneys to deal with the higher solute load of solid foods prior to six months of age;
- the impact on iron and zinc status, particularly in pre-term infants; and
- the influence of feeding practices during infancy on later food preferences.

2. Literature Search Strategy and Selection Criteria

The scientific literature used within this assessment has been obtained from the following sources:

- PubMed, using one or more combinations of the keywords 'infants', 'solid foods', 'timing', 'growth', 'weight', 'renal', 'kidney', 'iron', and 'zinc';

- references used in the Cochrane systematic review titled ‘Optimal duration of exclusive breastfeeding’ (Kramer and Kakuma, 2002);
- references from the WHO review ‘Nutrient Adequacy of Exclusive Breastfeeding for the Term Infant During the First Six Months of Life’ (Butte *et al.*, 2002); and
- references used in the review ‘Systematic review concerning the age of introduction of complementary foods to the healthy full-term infant’ (Lanigan *et al.*, 2007).

Studies were excluded from consideration if they did not directly compare the introduction of solids at around 6 months of age or the exclusivity of breast/formula feeding for the first six months to an earlier age cut-off between 4-6 months of age, were not published in the English language, or did not assess endpoints on either growth, kidney function, or iron/zinc status. In addition, some of the data from included studies was specifically excluded if they were related to other effects or involved the introduction of solids at ages less than 4 months.

Studies from developing countries were included with the caveat that their results may not be wholly applicable to the Australian and New Zealand context.

3. Displacement of human breast milk/infant formula, energy intake and growth of infants

Human breast milk and infant formulas are concentrated sources of a variety of vitamins and minerals, and are unlikely to be matched by ‘first’ solid foods that, unless fortified, have a low micronutrient density. In addition, the nutritional requirements of an infant increase at a consistent rate, and eventually reach a point where exclusive human milk/formula feeding may not provide sufficient nutrition. A delay in the introduction of solid foods could therefore hinder the progression to a diet that matches the increasing nutritional requirements of the older infant.

FSANZ has identified ten studies that investigate whether the timing of solid food introduction can affect an infant’s ability to meet its nutritional requirements, as assessed by changes in breast milk intake, total energy intakes, and anthropometric measurements of infant growth. Full details of these studies are provided in Tables 1 and 2 at the end of this attachment.

Three of the ten studies (Cohen *et al.*, 1994; Dewey *et al.*, 1999; Mehta *et al.*, 2007) are randomised controlled intervention trials, with subjects from both developing (Cohen *et al.*, 1994; Dewey *et al.*, 1999) and developed (Mehta *et al.*, 2007) countries. All three studies show that the introduction of solid foods at three to four months of age causes a reduction in breast milk. The introduction of solids did not, however, result in significantly different ($p > 0.05$) energy intakes compared to exclusive breastfeeding in two of the studies, with only Cohen *et al.* (1994) showing a comparative decrease in energy intakes for exclusive breastfeeding. All three studies reported no concurrent effect on anthropometric measurements of growth ($p > 0.05$), despite the displacement of total breast milk following the introduction of solids, and the differences across the studies in respect to birth weight and the nationality of the infant subjects.

The remaining seven studies are observational in design (Zumrawi *et al.*, 1987; Martines *et al.*, 1994; Piwoz *et al.*, 1996; Simondon and Simondon, 1997; Victora *et al.*, 1998; Onayade *et al.*, 2004; Khadivzadeh and Parsai, 2004).

These studies investigate the timing of solid food introduction between the ages of 3-7 months, and its effect on anthropometric measures of growth. None of the seven studies quantify the changes in breast milk/formula intakes; rather they identify the timing and types of foods/drinks that are introduced into the infant diet. All of the studies were conducted in developing countries. With one exception (Onayade *et al.*, 2004), the results of the studies are consistent with the findings of the three intervention trials above, and show that the timing of solid food introduction does not significantly affect the rate of increase in weight and length of the infant.

Onayade *et al.* (2004) showed a difference in weight gain across study populations, with exclusive breast/formula feeding up to the age of six months resulting in a significantly greater weight gain ($p < 0.05$) than those infants consuming complementary foods. It was noted however that infant girls receiving solids between 4-6 months of age weighed less at four months of age than infant girls who did not receive solids until around six months of age, although these differences were not significant ($p > 0.05$). Therefore the observation that children given solids at an earlier age were lighter in weight may reflect the reason for this early feeding practice, and might not be due to the timing of solid food introduction.

Overall the findings from the available evidence indicate that the timing of solid food introduction between the ages of 3-7 months is unlikely to influence infant growth, in either a positive or negative manner. The findings of intervention trials designed specifically to test the introduction of solid foods and its effects on infant growth demonstrate this outcome. The observational studies also confirm that anthropometric measures are not substantially influenced by the timing of solid food introduction.

4. Renal function

During the first few months of life, an infant's kidney is unable to effectively concentrate soluble waste products into urine. These soluble waste products are referred to as the renal solute load (RSL), and due to the limited concentrating capacity, a high RSL will increase the risk of dehydration in an infant independent of fluid intakes (Fomon and Ziegler, 1999). Over time, infant kidneys increase their ability to manage a higher RSL, until the age of 12 months, when the kidney is fully effective at concentrating soluble waste products.

Human breast milk and infant formula have a potential RSL (i.e. from the diet) that is suitable for the developing kidney³⁴. However, most complementary foods have a high potential RSL³⁵, especially those with a high protein content or with added salt, and may increase the concentrating requirements on an infant's kidneys (Fomon, 1993).

FSANZ has been unable to identify any studies that directly assess changes in RSL or water balance with the introduction of solid food during infancy. There is, however, commentary in the scientific literature that discusses the feeding of solid foods to infants during periods of illness.

Fomon (2000) has stated that when an infant is ill or unable to consume adequate fluids, then the infant's renal concentrating ability may be insufficient to manage a high potential RSL³⁶.

³⁴ Standard 2.9.1 – Infant Formula Products clause 5, prescribes limits on the potential RSL of infant formula.

³⁵ Foods manufactured specifically for infants in accordance with Standard 2.9.2 – Foods for Infants are unlikely to have a high RSL, as the sodium level of these foods is restricted.

³⁶ Unless there is significant non-renal water losses (such as diarrhoea), then the total RSL will be similar to the potential RSL (Fomon, 2000). Non-renal water losses will exacerbate a negative water balance during illness.

The potential RSL therefore becomes the predominant consideration in maintaining adequate water balance during illness. Commentary by Zeigler (2007) reinforces this conclusion, and adds that prolonged periods of negative water balance resulting from a high potential RSL can lead to serious dehydration in the infant.

From these discussions, it can be inferred that the introduction of solid foods earlier in the kidney's development phase will increase the risk of negative water balance if there is a concurrent episode of illness. As there are no studies directly assessing this issue up to the age of six months, it is uncertain whether a delay in the introduction of solid foods to around six months of age increases or lessens this risk. It is, however, unlikely that the risk of negative water balance will increase, given the limited quantities of complementary foods that infants are able to consume during periods of illness.

5. Iron and zinc

From six months of age, the iron and zinc requirements of infants have reached a point that is unlikely to be met by an exclusively liquid diet. *Exclusive* feeding of human breast milk or infant formula beyond six months of age is therefore inadvisable, as infants may develop deficiencies in iron and zinc (NHMRC, 2003).

In the ages four to six months, human breast milk/infant formula is generally considered sufficient to meet the iron and zinc needs to six months of age, however there is some concern that delaying solid food introduction will unnecessarily place infants at risk of receiving inadequate iron and zinc by six months of age (Krebs and Hambidge, 2007).

5.1 Iron

FSANZ has identified two studies that assess the duration of exclusive liquid feeding and its effect on iron status in infants. A summary of the details for the two iron studies is located in Table 3 at the end of this attachment.

In an intervention trial (Siimes *et al.*, 1984) infants were followed from birth to 3.5 months, at which point they were randomly assigned to commence on either infant formula and solid foods, or to exclusively receive human breast milk to nine months of age. The results show that the exclusively breastfed group had a higher serum haemoglobin (Hb) at six months of age compared to the early solids group ($p < 0.05$). Exclusive breastfeeding beyond this point to nine months of age produced a reduction in several markers of iron status (mean corpuscular volume, mean corpuscular Hb, serum iron, and iron saturation) to a level that was lower ($p < 0.05$) than infants that were receiving the partially liquid diet whereas serum haemoglobin values remained similar ($p = 0.6$) between the two groups. Despite these varied results, this study does not provide evidence that exclusive breastfeeding to six months of age pre-determines iron biomarker outcomes at nine months as the feeding regime between 6-9 months may influence these outcomes. There were no reports of iron deficiency anaemia (Hb < 10.5 g/L) in either group over the full study period.

In an observational study (Tympa-Psirropoulou *et al.*, 2005) exclusive breastfeeding for six months had no significant impact on iron status up to 2 years of age. This study was a case-control design on iron anaemic children aged 12-24 months of age. The results from the study show that the length of exclusive breast feeding, as well as the actual age of solid food introduction, was not associated with the risk of iron deficiency anaemia.

These two studies provide some evidence that exclusive breastfeeding to six months of age does not increase the risk of iron deficiency anaemia at a later age. From this, it could be inferred that delaying the introduction of solids to six months does not have a detrimental effect on iron status biomarkers.

5.2 Zinc

FSANZ has been unable to identify studies that investigate the introduction of solid foods during infancy and its effect on zinc status. It is, however, expected that the outcomes on zinc status would be similar to, and certainly no worse than those for iron, as infants have a better storage of zinc compared to iron in the first six months of life (NHMRC, 2003).

6. Other aspects of infant nutrition

6.1 Infant feeding practices

There is an emerging field of research that is investigating the effects of feeding practices during infancy, and its effect on the subsequent development of long-term dietary patterns. Preliminary evidence indicates that an early introduction to solid food allows for the development of a greater dietary diversity later in life (Cooke, 2007). Other research has indicated that early feeding practices during infancy are also likely to determine later food preferences (Birch, 1998).

Although the emerging evidence indicates that the timing of solid food introduction can influence later dietary outcomes, the currently available evidence is too limited to allow for conclusions to be made on infant feeding practices.

6.2 Pre-term infants

There is some commentary in the scientific literature that pre-term infants may be at a greater health risk from the late timing of solid food introduction than full-term infants (Fewtrell, 2003). Of particular concern is the risk from iron and zinc deficiencies, due to the different developmental requirements for pre-term infants.

FSANZ has been unable to identify any studies that can confirm or refute this commentary on pre-term infant dietary requirements.

7. Position of the ESPGHAN Committee on Nutrition

The Nutrition Committee of the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) has recently released a position on complementary feeding during infancy (Agostoni *et al.*, 2008). This report covers similar areas of research to this nutrition assessment, including the effects of complementary feeding on infant growth, iron status and zinc status.

ESPGHAN also investigated other areas of research outside the scope of this nutrition assessment, such as the influence of complementary feeding on the risk of developing adult chronic diseases, and the influence of specific foods introduced during the complementary feeding period.

ESPGHAN concluded that the introduction of solid foods should not occur any earlier than 17 weeks of age (i.e. four months), and should not be delayed beyond 26 weeks of age (i.e. six months). FSANZ notes that the ESPGHAN position paper does not identify any adverse effects from a delay in the introduction of solid foods to around six months of age.

8. Conclusion

The timing of solid food introduction is a highly subjective decision, as the actual developmental needs of infants will vary within the four to six month age period. The evidence presented in this nutritional assessment highlights this variability, and shows that infants are able to adapt their dietary intakes to suit their own specific nutritional needs, with the result that there is unlikely to be differences in the nutritional and developmental outcomes for infants that receive solids at an early (close to four months) versus a late (close to six months) age.

Table 1: Details of intervention trials assessing human milk intake, energy intake and growth between the ages of 3-6 months

Reference	Country	Duration & Design	Study Participants	Study endpoints	Dietary Regime	n	HBM Intake Results (g/day)*				Energy Intake Results (MJ/day)*				Other Outcomes
							Base	sd	6mth	sd	Base	sd	6mth	sd	
Cohen <i>et al.</i> (1994)	Honduras	RCT from 4-6 months of age. Single blinding.	Infants initially breastfed to the age of 4 months. Mothers were from low-income backgrounds.	HBM intake, total energy intake, weight, length, morbidity (fever, diarrhoea, upper respiratory illness)	EBM Group Exclusive regular breastfeeding to 6 months (control)	50	810 ^{a,b}	20	820 ^b	15	2.23 ^a		2.32 ^b		No significant (p>0.05) difference between baseline and follow-up to 6 months, or across groups, for energy intake, weight or length. Morbidity outcomes were the same across groups (p>0.05).
					Solids Group 1 Some solid food + Ad libitum breastfeeding	47	800 ^a	15	697 ^c	15	2.27 ^a		2.47 ^c		
					Solids Group 2 Some solid food + regular breastfeeding	44	775 ^a	15	713 ^c	20	2.15 ^a		2.41 ^c		
Dewey <i>et al.</i> (1999)	Honduras	RCT from 4-6 months of age. Single blinding.	All subjects were low birth weight infants initially breastfed to the age of 4 months.	HBM intake, total energy intake, weight, length, morbidity (days with fever, respiratory illness or diarrhoea)	EBM Group Exclusive breast feeding to 6 months (control)	59	725 ^a	30	753 ^b	27	2.19	0.5	2.27	0.6	No significant (p>0.05) difference between baseline and follow-up to 6 mths, or across groups for wt or length. Morbidity was the same across groups (p>0.05), except for diarrhoea >3 times/day higher in EBM (p<0.05).
					Solids Group Some solid food + Ad libitum breastfeeding	60	680 ^a	35	641 ^c	24	2.02	0.4	2.45	0.4	
Mehta <i>et al.</i> (1998)	United States	RCT from 3-12 months of age.	Infants initially breastfed to the age of 3 months	Total energy intake, weight, length	EBM Group Exclusive breast feeding to 6 months	71	702		840 ^a		2430		2850		No significant difference between groups in weight or length (p>0.05)
					Solids Group Some solid food from 3 months of age	76	775		675 ^b		2400		2800		

* = Results with different superscripts are significantly different from each other (p<0.05). The same superscripts or an absence of superscripts means the results are not different (p>0.05).
 EBM = Exclusively fed with human breast milk HBM = Human breast milk RCT = Randomised controlled trial

Table 2: Observational studies assessing anthropometric and morbidity changes associated with complementary feeding between 4-6 months of age

Reference	Nation	Duration & Design	Study Participants	Study endpoints	Dietary Regime	n	Mean Weight Results (kg)*#				Mean Length Results (cm)*#				Other Outcomes		
							Gain 0-4 mths	sd	Wt at 4 mths	sd	Gain 4-6 mths	sd	Lth at 4 mths	sd		Gain 4-6 mths	sd
Khadiv-zadeh and Parsai (2004)	Iran	Observational-prospective cohort study. Subjects were followed from 4-6 mths of age	Healthy newborn infants exclusively breast fed to 4 months of age	Wt, length, morbidity over study period (% subjects with respiratory infection or diarrhoea)	Exclusive breast feeding to 6 mths of age	100			6.56	0.7	0.96	0.8	62.9	29	3.6	3.0	Solids grp had higher rate diarrhoea but not respiratory infection: Diarrhoea: EBM = 11%, Solids = 27% (p = 0.004) Respiratory infection: EBM = 23%, Solids = 35% (p = 0.06)
					Solids introduced between 4-6 mths of age	100			6.71	0.7	1.02	0.8	63.1	29	3.5	3.0	
Martines <i>et al.</i> (1994)	Brazil	Observational-prospective cohort study. Subjects followed from 0-26 weeks of age	Newborn infants weight >1.5 kg. Mothers were from low-income background	Wt gain, access to water, days with diarrhoea	Exclusive breast feeding to 6 mths of age	26			5.84	0.8	1.27	0.4					Access to indoor water produced higher (p<0.001) wt gains at 0-3 mths, but not when older (p>0.05). Introduction of solids between 4-6 mths had more episodes of diarrhoea each day (p<0.05).
					Solids introduced between 4-6 mths of age	31			5.84	0.8	1.26	0.5					
Onayade <i>et al.</i> (2004)	Nigeria	Observational-prospective cohort study. Subjects were followed from 0-6 mths of age	Newborn infants weight >2.5 kg.	Weight	Boys - exclusive breast feeding to 6 mths of age	133	4.39 ^a	0.7	7.63 ^a	0.8	1.65 ^a	0.9					
					Boys - solids introduced between 4-6 mths of age	18	3.6 ^b	0.6	7.00 ^b	0.7	0.94 ^b	0.8					
					Girls - exclusive breast feeding to 6 mths of age	133	4.01	0.7	7.29 ^a	0.9	1.48 ^a	1.0					
					Girls - solids introduced between 4-6 mths of age	16	3.63	0.7	6.88 ^b	0.8	0.69 ^b	0.8					

Reference	Nation	Duration & Design	Study Participants	Study endpoints	Dietary Regime	n	Mean Weight Results (kg)*#						Mean Length Results (cm)*#				Other Outcomes
							Gain 0-4 mths	sd	Wt at 4 mths	sd	Gain 4-6 mths	sd	Lth at 4 mths	sd	Gain 4-6 mths	sd	
Piwoz <i>et al.</i> (1996)	Peru	Observational-prospective cohort study. Subjects followed from 0-1 yr of age	Newborn infants weight >2.5 kg	Weight gain	Exclusive breast feeding to 6 mths of age	29	2.8	1.3	7.02		0.9	0.3					
					Partial breast feeding between 4-6 mths of age	110	2.9	1.0	6.41		0.8	0.5					
Simondon <i>et al.</i> (1997)	Senegal	Observational-cross sectional survey. Subjects followed 2-12 mths of age	Healthy infants	Weight and length gain	Solids introduced between 4-6 mths of age	94					0.7	0.6			2.8 ^a	1.2	
					Exclusive breast feeding (+ water) to 6 mths of age	122					0.6	0.5			3.2 ^b	1.2	
Victoria <i>et al.</i> (1998)	Brazil	Observational-prospective cohort study. Subjects followed from 0-1 yr of age	Newborn infants weight >2.5 kg	Weight gain, length gain, ponderal index (wt/length ³)	Exclusive breastfeeding to 6 mths of age	90			5.80	0.5	1.8	0.6	60.1	1.7	6.1	2.1	No significant change in the ponderal index between groups (p>0.05)
					Breastfeeding + other fluids between 3-6 mths	102			5.74	0.3	2.0	0.6	59.6	1.7	6.4	1.7	
					Solids introduced between 3-6 mths of age	173			5.90	0.5	2.0	0.6	60.1	1.8	6.7	1.9	
Zumrawi <i>et al.</i> (1987)	Sudan	Observational-prospective cohort study. Subjects followed from 0-1 yr of age	Newborn infants wt >2.3 kg. Mothers 18-30 yr of age	Weight gain, length	Exclusive breastfeeding to 6 mths of age	58	3.0	0.6			1.06	0.9					Lth data was not reported. The authors state there was no significant difference (p>0.05) in the rates of lth gain between the different groups.
					Solids introduced between 4-6 mths of age	145	3.0	0.6			0.87	0.9					

* = Results with different superscripts are significantly different from each other (p<0.05). The same superscripts or an absence of superscripts means the results are not different (p>0.05).

= Victoria *et al.* (1998) assessed weight and length changes between 3-6 months of age.

Table 3: Details of Studies on Complementary Feeding and Iron Status

Reference	Duration & Design	Study Participants	Study endpoints	Dietary Regime	n	Outcomes
Siimes <i>et al.</i> (1984)	Randomised controlled trial. Subjects followed from 3.5-9 mths of age Single blinding	Healthy infants breastfed to 3.5 mths of age	Serum Hb at 4, 6 and 9 mths of age; serum ferritin, TIBC, serum iron and iron saturation at 9 mths of age. Anaemia (<10.5 g Hb/100 mL) was also recorded	EBM group Exclusive breast feeding to 9 months of age	36	<p>Mean Hb (g/L): At 4 months of age: EBM = 12.2, Solids = 11.7 (p<0.01) At 6 months of age: EBM = 12.4, Solids = 12.0 (p<0.05) At 9 months of age: EBM = 12.1, Solids = 12.2 (p>0.05)</p> <p>Other endpoints reported as a comparison of distributions (9 month data available only): Serum ferritin (µg/L): Solids group higher at 9 months (p=0.001) TIBC (µg/dL): EBM higher at 9 months (p=0.006) Serum iron (µg/dL): Solids group higher at 9 months (p=0.01) Iron saturation (%): Solids group higher at 9 months (p=0.002)</p> <p>No cases of anaemia were recorded in either group over the 9 month period.</p>
				Solids group Use of infant formula with solid food from 3.5-9 months of age	32	
Tympani-Psirropoulou <i>et al.</i> (2005)	Observational case-control study	Children aged 1-2 years. Matched controls	Previous duration of breast feeding, age of solid food introduction	Cases Children with anaemia (<11 g Hb/100 mL)	75	<p>There was a greater duration of breastfeeding in controls compared to cases with anaemia (p<0.001). 52% of controls had been breast fed for 6 months compared to 11% in cases.</p> <p>There was no significant difference between the two groups in the age of solid introduction (p=0.7).</p>
				Controls Children without anaemia.	75	

EBM = Exclusively fed human breast milk Hb = haemoglobin

Reference List

- Agostoni, C., Decsi, T., Fewtrell, M., Goulet, O., Kolacek, S., Koletzko, B., Michaelsen, K.F., Moreno, L., Puntis, J., Rigo, J., Shamir, R., Szajewska, H., Turck, D. and van, G.J. (2008) Complementary feeding: a commentary by the ESPGHAN Committee on Nutrition. *J Pediatr Gastroenterol Nutr* 46(1):99-110.
- Birch, L.L. (1998) Development of food acceptance patterns in the first years of life. *Proc.Nutr Soc.* 57(4):617-624.
- Butte, N.F., Lopez-Alarcon, M.G. and Garza, C. (2002) *Nutrient Adequacy of Exclusive Breastfeeding for the Term Infant During the First Six Months of Life*. World Health Organization, Geneva, pp34-37. http://www.who.int/nutrition/publications/nut_adequacy_of_exc_bfeeding_eng.pdf. Accessed on 17 December 2007.
- Cohen, R.J., Brown, K.H., Canahuati, J., Rivera, L.L. and Dewey, K.G. (1994) Effects of age of introduction of complementary foods on infant breast milk intake, total energy intake, and growth: a randomised intervention study in Honduras. *Lancet* 344:288-293.
- Cooke, L. (2007) The importance of exposure for healthy eating in childhood: a review. *J Hum Nutr Diet* 20(4):294-301.
- Dewey, K.G., Cohen, R.J., Brown, K.H. and Rivera, L.L. (1999) Age of introduction of complementary foods and growth of term, low-birth-weight, breast-fed infants: a randomized intervention study in Honduras. *Am J Clin Nutr* 69:679-686.
- Fewtrell, M.S. (2003) Growth and nutrition after discharge. *Semin.Neonatol.* 8(2):169-176.
- Fomon, S.J. (1993) *Nutrition of normal infants*. Mosby-Year Book Inc., Missouri, pp94-95.
- Fomon, S.J. (2000) Potential renal solute load: considerations relating to complementary feedings of breastfed infants. *Pediatrics* 106(5):1284.
- Fomon, S.J. and Ziegler, E.E. (1999) Renal solute load and potential renal solute load in infancy. *J Pediatr* 134(1):11-14.
- Khadivzadeh, T. and Parsai, S. (2004) Effect of exclusive breastfeeding and complementary feeding on infant growth and morbidity. *East Mediterr Health J* 10(3):289-294.
- Kramer, M.S. and Kakuma, R. (2002) Optimal duration of exclusive breastfeeding (review). *Cochrane Collaboration* Issue 1:1-25.
- Krebs, N.F. and Hambidge, K.M. (2007) Complementary feeding: clinically relevant factors affecting timing and composition. *Am J Clin Nutr* 85(Suppl):639S-645S.
- Lanigan, J.A., Bishop, J., Kimber, A.C. and Morgan, J. (2007) Systematic review concerning the age of introduction of complementary foods to the healthy full-term infant. *Eur J Clin Nutr* 55:309-320.
- Martines, J.C., Habicht, J.P., Ashworth, A. and Kirkwood, B.R. (1994) Weaning in southern Brazil: is there a "weanling's dilemma"? *J Nutr* 124(8):1189-1198.
- Mehta, K.C., Specker, B.L., Bartholmey, S., Giddens, J. and Ho, M.L. (2007) Trial on timing of introduction to solids and food type on infant growth. *Pediatrics* 102(3):569-573.

NHMRC. (2003) *Food for Health: Dietary Guidelines for Children and Adolescents in Australia, incorporating the Infant Feeding Guidelines for Health Workers*. Commonwealth Department of Health and Ageing, Canberra, pp45-66.

Onayade, A.A., Abiona, T.C., Abayomi, I.O. and Makanjuola, R.O. (2004) The first six month growth and illness of exclusively and non-exclusively breast-fed infants in Nigeria. *East Afr Med J* 81(3):146-153.

Piwoz, E.G., Creed de Kanashiro, H., Lopez de Romaña, G.L., Black, R.E. and Brown, K.H. (1996) Feeding practices and growth among low-income Peruvian infants: a comparison of internationally-recommended definitions. *Int J Epidemiol* 25(1):103-114.

Siimes, M.A., Salmenperä, L. and Perheentupa, J. (1984) Exclusive breast-feeding for 9 months: risk of iron deficiency. *J Pediatr* 104(2):196-199.

Simondon, K.B. and Simondon, F. (1997) Age at introduction of complementary food and physical growth from 2 to 9 months in rural Senegal. *Eur J Clin Nutr* 51(10):703-707.

Tympa-Psirropoulou, E., Vagenas, C., Psirropoulos, D., Dafni, O., Matala, A. and Skopouli, F. (2005) Nutritional risk factors for iron-deficiency anaemia in children 12-24 months old in the area of Thessalia in Greece. *Int J Food Sci Nutr* 56(1):1-12.

Victora, C.G., Morris, S.S., Barros, F.C., Horta, B.L., Weiderpass, E. and Tomasi, E. (1998) Breast-feeding and growth in Brazilian infants. *Am J Clin Nutr* 67(3):452-458.

Ziegler, E.E. (2007) Adverse effects of cow's milk in infants. *Nestle Nutr Workshop Ser Pediatr Program* 60:185-196.

Zumrawi, F.Y., Dimond, H. and Waterlow, J.C. (1987) Faltering in infant growth in Khartoum province, Sudan. *Hum Nutr Clin Nutr* 41(5):381-387.

Risk of allergy and other immune-mediated diseases in relation to timing of introduction of solid foods

There is a debate in the medical community on the potential association between the timing of initial dietary exposure of infants to solid food and immune-mediated diseases. A number of observational studies suggest that there may be an increased risk of food allergy, coeliac disease and Type 1 diabetes mellitus, when introduction of solid food to infants' diet was delayed. Research in this area is currently at an early stage and critical information on potential risk factors in the development of immune-mediated diseases in infants and children is lacking. The following is an outline of information available from the published scientific literature on the potential association between infant feeding practices and the risk of immune-related disease.

Allergy

Allergy is an abnormal immune response to a variety of external proteins such as pollen, insect venom and food proteins. The development of allergic disease depends on interactions between a variety of environmental factors and the genetic susceptibility of the individual. The contribution of the various factors may be positive or negative to the sensitisation and development of allergic disease. The interplay between the different factors is likely to be complex and is yet to be fully understood.

Developed countries are reporting an increase in the prevalence of allergic diseases, including food allergy. A trend of increasing food-related allergic reactions and anaphylaxis was recently reported in Australia (Mullins, 2007; Poulos et al, 2007). The reasons for the increase in food allergies have not been investigated but proposed risk factors include the microbial environment of the gut, inefficient digestion of food proteins, early exposure to food proteins through maternal diet and timing of infant exposure to solid food.

Although it is currently unclear whether delayed introduction of allergenic foods like egg, milk, peanut, tree nuts, or seafood beyond the age of 6 months reduces the risk of food allergy, advice is commonly given to this effect. A position statement by the Australasian Society of Clinical Immunology and Allergy (ASCI) identifies a number of risk factors for developing allergic disease in infants and children (Prescott and Tang, 2005). The paper makes recommendations, including a delay in the introduction of complementary foods until 4-6 months of age but finds no evidence to support dietary elimination after the age of 4-6 months to prevent allergy in children.

A review by Tarini et al (2006) found that available evidence associates the introduction of solids before the age of 3-4 months with eczema. However, little data was available to support an association between early introduction of solid food and other allergic conditions. The authors are of the view that since many studies had problematic methods, additional controlled trials are needed to help guide physicians as they advise parents about the risks of allergy in relation to infant feeding.

There is now evidence to suggest that early exposure to food may actually result in 'tolerance' rather than allergy. A US study examined the association between the timing of infant exposure to cereal-grains in the diet and the development of wheat allergy (Poole et al., 2006).

The main outcome measure in the study was a parent report of wheat allergy and wheat-specific IgE. Children reporting coeliac disease were not included in the analysis. Sixteen children (1%) developed wheat allergy at the mean age of 13.2 months but only four children tested positive for wheat-specific IgE. A physician diagnosis was indicated for these four children all of whom were first exposed to wheat-containing cereal food after 6 months of age.

The role of early complementary feeding in the development of oral tolerance has been recently reviewed by Prescott et al (2008). The authors examine available evidence and conclude that there is a growing case for the introduction of complementary foods from around 4 months of age while maintaining breastfeeding to at least 6 months.

Clearly this is a complex area of research with many conflicting and paradoxical observations reported in the literature. Although preliminary information suggests that a small window may exist between 4 and 6 months to minimise allergy risk, conclusive evidence is still lacking. Several studies are currently underway, in Australia and internationally, with the aim of further informing allergen prevention strategies.

Coeliac Disease

Coeliac disease (CD), also known as gluten-sensitive enteropathy, is characterised by an immune reaction to gluten proteins in wheat and other cereals. Symptoms include chronic diarrhoea, malnutrition, anaemia, fatigue and growth retardation caused by lesions in the small intestine. Gluten avoidance leads to recovery of the small intestine and symptom clearance. The classic form of CD typically presents in early childhood but it is not known what factors are involved. Genetic susceptibility is a prerequisite but not all susceptible individuals develop CD, despite the wide exposure to gluten in the diet.

A number of studies have explored whether breastfeeding and the timing of introduction of gluten-containing food to infants play a role in the development of CD. A retrospective case-control study from Sweden found that breastfeeding had a protective effect against CD if the infants were breastfed at the time when gluten-containing food was introduced (Ivarsson et al., 2002). The study was performed in a population in which most infants were breastfed for 6 months or longer and gluten was introduced at 5-6 months. On the other hand, a prospective observational study of children at high risk of CD suggests that initial exposure to gluten-containing food in the first 3 months of life increased CD risk compared with exposure at 4-6 months (Norris et al 2005). Delayed introduction of food containing gluten until the 7th month or later also appears to increase the risk of CD.

Type 1 Diabetes Mellitus

Type 1 diabetes mellitus (DM) is caused by autoimmunity to insulin-producing islet cells in the pancreas of genetic susceptible individuals. Islet autoimmunity (IA) precedes Type 1 DM and can appear in the first year of infant's life suggesting that exposure to factors during this period is the trigger.

In relation to infant feeding, a link has been proposed between the introduction of gluten before 3 months and increased risk of for IA (Ziegler et al., 2003; Norris et al, 2003).

A prospective study of a birth cohort in the United States examined the association between exposure to cereals and cows' milk in the infant diet and the appearance of IA in children at high risk of DM (Norris et al, 2005). Data from the study suggests that introducing cereals prior to 4 months of age may increase a child's risk of IA, and similarly when cereals are introduced at 7 months or later. No association was found between age at first exposure to cows' milk and IA. The study also found that if cereals were introduced while the child was still breastfeeding, the risk of IA was reduced.

Overall conclusion

Preliminary information suggests that delay in the introduction of solid food to infants' diet may contribute to the risk of developing allergy and other immune-mediated diseases. However, this is an emerging area of research and the potential role of the various factors, including infant feeding practices, in the development of allergy and other immune-mediated diseases require further investigation.

References

Ivarsson A et al. (2002). Breast-feeding protects against celiac disease. *Am J Clin Nutr*; **75**:914-21.

Norris JM et al. (2005). Risk of celiac disease autoimmunity and timing of gluten introduction in the diet of infants at increased risk of disease. *JAMA* **293**:2343-51.

Norris JM et al. (2003). Timing of initial cereal exposure in infancy and risk of islet autoimmunity. *JAMA* 290:1713-1720.

Mullins RJ. (2007). Paediatric food allergy trends in a community-based specialist allergy practice, 1995-2006. *Med J Aust* 186:618-621.

Polous, LM et al. (2007). Trends in hospitalizations for anaphylaxis, angioedema, and urticaria in Australia, 1993-1994 to 2004-2005. *J Allergy Clin Immunol.* 120:878-884.

Poole JA et al. (2006). Timing of initial exposure to cereal grains and the risk of wheat allergy. *Pediatrics*; 117:2175-2182.

Prescott SL et al. (2008). The importance of early complementary feeding in the development of oral tolerance: Concerns and controversies. *Pediatr Allergy Immunol*; OnlineEarly Articles
Published: 10-Feb-2008

Prescott SL, Tang ML (2005). The Australasian Society of Clinical Immunology and Allergy position statement: summary of allergy prevention in children. *Med J Aust*; 182:464-467.

Tarini BA et al. (2006). Systematic review of the relationship between early introduction of solid foods to infants and the development of allergic disease. *Arch Pediatr Adolesc Med*; 160:502-507.

Ziegler AG et al. (2003). Early infant feeding and risk of developing Type 1 diabetes associated autoantibodies. *JAMA*; 290:1721-1728.

Terms of Reference

Infant and Young Child Scientific Advisory Group (ICSAG)

In accordance with the provisions of section 118 of the *Food Standards Australia New Zealand Act 1991*, Food Standards Australia New Zealand (FSANZ) has established a committee to assist it in carrying out its functions.

The Committee will be known as the Infant and Young Child Scientific Advisory Group (ICSAG).

The role of the Infant and Young Child Scientific Advisory Group is to provide scientific advice to FSANZ on the following issues:

- risk assessment matters in relation to consideration of applications and proposals to amend the following standards in the Australia New Zealand Food Standards Code (the Code):
 - Standard 2.9.1 – Infant Formula Products;
 - Standard 2.9.2 – Foods for Infants;
 - Standard 2.9.3 Division 4 –Formulated Supplementary Foods for young children.
- assessment reports and commissioned reviews relating to the development or variation of Food Standards.
- risk assessment matters associated with possible risk management strategies; and
- if required, any other matters related to infant and young child foods.

Conflict of interest and confidentiality provisions for the Scientific Advisory Group

Scientific Advisory Group (SAG) member includes contractors and employees of the SAG member.

Confidentiality

Confidential Information means any information that:

- a. by its nature is confidential;
- b. is designated as confidential by FSANZ;
- c. a SAG member knows or ought to know is or ought to be confidential; or
- d. is confidential commercial information as defined under section 4 of the *Food Standards Australia New Zealand Act 1991*.

1. Obligations

SAG members agree to:

- a. keep confidential information confidential;
- b. only use or copy the confidential information as strictly necessary for SAG meetings;
- c. not disclose the confidential information to any other person without prior written approval by FSANZ; and
- d. immediately notify FSANZ if the he or she believes or has knowledge that any confidential information has been used, copied or disclosed other than in accordance with paragraph (c) or as otherwise required by law.

2. Exceptions

The obligation of confidentiality does not apply to information that is:

- a. in the public domain;
- b. independently developed or acquired by a SAG member; or
- c. required to be disclosed by law.

3. Return or destruction of Confidential Information

SAG members must return to FSANZ, or destroy all copies and delete electronic forms of confidential information, within 14 days of receiving a written request from FSANZ to destroy or delete such information.

Conflict of Interest

A conflict of interest includes an actual or perceived conflict, direct or indirect financial or non-financial conflict. The SAG will determine whether such conflict of interest exists but must advise the SAG committee.

1. All SAG members must disclose at the start of each meeting, whether they believe they have a conflict of interest with respect to any agenda item for that meeting.
2. If, during a meeting of the SAG, a conflict of interest arises or appears likely to arise, the SAG member agrees to:
 - a. immediately make full disclosure of all relevant information relating to the conflict or potential conflict to the SAG; and
 - b. take such steps as the SAG may reasonably require to resolve or otherwise deal with the conflict.
3. A SAG member must not, unless the SAG otherwise determines:
 - a. be present during any deliberation of the SAG with respect to the matter in relation to which a conflict has been determined to exist; or
 - b. take part in any decision of the SAG with respect to that matter.
4. If a SAG member fails to make a full disclosure of the conflict, or potential conflict to the SAG, or is unable or unwilling to resolve or deal with the conflict as reasonably required, FSANZ may immediately terminate their membership of the SAG.
5. Without limiting the circumstances in which a conflict of interest may be found to exist, a conflict of interest exists if a member:
 - a. has made, or is preparing to make an application to FSANZ in relation to a matter;
 - b. is a board member of an organisation which has an interest in a matter;
 - c. is an adviser to a consultancy and/or a market research business which has an interest in a matter.

Summary of Research with Australian Health Professionals

In November 2003, FSANZ contacted a total of 15 Australian health professionals or policy officers from Australian jurisdictions to participate in a one-off telephone interview. The purpose of the research was to:

1. assess the level of awareness of the revised NHMRC's recommendation amongst health services/professionals working with the parents/caregivers of infants; and
2. determine how 'around 6 months' is being interpreted and practically applied by health services/professionals when educating parents/carers on infant feeding.

The findings of the research would be used to assist FSANZ in progressing Proposal P274.

Research findings

Levels of awareness

All interviewees were aware of the recent changes to the NHMRC guidelines; only some had obtained copies of the revised publication.

Interpretation of 'around six months'

The statement 'around six months' was being interpreted in several different ways both within, and between, jurisdictions. These interpretations included:

1. advising of before 6 months but after 4 months if required;
2. 4-6 months;
3. 5-7 months;
4. 6-7 months;
5. 5-6 months;
6. around 6 months depending on individual infant;
7. around but not '6 months per se';
8. 6 months but earlier if the signs are there; and
9. 6 months plus or minus two weeks (but NOT 5 months).

Preferred approach

'Stages with ages' was the most preferred approach, as the label space would not allow sufficient information regarding developmental cues for a stages only approach. There were also concerns that using stages only may be difficult for poorly educated parents, who are also more likely to introduce solids early, to interpret. One respondent preferred an age statement of 'around six months' on first foods only, noting if subsequent foods were labelled with ages and the introduction of solids occurred later there was a potential risk that some mothers could skip one stage. Although physiological cues are harder to interpret for parents, one respondent commented that this approach would not impact on breast-feeding rates.

A 'Stages' approach was considered to be less prescriptive but an 'age' approach was considered somewhat clearer. Some interviewees voiced concerns that parents who considered their infants to be developed may in fact misinterpret cues.

Not before 4 months

There were mixed feelings in relation to warning statement 'not before 4 months' but the overall conclusion was to retain the statement for safety reasons. It was also noted that this statement could portray the message that feeding after the age of four months is acceptable. A few respondents believed that the statement was contrary to the guidelines.

Additional issues

Formula-fed infants

Some interviewees considered that the guidelines were not as appropriate for formula-fed infants as breast fed infants and were giving individuals information accordingly. Others were recommending delaying the introduction of solids until 6 months of age regardless of feeding regimes.

Lack of implementation plans/guidance

There was a concern among several respondents that the guidelines did not fully explain how to implement the guidelines and did not provide a 'plan' for introducing solids. There was also concern that it was going to take a very long time to introduce foods when a new food was being given every 5-10 days.

'Missing the opportunity'

Concerns were also expressed about infants who were not being given solids until too late and that the 'window of opportunity' was being missed, making the feeding of solids difficult in the long term.

Nutritional compromise

More than one respondent mentioned the issue of nutritional compromise particularly in relation to iron.

Summary of Submissions to the Draft Assessment Report

In December 2004, FSANZ received 12 submissions in response to the Draft Assessment of Proposal P274 – Review of Minimum Age Labelling of Foods for Infants during the public consultation period between 20 October and 1 December.

There were two options proposed at Draft Assessment:

Option 1 – Maintain the *status quo*

Option 2 – Amend the minimum age labelling requirements in Standard 2.9.2 by varying the minimum reference age to ‘around six months’.

The issues considered in this Proposal fall into the following categories:

- amendment of minimum age labelling from 4-6 months to ‘around 6 months’ to reflect Australian and proposed New Zealand infant feeding guidelines;
- raising the minimum age to ‘around 6 months’ or replace the reference to ‘age’ with an alternate scheme, e.g. phases or stages;
- inclusion of an advisory statement on the label encouraging parents/carers to consult a health professional to seek assistance when introducing solids;
- retention of a warning statement on the label of infant foods not recommended for infants under the age of four months; and
- removal of clause 2(4) which states that foods for infants under the age of 6 months must be formulated and manufactured to a consistency that minimises the risk of choking.

A submitter list and summary of submitter comments is provided in the table below.

Submitter	Summary of Submissions
<p>1. Australian Breastfeeding Association (ABA)</p> <p><i>Dr Julie Smith</i></p>	<p>Supports Option 2</p> <ul style="list-style-type: none"> • Best meets statutory objective for food standards of protecting the health and safety of infants and providing adequate information for parents to make informed choices. • Australia’s leading source of breastfeeding information and support. Advocates for new public policy and assists governments to implement supportive breastfeeding policy. • The low current rates of exclusive breastfeeding at six months emphasise that the priority objective of changes to infant food labelling should be to reduce the extent of premature introduction of solids or drinks, and to support and promote exclusive breastfeeding to six months with continued breastfeeding after that. <p><i>Regulatory problem</i></p> <ul style="list-style-type: none"> • States that the inconsistency between WHO and NHMRC guidelines, and current food labelling compromises the health of Australian babies. It also confuses parents, creates uncertainty about the appropriate age to introduce solids and severely damages the credibility of infant food labelling.

Submitter	Summary of Submissions
	<p><i>Objectives</i></p> <ul style="list-style-type: none"> • Infants who are not breast fed are a high risk group requiring special attention from the health and social welfare system ³⁷ • Promoting consistency with NZ feeding guidelines is not a relevant consideration in this case as introducing infant food and drinks before six months increases health risks to infants. <p><i>Risk assessment</i></p> <ul style="list-style-type: none"> • Around one in ten infants are exclusively breastfed at six months. Around half Australian infants are breastfed at six months and two in ten are breastfed at 12 months. • A significant risk of current labelling practices is that it discourages continued breastfeeding after six months through actual and implied messages that emphasise the importance of introducing infant solids and drinks and weaning from breast milk. Breast milk alone can be adequate nutrition for a period of months after six months of age. • Actual predominant risk is that solid food and drinks are introduced too early and exclusive breastfeeding is not maintained until six months rather than these being introduced too late. Risks to infant health and safety from current practices are significant and well established and health costs in Australia substantiated³⁸. <p><i>Consistency with Australia/NZ policy</i></p> <ul style="list-style-type: none"> • Supports option 2 to vary the minimum age reference to ‘around six months’ as this best addresses the actual and substantial current risk of food labelling encouraging mothers to introduce solids too early. • As per previous submission, urges FSANZ to extend the standard to cover juices and bottled water as there is evidence that premature use of these products is harmful to breastfeeding and infant nutrition. <p><i>Warning statement – Not recommended for infants under 4 months</i></p> <ul style="list-style-type: none"> • Supports retaining warning statement on the label of foods promoted as suitable for ‘around six months’. However, recommends warning statement be revised to ‘not suitable for infants under four months’ to avoid the imputation that such a product is ‘recommended for infants over four months’. <p><i>Labelling in consumer education(Advisory statement)</i></p> <ul style="list-style-type: none"> • Supports a mandatory advisory statement referring parents to health professionals for guidance on introducing solids. Also urges a recommendation for mandatory labelling of all infant food and drink products stating that early weaning from exclusive breastfeeding increases the risk of ill health in the mother and the baby.

³⁷ WHO (2002) Infant and young child nutrition Global strategy on infant and young child feeding. World Health Organization, Geneva.

³⁸ Smith, J.P., Thompson, J.F., and Ellwood, D.A. (2002) Hospital system costs of artificial infant feeding: Estimates for the Australian Capital Territory. Aust New Zealand J Pub Hlth; 26: 543-551.

Submitter	Summary of Submissions
	<ul style="list-style-type: none"> • Labelling of all infant and toddler drinks and food products should also state that after exclusive breastfeeding for around the first six months of life, continued breastfeeding along with appropriate complementary foods is supported by the WHO up to two years and beyond for the benefit of mother and child health. <p><i>Impact analysis</i></p> <ul style="list-style-type: none"> • States that premature weaning of infants less than six months has a substantial health cost of hundreds of millions of dollars annually in Australia.^{39,40} Hospital system costs of early weaning have recently been estimated at more than \$AUD20 million annually for NSW alone.⁴¹ • Labelling changes emphasising six rather than four months as the minimum age for introducing solids will reduce the extent of premature weaning from breast milk. • Industry estimates of changing labelling of \$AUD320,000 are a maximum cost and are ‘one-off’. As there are likely to be labelling updates required over a period of years, the costs attributed to implementation of FSANZ option 2 should be discounted. In contrast to small, one-off industry costs, the much larger financial and other benefits of the change for infant health and in reducing national health costs have been substantiated in peer reviewed journals and are ongoing. <p><i>Education</i></p> <ul style="list-style-type: none"> • Supports an education strategy to explain the new labelling in the context of the NHMRC guidelines, to promote exclusive breastfeeding to six months as per international and national health recommendations, and to explain the adverse health impacts of early introduction of solids and weaning from exclusive breastfeeding before six months. • Urges the Australian Government to adopt a comprehensive, multi-faceted strategy such as the <i>Australian Breastfeeding Leadership Plan</i>⁴² to be effective in increasing exclusive breastfeeding rates⁴³ and to protect public health and safety. • Since consultation on the Initial Assessment Report, additional studies in NSW and WA have shown a decline in the prevalence of breastfeeding in infants less than six months.⁴⁴ <p><i>Transitional arrangements</i></p> <ul style="list-style-type: none"> • Recommends proposal be fast tracked and implementation period be reduced to six months rather than 12 months.

39 NHMRC (2003); Smith, Thompson, Ellwood, 2002, op cit.

40 Smith, Thompson, Ellwood, (2002) op cit.

41 Hector, D., Webb, K., and Lymer, S. (2004). Report on breastfeeding in NSW. NSW Centre for Public Health Nutrition, NSW Department of Health.

42 Australian Breastfeeding Leadership Plan (2004) Available from ABA website www.breastfeeding.asn.au

43 Hector, D., King, L., Webb, K. (2004) Overview of recent reviews of interventions to promote and support breastfeeding. NSW Centre for Public Health Nutrition, NSW Department of Health.

44 Hector D, Webb K, Lymer S. Report on breastfeeding in NSW 2004. NSW Centre for Public Health Nutrition, NSW Department of Health.

Submitter	Summary of Submissions
	<p><i>Consultation</i></p> <ul style="list-style-type: none"> Expresses disappointment that no consumer representative was appointed to the 'Expert advisory group' with the process open to bias and potential conflict of interest.
<p>2. Ministry of Health New Zealand <i>Dr Ruth Richards</i></p>	<p>Supports amended Option 2</p> <p>Labelling must cater for individual variations among infants due to lack of evidence on recommended age for introduction of solids for formula fed infants, and the need to accommodate the needs of infants who may be ready for solids before six months.</p> <p>Has similar views to the NZ Food Safety Authority. Intention of NZ position is that infants are given complementary foods as close to six months as possible, depending on developmental cues and certainly not before four months.</p> <p><i>Labelling in consumer education (Age vs. Stage)</i></p> <ul style="list-style-type: none"> Position on introduction of complementary foods, which is based on developmental cues and recognises individual variation, was outlined in their submission at Initial Assessment and is consistent with the NZ <i>Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0 – 2)</i>⁴⁵ Acknowledges FSANZ research which showed that the majority of NZ parents introduced solids at four months or just before, which is inappropriate. Supports infant labelling which indicates the stage for which complementary food is suitable to enable parents and caregivers to follow a sequence of texture changes to develop infants' acceptability of increasing texture e.g. Foods labelled as suitable for around six months should be identified as a first food so that parents and caregivers would know to choose that option if their infant requires solids earlier than six months. <p><i>Labelling in consumer education (Advisory statement)</i></p> <ul style="list-style-type: none"> Acknowledges that the decision to introduce solids should be made in consultation with a health professional. However, considers that access to health professionals and whether parents or caregivers of all socioeconomic groups would respond equally to advisory statement has not been adequately addressed in the discussion. Recommends advisory statement be a voluntary provision only. <p><i>Warning statement 'Not recommended for infants under 4 months'</i></p> <ul style="list-style-type: none"> Supports proposed warning statement. <p><i>Draft variations to the Code</i></p> <ul style="list-style-type: none"> Supports retention of subclause 2(4) and editorial note to ensure that first foods are soft and free of lumps. Supports inclusion of a statement in subclause 5(3) subclause (b) to indicate sequential staging i.e. stage 1 for first foods, stage 2, stage 3 etc.

⁴⁵ Ministry of Health, (2000) *Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2)* A Background Paper. Ministry of Health, Wellington, NZ.
[http://www.moh.govt.nz/moh.nsf/pagesmh/1274/\\$File/fnghit2.pdf](http://www.moh.govt.nz/moh.nsf/pagesmh/1274/$File/fnghit2.pdf)

Submitter	Summary of Submissions
	<ul style="list-style-type: none"> Supports additional requirement to subclause 5(3) (that the label should include words to the effect that the decision to begin feeding solids should be made in consultation with a health professional) should be a voluntary provision only.
<p>3. Golden Circle Ltd Australia Mr Peter Swain</p>	<p>Supports Option 2 with amendments</p> <p>Reiterates previous concerns about changing age labelling requirements.</p> <p><i>Risk assessment</i></p> <p>States that while the NHMRC guidelines recommend exclusive breast feeding to six months, they:</p> <ul style="list-style-type: none"> Do not acknowledge that some infants may require introduction of solids prior to six months; Ignore the lack of data to support exclusion of solid foods until six months as suitable for formula fed or partially breast fed babies; and Create additional risk that infants developmentally ready for solids prior to six months may be nutritionally disadvantaged. <p><i>Consistency with Australia/NZ policy</i></p> <ul style="list-style-type: none"> FSANZ has a responsibility to ensure regulations are appropriate for both Australia and New Zealand. Acknowledges that the current system is causing confusion for mothers, health professionals and manufacturers and labelling should support policy. <p><i>Labelling in consumer education (Advisory statement)</i></p> <ul style="list-style-type: none"> Point 5 subclause (3) statement 3 - While agree with the suggested process, does not support the role of the label to provide this advice as consumers do not seek this advice from labels as noted in the results of the Qualitative consumer study ‘the label had little if any influence on the decision to start solids’. Label information became much more useful when parents began to regularly buy infant foods and to assist them in the transition to more textured foods. Space is at a premium on infant food labels and additional text will decrease the space available for information parents seek on the label e.g. texture, ingredients etc. Recommends this statement be deleted. <p><i>Labelling in consumer education (Age vs. stage)</i></p> <ul style="list-style-type: none"> Supports a labelling system incorporating a ‘stage’ concept, a numerical age, a colour code and a descriptor of textures as this allows the consumer to have maximum relevant information to assist with their purchase. Supports: <ul style="list-style-type: none"> Stage 1 around 6 months puréed Stage 2 around 8 months mashed Stage 3 around 10 months chunky All stages 6, 8, 10 months+ smooth Recommends inclusion of age categories to ensure uniformity across the category and to avoid consumer confusion. Infants should not be rushed through stages, so it is suggested approximately two months be allowed between each stage.

Submitter	Summary of Submissions
	<ul style="list-style-type: none"> • Considers it appropriate for the actual descriptors of stages and textures to remain the responsibility of the manufacturers. • Recommends point 5 labelling, subclause 3 be amended to ‘A statement from the following options, expressed in numbers indicating the age for which the food is suitable: <ul style="list-style-type: none"> Around 6 months Around 8 months 10 months + 6, 8, 10 months+ <p><i>Education</i></p> <ul style="list-style-type: none"> • Supports a comprehensive and appropriate education campaign for consumers and health professionals to accompany the implementation of these changes. Support collaboration between government, professional organisations and industry.
<p>4. Department of Human Services Victoria</p> <p><i>Mr Victor Di Paola</i></p>	<p>Appears to support Option 2</p> <p>No other comments.</p>
<p>5. New Zealand Dietetic Association (NZDA)</p> <p><i>Mrs Carole Gibb</i></p>	<p>Supports Option 2</p> <ul style="list-style-type: none"> • Reiterates previous comments submitted in response to the Initial Assessment Report. • Notes that option 2 will address the inconsistency between infant feeding guidelines of Australia and current labelling requirements for infant foods. <p><i>Education</i></p> <ul style="list-style-type: none"> • Notes the need for clarification for some parents and caregivers of ‘around’ and recommends distributing explanatory information via the channels identified in the consumer research survey as trusted sources of information on the commencement of solids.
<p>6. Commission for Children and Young People and Child Guardian (Qld)</p> <p><i>Ms Natalie Kenney</i></p>	<p>Supports Option 2</p> <p>Will ensure a consistent approach to WHO and NHMRC recommendations.</p> <p><i>Labelling in consumer education (age vs. stage)</i></p> <ul style="list-style-type: none"> • Supports age reference ‘around 6 months’ on infant food labelling. <p><i>Labelling in consumer education (Advisory statement)</i></p> <ul style="list-style-type: none"> • Supports mandatory statement on infant food which encourages parents or carers to seek assistance from health professionals to guide their decision-making. • Suggests the advisory statement be amended to ‘...seek assistance from health professionals if contemplating the introduction of solid foods earlier than six months.’

Submitter	Summary of Submissions
	<p><i>Warning statement ‘Not recommended for infants under 4 months’</i></p> <ul style="list-style-type: none"> • Expresses concern that the mandatory warning statement ‘not recommended for infants under the age of four months’ on labels of foods promoted as suitable from ‘around six months’ may confuse some parents as to the appropriate timing of the introduction of solids foods. • See above suggested amendment to the advisory statement to encourage parents to consult with a health professional and minimise confusion with two different ages on the label. <p><i>Consistency to minimise risk of choking</i></p> <ul style="list-style-type: none"> • Supports removal of ‘consistency’ declaration on infant food labels as other information should provide sufficient information to determine appropriateness of the food. • Suggests the Code should require manufacturers to formulate foods to a consistency appropriate for the age of the infant for whom the food is being promoted as suitable. <p><i>Additional compositional provisions</i></p> <ul style="list-style-type: none"> • Supports removal of subclause 3(2) of Standard 2.9.2 and amendment of subclause 3(1) to permit the voluntary addition of vitamins and minerals to foods developed for introduction at around six months, providing these are within the range that is safe for the infant. <p><i>Transitional arrangements</i></p> <ul style="list-style-type: none"> • Supports 12-month transition period.
<p>7. Food Technology Association of Australia Inc Australia <i>Mr David Gill</i></p>	<p>Supports Option 2 No other comments</p>
<p>8. Queensland Health, Australia <i>Mr Gary Bielby</i></p>	<p>Supports Option 2</p> <p>Comments made by the Environmental Health Unit of Qld Health, with expert dietary advice from Statewide Health Promotion Unit, and Child and Youth Health Unit of Queensland Health.</p> <p><i>Objectives</i></p> <p>Considers that the current regulatory requirements for minimum age labelling of food for infants do not meet FSANZ primary objectives regarding:</p> <ul style="list-style-type: none"> • protection of public health and safety of children (changes in recommendations for appropriate timing of introduction to solids and increased risk of allergies and gastrointestinal problems from early introduction of solids); • providing adequate information for parents/carers to make appropriate choices for infant feeding (‘from four months’ statement is misleading); • consistency with Australian and New Zealand infant feeding guidelines; and • being based on current scientific evidence and guidelines.

Submitter	Summary of Submissions
	<p><i>Other issues</i></p> <ul style="list-style-type: none"> • Expresses concern that foods currently labelled as appropriate for infants of a certain age are inconsistent with the NHMRC guidelines e.g. custard (currently labelled as suitable from four months, but NHMRC guidelines state small amounts of cow's milk in foods such as yoghurt can be given after 9 months). • Supports labelling of foods for 1st, 2nd or 3rd stage/phase should be consistent with Dietary Guidelines with respect to type of food and consistency. • Supports depictions of infants and children on labels to be consistent with age group for which they are intended. • Expresses concern about foods used as inappropriate substitutes for infant foods e.g. yoghurts specially formulated for babies from 6 months. • Requests consideration of advisory or warning statements for parents/carers that these foods are inappropriate for infants under 12 months. • Notes that labelling on foods should be based on population health messages. • Supports an appropriate advisory statement on labels to encourage parents/carers to seek individual medical assistance when required. • Concurs with Consumer research results that food labels are not used as an education source by many of the mothers most likely to begin solids before four months. • Data⁴⁶⁴⁷ indicate that 30% of indigenous infants are given solids before 4 months of age (most common solids being Weet-bix or Farex with cow's milk).
<p>9. New Zealand Food Safety Authority (NZFSA)</p> <p><i>Mrs Carole Inkster</i></p>	<p>Does not specify support for either Option. Submission generally reflects the view of NZFSA and Ministry of Health.</p> <p>Without reference to 'stages' for infant foods, NZFSA would have difficulty supporting the amendment.</p> <p><i>Consistency to minimise risk of choking</i></p> <ul style="list-style-type: none"> • Supports retaining subclause 2(4) or amending to reflect the following intent: 'Foods intended as first foods for infants aged around six months must be of a consistency that minimises the risk of choking'. This will help assure care givers that first foods are of an appropriate consistency without having to be dependent on reading the label. <p><i>Labelling in consumer education (Age vs. stage)</i></p> <ul style="list-style-type: none"> • Does not support an 'age only approach' as per revised paragraph 5(3)(b). Supports including a 'stages of development' approach as this is well recognised and supported in policy documents and health education material in NZ. Key issue is 'is the infant ready to start solids' and when are they ready for the next stage of food?

⁴⁶ Townsville Aboriginal and Islander Breastfeeding and Infant Feeding Project (1998).

⁴⁷ Inala Indigenous Infant Feeding Project (1998).

Submitter	Summary of Submissions
	<ul style="list-style-type: none"> • Supports inclusion of ‘around six months’ for ‘first stage foods’ providing the stage and consistency of the food are also on the label. • For second and third stage foods, supports reference to ‘stage’ and ‘consistency’ only, NOT an age or age range. <p><i>Labelling in consumer education (Advisory statement)</i></p> <ul style="list-style-type: none"> • Considers there is insufficient justification provided to demonstrate that the current requirements are inadequate. Caregivers who prepare first foods in the home are not subject to information about feeding. Advice for feeding infants has historically and is adequately covered by health education material, industry support and advice from family and friends. <p>Supports proposed statement as a voluntary provision only.</p>
<p>10. Australian Food and Grocery Council (AFGC) Australia <i>Mr Tony Downer</i></p>	<p>Supports Option 1</p> <p>Reiterates its view that there is a lack of consistent evidence to support a change in labelling, while there is evidence of safe use of complementary foods in the age range 4-6 months in Australia and NZ (presence in the food supply over many years). Notes government policy and principles on ‘minimum effective regulation’.</p> <p><i>International regulation of minimum age labelling</i></p> <ul style="list-style-type: none"> • Notes contradiction of statements included in the Draft Codex standard for processed cereal based foods intended for feeding infants as a complementary food (ALINORM 04/27/26). • Recommends the contradiction be resolved with CODEX before using it as evidence. <p><i>Consumer research</i></p> <ul style="list-style-type: none"> • Research confirms that the decision to introduce solids was not influenced by label information, but by child health nurses, reference materials, mothers’ groups and signals from their babies. • Research indicated useful elements on the label included a texture descriptor, consistent age recommendation through an age range, and colour coding. (already present on labels). <p><i>Consistency to minimise risk of choking</i></p> <ul style="list-style-type: none"> • Supports removal of subclause 2(4) as it is the responsibility of manufacturers to formulate foods to a consistency appropriate for the developmental stage/age of the infant for whom the food is being promoted as suitable. <p><i>Labelling in consumer education (Advisory statement)</i></p> <ul style="list-style-type: none"> • Considers labelling should provide information about the safety of food and constituents, while providing simple advice on the timing of the introduction of solids. • Supports using existing standard with use of minimum age labelling of infant foods.

Submitter	Summary of Submissions
	<ul style="list-style-type: none"> • Does not support use of a mandatory advisory statement to ‘consult a health professional’ on labels as is not justified according to FSANZ Consumer research and the section 18 objectives of the FSANZ Act which relate to protection of public health and safety and the provision of adequate information to enable consumers to make informed choice. • Detailed information is better provided in pamphlets or brochures developed by health professionals and organisations with an interest in baby health care. • Accepts the voluntary use of an advisory statement ‘to consult a health professional’, but considers there is a lack of appropriate evidence to mandate use of the advisory statement which would place an additional regulatory burden on industry. <p><i>Labelling in consumer education (Warning statement)</i></p> <ul style="list-style-type: none"> • Supports continued use of the warning statement ‘Not recommended for infants under the age of four months’ on foods intended for infants from 4-6 months. • States that limited space on single serve package after meeting customer and regulatory labelling requirements with no space left for marketing or consumer information. <p><i>Transitional arrangements</i></p> <ul style="list-style-type: none"> • Recommends a two year transition period with a further two years stock in trade for long shelf life products to enable as economic transition as possible. Extra time is required to take account of seasonal production schedules, long shelf life, the number of SKUs and the design, consumer research and label constraints. <p><i>Impact analysis</i></p> <ul style="list-style-type: none"> • Notes that maintaining the <i>status quo</i> represents a risk to industry. • Expresses concern that the proposed changes may increase consumer confusion in the absence of appropriate justification, risk analysis and sound science. • Notes that industry will incur significant costs if proposed changes to labelling requirements are introduced. • Changing labelling of infant foods would require extensive education strategy at significant cost to government and industry without providing a net benefit to consumers over existing arrangements. <p><i>Proposed variation to standard 2.9.2</i></p> <ul style="list-style-type: none"> • Supports inclusion of ‘around 6 months’ and ‘not recommended for infants under the age of four months’ on labels for foods for infants. • Does not support inclusion of an advisory statement ‘words to the effect that the decision to begin feeding solids should be made in consultation with a health professional.’

Submitter	Summary of Submissions
<p>11. Heinz Wattie's Australia and New Zealand <i>Mr Jason Arnheim</i></p>	<p>Supports Option 2</p> <p>Considers the objectives of the proposal are met e.g. protect health and safety of infants; provide adequate information for informed choice and consistency with infant feeding guidelines.</p> <p><i>Labelling in consumer education (Advisory statement)</i></p> <ul style="list-style-type: none"> • Does not support mandatory advisory statement as considers it is not justified, is not necessary and practical space constraints on an already regulated label. • Supports use of the statement on supporting materials rather than on the label of foods for 4-6 month infants. • Key information source for carers on when to start solids is not the label (top three being health professionals, reference materials and informal groups). • FSANZ has not demonstrated that the statement is required to fulfil an objective of the FSANZ Act. (Reference to proposed statement in a Codex proposal is not evidence of need in Australia and NZ). <p><i>Impact Analysis</i></p> <ul style="list-style-type: none"> • Anticipated cost of label changes exceeds \$AUD500,000, assuming a smooth transition without any loss of stock. • Proposed changes could impact on up to 116 labels in Australia and 82 in NZ. <p><i>Transitional arrangements</i></p> <ul style="list-style-type: none"> • Recommends a two year stock in trade provision for long-life products in line with the precedent set for the end of the transition period for the Joint Code. This would allow all stock legally made during transition period to be sold through. • Infant food manufactured in jars and tins are a long-life shelf stable food. A number of products use seasonal fruit and vegetables which may only be produced once or twice a year and are usually labelled at production time. • Believes a longer stock-in-trade period would support an internationally competitive food industry and be fairer. <p><i>Proposed Draft Variation</i></p> <ul style="list-style-type: none"> • Amendment to Standard 1.1.1 'warning statement' definition at (d) will need to be made to ensure the current warning statement of 'not recommended for infants under the age of four months' is retained after the drafting changes.
<p>12. La Leche League New Zealand <i>Ms Rosemary Gordon</i></p>	<p>Supports Option 2A (option 2)</p> <ul style="list-style-type: none"> • Expresses disappointment that there seems to have been more emphasis on current NZ, rather than Australian infant feeding guidelines. • Considers the amendments to be a 'watered down' version of the optimum standard of exclusive breastfeeding for the first six months. • Concern that parents will continue to believe foods are suitable for infants from 4 months onwards.

Submitter	Summary of Submissions
	<ul style="list-style-type: none"><li data-bbox="443 232 1398 331">• Not confident that an advisory statement recommending that the decision to introduce solids be made in consultation with a health professional will increase the average age for introducing solids from four months.

Summary of Comments on the Consultation Paper 5 October 2007

FSANZ received 20 responses to the Consultation Paper for P274 – Review of Minimum Age Labelling of Foods for Infants during the consultation period from 5 October 2007 to 19 October 2007.

The following regulatory approach was proposed in the Consultation Paper:

- amend the minimum age labelling requirements in Standard 2.9.2 to ‘around six months’ to reflect Australian and New Zealand infant feeding guidelines;
- retain the minimum age reference labelling, expressed in numbers, from which the food is suitable, rather than amending the reference to ‘age’ with an alternate scheme, e.g. phases or stages;
- retain the warning statement not recommended for infants under the age of four months on the label of infant foods promoted as suitable from ‘around 6 months’;
- amend subclause 2(4) to state that foods intended for infants from around the age of 6 months must be formulated and manufactured to a consistency that is soft and free of lumps; and as a result remove the redundant Editorial note; and
- consequentially amend the clause relating to the voluntary addition of vitamins and minerals to cereal-based foods for infants to reflect the minimum age labelling of ‘around 6 months’.

A list of responders and summary of their comments is provided in the table below.

Responder	Summary of Comments
1. Australian Lactation Consultants Association Australia <i>Ms Gwen Moody</i>	<ul style="list-style-type: none"> • Fully supports the proposed changes as they are in line with WHO recommendations for the introduction of solids and NHMRC infant feeding guidelines.
2. Private Australia <i>Ms Maureen Minchin</i>	<ul style="list-style-type: none"> • Supports proposed approach for breastfed infants but suggests different recommendations of no later than 4 months for infants on infant formula. • Fully supports WHO recommendations of introducing complementary foods around six months for breastfed infants, but states that WHO has never given advice on the management of diet for artificially fed infants. Believes changing labels to around six months creates risks for artificially fed infants, who are the majority of Australian children by six months. • Believes that common sense suggests widening the diet and allowing more expression of infant autonomy in food and fluid intake. Notes that babies have survived the four to six months policy and previous policies encouraging early introduction of solids at two months. • Believes vested interests of infant formula manufacturers and baby food manufacturers, health professionals and women who bottlefeed would oppose the differing recommendations for infant formula fed and breast fed infants.

Responder	Summary of Comments
3. New Zealand Dietetic Association <i>Mrs Jan Milne</i>	<p>Supports the proposed minimum age labelling and changes to Standard 2.9.2</p> <ul style="list-style-type: none"> • Mindful that delayed introduction of complementary foods beyond six months may be detrimental to the infants nutrient intake, food variety and oral stimulation for language development • Notes there is ongoing research and discussion regarding food introduction after six months of age and increased risk of allergic disease. Also notes the Australasian Society of Clinical Immunology and Allergy updated position statement stating that ‘delayed introduction of complimentary foods (including normal cow’s milk formula) until 4-6 months modestly reduces the risk of allergy in high-risk infants, but there is no evidence that dietary restrictions after the age of 4-6 months provides a protective effect’.
4. Royal Children’s Hospital Brisbane <i>Dr Melinda White</i>	<p>Supports the Proposal and proposed changes</p>
5. University of Western Australia <i>Professor Susan Prescott</i>	<p>Recommends guidelines not be change from ‘4-6 months’ to ‘6 months’ until studies underway have been completed.</p> <ul style="list-style-type: none"> • A number of recent studies suggest that children not exposed to specific foods in the 4-6 month age range may be at increased risk of allergies to those foods and other immune mediated diseases. New studies are underway to address the role of early exposure to allergenic foods to prevent allergic disease. • Professor Prescott is leading a group of international experts in the field of allergy who are reviewing this area.
6. NSW Food Authority <i>Ms Jo Dellow</i>	<ul style="list-style-type: none"> • Supports minimum age of ‘around 6 months’ but believes the proposed draft variations to Standard 2.9.2 do not specifically prohibit the labelling of foods as suitable for infants ‘from 4 months’. • Recommends a specific prohibition in Standard 2.9.2 preventing the sale of foods that are suitable for infants under the age of 6 months.
7. Bond University Queensland <i>Professor Pete Smith</i>	<p>Recommends hesitancy in making firm comments on the age of weaning at this stage.</p> <ul style="list-style-type: none"> • Late weaning to wheat has been associated with higher rates of coeliac disease, diabetes and wheat allergy. Notes a study on nut exposure in infancy is in progress.
8. Dietitians Association of Australia <i>Ms Kate Poyner</i>	<p>Supports the proposed minimum age labelling and changes to Standard 2.9.2</p> <ul style="list-style-type: none"> • Reiterates previous submission comments noting the importance of education programs for health workers and consumers to ensure that the intended benefits of labelling changes are gained. • Inclusion of a statement regarding consulting a health professional for further information may direct concerned consumers to seek advice if required.
9. Department of Health and Human Services, Tasmania	<p>Supports the proposed minimum age labelling and changes to Standard 2.9.2</p> <ul style="list-style-type: none"> • Supportive of the use of physiological cues of readiness for further introduction of solids after the age of 6 months rather than relying on age criteria but recognises that this may cause further confusion, therefore supports mandatory use of age labelling and voluntary use of consistent stage

Responder	Summary of Comments
<i>Ms Jennifer Savenake</i>	<p>labelling.</p> <ul style="list-style-type: none"> Notes that Standard 2.9.1 definition of infant formula ‘means an infant formula product presented as a breast milk substitute for infants which satisfies the nutritional requirements for infants aged up to four to six months’. It may be appropriate to consider consistency within the Code to remove the reference to four months and change to ‘up to six months’.
<p>10. Food Technology Association of Australia</p> <p><i>Mr David Gill</i></p>	<p>Supports the proposed minimum age labelling and changes to Standard 2.9.2</p> <ul style="list-style-type: none"> The technical subcommittee who reviewed the Proposal had some support for the retention of the ‘stages’ approach, but noted that the amendments did not prevent the voluntary use of the ‘stage’ approach in conjunction with the ‘age’ approach.
<p>11. Heinz Wattie’s Australia and New Zealand</p> <p><i>Ms Julie Dick</i></p>	<p>Supports the proposed minimum age labelling and changes to Standard 2.9.2</p> <ul style="list-style-type: none"> While supporting the warning statement, believes this is unnecessarily lengthy and should be an advisory rather than a warning statement. Therefore proposes amending to ‘not for infants under 4 months’ Requests a 24-month stock-in-trade period as any change to Standard 2.9.2 which will have a significant cost impact. The majority of Heinz Wattie’s infant foods have a shelf life of 24 months. Notes Heinz sells 125 individuals SKUs in Australia and 90 in New Zealand.
<p>12. La Leche League New Zealand</p> <p><i>Ms Barbara Sturmfels</i></p>	<p>Supports the proposed minimum age labelling and changes to Standard 2.9.2</p> <ul style="list-style-type: none"> The directive ‘not recommended for infants under the age of 4 months’ will still give the message that solids may be introduced at four months. Recommends that the Standard not require all foods suitable for infants around six months to be finely pureed slops. The directive for finely pureed foods without lumps for infants around six months will cause manufacturers to re-label pureed and liquefied foods previously marketed for four to six months thus providing foods to ‘drink’ for babies who do not need highly processed foods. Believe there should be at least a recommendation on infant food packaging which says ‘it is recommended that infants be fed exclusively breast milk for their first six months’.
<p>13. Nestle Australia and New Zealand</p> <p><i>Ms Stephanie Rajczyk</i></p>	<p>Supports status quo for following reasons:</p> <ul style="list-style-type: none"> Nestlé’s Infant Formula Policy in developing countries ensures that the company supports the WHO global public health recommendation of exclusive breastfeeding for six months and introduction of safe and appropriate complementary foods thereafter. Raises the question whether exclusive breastfeeding meets the energy and micronutrient requirements for all infants at six months. There have been recent discussions on the topic of exclusive breastfeeding and the age for introduction of complementary foods since the Draft Assessment in October 2004. Quotes the report by Fewtrell et al 2007 which reviewed the evidence to support the WHO recommendations of exclusive breastfeeding to six months and believes the data suggest that breast milk may not meet the full requirements for energy and certain micronutrients for the average infant at 6 months of age.

Responder	Summary of Comments
	<ul style="list-style-type: none"> • For infants who are exclusively formula-fed at 4-6 months of age, there is very little or no data to form evidence based recommendations for the introduction of solids for formula fed infants. More investigation is needed before generic recommendations are made for all infants. Notes WHO recommendations are for exclusively breastfed babies only. • Suggests that both early (<3 months) and late (>6 months) introduction of gluten containing cereal may increase the risk of coeliac disease or wheat allergy in at risk infants. <p>Additional comments</p> <ul style="list-style-type: none"> • The recommended minimum reference age to ‘around 6 months’ and ‘not recommended for infants under the age of 4 months’ is confusing and may lead to confusion of what ‘around’ six months means. Believes current age reference of ‘4-6 months’ is much clearer to the consumer. • EU legislation (2006/125/EC) on processed cereal-based foods and baby foods for infants and young children states that labelling on these products must bear ‘the age from which the product may be used, which must not be less than four months’. • Disagrees with the comment in the consultation paper that the labelling changes will have little effect on international trade. The importation of infant food products produced for overseas markets would need to be relabelled for Australia and New Zealand because Europe and USA have different labelling requirements.
<p>14. Northern Sydney Central Coast NSW Health</p> <p><i>Dr John Sinn</i></p>	<p>Expresses concern regarding the proposed raising of the minimum age labelling because:</p> <ul style="list-style-type: none"> • Allergy is in epidemic proportions in Australia and New Zealand and delaying the introduction of solids may potentially increase allergy in the community.; and • The recent systematic review and study on introduction of solids found little evidence to suggest that early introduction of solids is associated with increased allergy.
<p>15. Royal New Zealand Plunket Society</p> <p><i>Ms Angela Baldwin</i></p>	<p>Supports the proposed minimum age labelling and changes to Standard 2.9.2</p>
<p>16. New Zealand Food Safety Authority (NZFSA)</p> <p><i>Carole Inkster</i></p>	<p>Comments reflect the views of the New Zealand Food Safety Authority (NZFSA) and Ministry of Health (MoH).</p> <p>Supports the proposed minimum age labelling with following recommendations:</p> <ul style="list-style-type: none"> • The proposed draft variations would still allow for the sale of foods for infants from the age of four months therefore there is potential for consumer confusion as the labelling of infant foods may continue to be inconsistent with Australian and revised New Zealand food and nutrition guidelines.

Responder	Summary of Comments
	<ul style="list-style-type: none"> • Guidance on age range and associated textures is not provided. There are some risks associated with using an ‘age’ only approach for infant food labelling. There is an absence of guidance on what age/age ranges and associated textures should be used for these products. There is potential for consumer confusions if manufacturers use different age/age ranges. The use of a definitive age on product labels does not recognise individual differences in development. States that some Australian infant food manufacturers are now using ‘stages’ rather than ‘ages’ as the primary labelling on foods for infants. While believes that ideally age/age ranges and associated textures should not left to the manufacturers discretion, acknowledges this is not consistent with FSANZ objective of minimum effective regulation. <p>Proposed solution for these two issues:</p> <ul style="list-style-type: none"> • The statement ‘around 6 months’ be accompanied with wording to the effect that this intended as a first complementary food for the infant. The words suggested for the label are ‘Stage 1’ or ‘1st Stage’ to be associated with ‘around 6 months’. However, NZFSA would like to consider this further and discuss the options for stage labelling with FSANZ prior to the completion of the Final Assessment. • Believes that subclause 2(4) should not be omitted. Support retaining the subclause with the editorial note which follows. Believes that parent/carers need to be assured that first foods are of an appropriate consistency which minimises the risk of choking. <p>Additional comments</p> <ul style="list-style-type: none"> • Recommends rewording so that ‘folic acid’ is listed, not ‘folate’ as it is folic acid which is added not folate. This is consistent with NZFSA and MoH previous submissions regarding the addition of folic acid to food.
<p>17. Nutricia Australia and New Zealand</p> <p><i>Mr Samartin Saenz</i></p>	<p>Supports AFGC submission. Does not support the proposed minimum age labelling change to ‘around 6 months’ because:</p> <ul style="list-style-type: none"> • There is a lack of clarity regarding the proposed labelling ‘around 6 months’ and ‘not before 4 months’. This may cause uncertainty in mothers or carers. The proposed regulation is not clear as to whether ‘around 6 months’ is the minimum aged labelling permitted. • There are infants who need to state solids before the age of 6 months <p>Additional comments</p> <ul style="list-style-type: none"> • Supports the WHO recommendation of exclusive breastfeeding for six months, and notes that <i>the expert consultation recognises that some mothers will be unable to, or choose not to, follow this recommendation. These mothers should also be supported to optimise their infant’s nutrition.</i> Therefore manufacturers need to keep on the market food products clearly showing that they are suitable for infants between 4 and 6 months of age. • Nutricia’s consumer research with regard to infant formula choices shows that mothers would prefer to choose a product showing clearly suitability in terms of ages, as in ‘from 4 to 6 months’. If infant food products do not have clear age labelling then mothers may use general foods which do not meet the current food standards regulations for infant nutrition.

Responder	Summary of Comments
	<ul style="list-style-type: none"> • The ‘exclusive breastfeeding until six months’ is a one size fits all approach to weaning and may not take sufficient account of the specific needs of some infants. • After six months, iron provided through breast milk and infant’s iron stores are not sufficient to assist with growth demands. With the introduction of solids at 6 months fussy eaters may be at risk of developing iron deficiency. • Some infants between 4 to 6 months struggle with the volumes of infant formula or breast milk required to meet their nutritional needs and could therefore suffer from digestive problems that could be remitted by the introduction of solids between 4 to 6 months. • Delayed introduction of solid foods in the prevention of asthma and allergic disease remains controversial. Although current feeding guidelines recommend delayed introduction of solids for the prevention of asthma and allergy in infants at risk, the evidence is inconclusive and recent emerging evidences provides indications that amongst at risk populations there may be benefit from earlier introduction of solids. • Suggests the following warning statement should be used; <ul style="list-style-type: none"> - ‘from around 6 months; - not before 4 months’; - in a 1.5 mm font type on packages under 500 g; and - the use of statement 1 and 2 satisfies the requirement of the draft paragraph 5(3)(b) that requires the age from which the food is suitable to be expressed in numbers.
<p>18. Royal Children’s Hospital Melbourne</p> <p><i>Dr Ralf G Heine</i></p>	<p>Expresses concern at the proposal, noting the following:</p> <ul style="list-style-type: none"> • In view of the recent increase in food allergies and other allergic conditions in Australia and New Zealand several preventive strategies have been implemented. One of the key strategies, which is undisputed, is exclusive breastfeeding for 4-6 months. The benefits of a delayed introduction of solids are however less clear. Some studies have shown a protective effect against eczema, particularly in those with a positive family history of allergies while the benefits in other infants are less well documented. • Two recent studies suggest that tolerance to gluten was most likely when it was introduced into the infants’ diet between four to six months, suggesting a ‘window of opportunity’ for that period. • Based on the findings of recent clinical studies there is increasing concern that the delayed introduction of solids may have a paradoxical effect and potentially increase the risk of allergic disease. This is a complex area and understanding is still evolving. • Evidence-based recommendations on the introduction of certain weaning foods after 6 months of age cannot be made with confidence at the present time.

Responder	Summary of Comments
<p>19. Australian Food and Grocery Council <i>Mr Kim Leighton</i></p>	<p>Rejects the use of the term ‘around 6 months’ and recommends reconsideration of retaining the term ‘from 4 to 6 months’.</p> <ul style="list-style-type: none"> • NHMRC, NZ ministry of Health guidelines and WHO guidelines refer to breastfed infants which fails to take into account the nutritional and developmental needs of infants who require feeding with infant formula. • Proposed amendments are inconsistent with current requirements for the European Union and the USA, which currently retain the provision for 4-6 months. This inconsistency with major trading partners is a concern for industry as it will limit opportunities and increase costs for imported and exported products. <p>Warning statement</p> <ul style="list-style-type: none"> • Notes that infants under the age of 4 months should not be introduced to solids. Therefore recommends that the warning statement delete the word ‘recommended’ so that the statement is ‘not for infants under the age of 4 months’ <p>Print size and consistency with Standard 2.9.1</p> <ul style="list-style-type: none"> • Recommends that print and package size for Standard 2.9.2 be consistent with Standard 2.9.1. This would enable smaller package sizes of less than 500 g to comply with the mandatory warning requirements, but provide the flexibility of using a smaller font size of 1.5 mm. <p>‘Around 6 months’</p> <ul style="list-style-type: none"> • Concerned that the use of the word ‘around’ in mandating ‘around 6 months’ creates ambiguity for carers and their advisers. Manufacturers will need to provide additional information clarifying when an infant ‘around’ six months might be ready for the introduction of solids. • It is critical that the term ‘around 6 months’ is not interpreted by jurisdictions to mean that manufacturers cannot provide advice about developmental cues for infants between 4 and 6 months. <p>Transitional period</p> <ul style="list-style-type: none"> • Strongly advises that industry be given a two year transition period. The standard transitional requirements of 12 months impose economic hardship on industry. Labelling changes need considerable time to implement, given the seasonal production schedules, long shelf life and number of SKU’s affected and the design and label constraints especially for smaller packaging.

Responder	Summary of Comments
<p>20. Queensland Health Australia</p> <p><i>Ms Tenille Fort</i></p>	<p>Supports the proposed minimum age labelling and changes to Standard 2.9.2</p> <p>Age or Stage labelling</p> <p>Agrees that the use of physiological cues of readiness rather than age is preferred basis for introduction of solids after the age of six months, but recognises that a ‘stage’ approach could cause confusion without sufficient supporting information.</p> <p>Advisory statement</p> <p>Supports the use of an advisory statement as a prompt to busy parents/carers to seek advice or consult professional guidance when introducing solids.</p> <p>Educational support:</p> <p>An education strategy about the labelling changes will be required for parents/carers and for health professionals providing advice on infant feeding. Suggests it would be appropriate and cost effective if the new Early Childhood Section in the Commonwealth Department of Health and Ageing produced information nationally.</p> <p>Standard 2.9.1</p> <p>Notes that Standard 2.9.1 definition of infant formula refers to ‘an infant formula product presented as a breast milk substitute for infants which satisfies the nutritional requirements for infants aged up to four to six months’. Recommends removing the reference to four months in Standard 2.9.1 and changing to ‘up to six months’.</p>