

**1 October 2013**  
**[18-13]**

## Consultation Paper

### Proposal P274 – Minimum Age Labelling of Foods for Infants

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FSANZ has further assessed Proposal P274, prepared to consider amending the youngest minimum age labelling requirements in Standard 2.9.2 of the *Australia New Zealand Food Standards Code*, to reflect the national infant feeding guidelines of Australia and New Zealand. FSANZ now calls for submissions to assist FSANZ's consideration of the draft food regulatory measure it has prepared arising from this Proposal.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly 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 via the link on [documents for public comment](#). You can also email your submission directly to [submissions@foodstandards.gov.au](mailto:submissions@foodstandards.gov.au).

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

#### **DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 12 November 2013**

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to [standards.management@foodstandards.gov.au](mailto:standards.management@foodstandards.gov.au).

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 +61 2 6271 2222

Food Standards Australia New Zealand  
PO Box 10559  
The Terrace WELLINGTON 6143  
NEW ZEALAND  
Tel +64 4 978 5630

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## Supporting Documents

The following documents which informed the assessment of this Proposal are available on the FSANZ website at

<http://www.foodstandards.gov.au/code/proposals/Pages/proposalp274reviewofminimumagelabellingoffoodsforinfants/Default.aspx>

- SD1 Risk Assessment**
- SD2 Risk Management**
- SD3 Summary of Issues from Preliminary Final Assessment and FSANZ response**

# 1. Executive summary

In April 2003, Food Standards Australia New Zealand (FSANZ) was requested by the (then) Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council), now the Legislative and Governance Forum on Food Regulation (the Forum), to review the youngest minimum age labelling requirements for infant foods in Standard 2.9.2 – Foods for Infants, in the *Australia New Zealand Food Standards Code* (the Code). This was to resolve an inconsistency with the 2003 Australian Infant Feeding Guidelines<sup>1</sup>. These guidelines recommended exclusive breastfeeding for the first 6 months of life and the introduction of solid foods at ‘around 6 months’ of age. Ministers also asked that a review of minimum age labelling accommodate New Zealand Infant Feeding Guidelines

In 2007, the New Zealand *Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0–2 years)* were revised and changed the previously recommended age for the introduction of complementary (solid) foods from ‘around four to six months’, to ‘around six months’. These guidelines were finalised in 2008<sup>2</sup>.

In 2008, the National Health and Medical Research Council (NHMRC) commenced a revision of the 2003 Australian guidelines. There was also new evidence emerging in relation to the introduction of solid foods to infants and the potential development of allergies. This was expected to be included in the NHMRC review. Therefore, Proposal P274 was put on hold awaiting completion of the review. The revised Australian guidelines were released in early 2013 and continue to recommend introduction of solid foods to infants at ‘around 6 months’ of age<sup>3</sup>.

Standard 2.9.2 – Foods for Infants provides the compositional and labelling requirements for infant food. The label of an infant food must include a statement indicating the consistency of the food and the minimum age, expressed in numbers, of the infants for whom the food is recommended. The label must not include a recommendation, expressed or implied, that the food is suitable for infants less than 4 months of age. The youngest minimum age requirement is not consistent with the infant feeding recommendations for the age of introducing solid food to an infant i.e. around 6 months of age.

Overseas regulations and guidelines prescribe various labelling requirements including youngest minimum age labelling of ‘not less than six months’ (World Health Organization, Canada, and the Codex Alimentarius cereal-based food standard); some have no age requirements (USA, and Codex canned baby foods standard); and the European Commission requires ‘not less than 4 months of age’ as the youngest minimum age permitted on infant food.

Previous consultation at Preliminary Final Assessment in 2008 indicated that most submitters generally supported amending Standard 2.9.2 to reflect the infant feeding guidelines of Australia and New Zealand; whereas others supported retaining the current age requirements; and some recommended delaying any amendments until further evidence was available regarding the optimum time to introduce solid foods.

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<sup>1</sup> NHMRC Dietary Guidelines for Children and Adolescents (incorporating Infant Feeding Guidelines for Health Workers) (2003)

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

<sup>3</sup> Summary table of infant feeding guideline recommendations and Proposal P274 over time

Key issues included the emerging evidence that there may be a window of opportunity to reduce the development of allergies by introducing solid food to infants between 4–7 months of age; some recommended a mandatory labelling requirement to indicate a ‘first food’ on products suitable for ‘around 6 months’; and some concern was raised regarding the impact of applying the Recommended Dietary Intake (RDI) for iron for infants aged 6 months and over, to infants over the youngest minimum age of ‘around 6 months’.

FSANZ undertook a risk assessment at Preliminary Final Assessment stage in 2008. Both the FSANZ assessment and the NHMRC review of the Australian infant feeding guidelines primarily considered evidence until 2008. Therefore, when Proposal P274 recommenced in 2013, FSANZ reviewed research literature from 2008.

The main purpose of the risk assessment was to consider risks to an infant’s health and safety that would be linked to the introduction of solid food at ‘around 6 months’, as compared to ‘from 4 months’ of age. General health factors associated with introducing solid food to infants, including the risk of allergies, were considered.

Allergy risk appears to be increased with solid foods introduced to infants at less than 4 months of age, based on several cohort studies. There is increasing evidence that the timing of solid food introduction may be related to a decreased risk of food-related allergy; the critical period to minimise the risk seems to be between the ages of 4 and 7 months. However, the evidence is not conclusive; randomised trials are currently underway on this topic. The risk assessment has concluded that the timing of ‘around 6 months’ as the appropriate age for the introduction of solid foods for infants, would have minimal effect on the risk of adverse health outcomes, compared to ‘from 4 months’ of age.

Available research on the effect of labels on consumer behaviour suggests that the youngest minimum age declared on infant food labels is unlikely to have a large impact on the age at which most caregivers introduce solids to infants. However, FSANZ consumer research found that caregivers do value age and consistency information, particularly for deciding when to move from one stage of solids to the next.

FSANZ has considered the options for labelling infant food and determined it is not appropriate to maintain the status quo, because it does not align with current infant feeding recommendations. Therefore, it is proposed to amend Standard 2.9.2 so that the youngest minimum age declaration required on a label of an infant food is ‘around 6 months’ and for this wording to be displayed on first-stage weaning foods. This phrase would be prescribed to align with the words used in the Australian and New Zealand infant feeding guidelines. Also, it is proposed that the age (number) should always appear on the front of the food label. The warning statement that refers to infants under the age of 4 months is proposed to apply only to foods labelled as ‘around 6 months’ however, the placement of that statement need not be in association with the minimum age statement. The text of the warning statement is proposed to be shortened to ‘not before 4 months of age’. A statement indicating the consistency of the food continues to be required. Consequential amendments and a small number of corrections to the Standard are also proposed.

This approach is proposed because it:

- continues to protect the health and safety of infants
- provides consistency with the infant feeding recommendations in Australia and New Zealand thereby reinforcing caregiver education and promoting infant health
- provides caregivers with sufficient information in relation to the timing and consistency of infant foods, to make appropriate choices
- permits flexibility and recognises the natural variation of individual infants development
- maintains the harmonisation of regulations for Australia and New Zealand

- aligns with Ministerial guidelines
- provides net benefits to affected parties
- is in line with minimum effective regulation.

Transition arrangements over a 3-year period are proposed i.e. a 2-year transition period for infant food manufacturers to comply with the new requirements, plus a 12-month 'stock in trade' provision. This is expected to minimise costs to industry.

## 2. Introduction

### 2.1 Background to the Proposal

This Proposal dates from 2003. As such, it is subject to transitional provisions which apply the provisions of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) as it was in force prior to 1 July 2007. The Proposal has undergone the initial and draft assessments and public consultation processes required by that Act as it was in force prior to 1 July 2007. The Proposal has yet to undergo Final Assessment under that Act. This consultation process is being undertaken as an administrative step prior to final assessment and approval by the Board.

In April 2003, Food Standards Australia New Zealand (FSANZ) was requested by the (then) Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council), now the Legislative and Governance Forum on Food Regulation (the Forum), to review the minimum age labelling requirements for infant foods in Standard 2.9.2. This was to resolve an inconsistency with the 2003 Australian Infant Feeding Guidelines<sup>4</sup>. These Guidelines recommended exclusive breastfeeding for the first 6 months of life and the introduction of solid foods at 'around 6 months'. In addition, Ministers asked that a review of minimum age labelling also consider and accommodate New Zealand Infant Feeding Guidelines

In 2007, the New Zealand *Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0–2 years)* revised the previous recommended age for the introduction of complementary solid foods from 'around four to six months' to 'around six months'. The revised New Zealand guidelines were finalised in 2008<sup>5</sup>.

Proposal P274 progressed to Preliminary Final Assessment in 2008 and proposed to amend the youngest minimum age labelling permitted on infant foods from 4 months to 'around 6 months' of age to align with the infant feeding recommendations of both Australia and New Zealand. However, also in 2008, the National Health and Medical Research Council (NHMRC) commenced a revision of the 2003 Australian Infant Feeding Guidelines. Also, there was new evidence emerging in relation to the introduction of solid foods to infants and the development of allergies. Since this was expected to be included in the NHMRC review, Proposal P274 was put on hold awaiting the outcome of the NHMRC review.

The revised Australian Guidelines were released in February 2013. The NHMRC retained the previous recommendation regarding the introduction of infant food i.e. that solid foods be introduced at 'around 6 months' of age. This continues to align with the current New Zealand Guidelines. P274 has therefore recommenced to further consider aligning the labelling requirements in the Code with the respective national recommendations.

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<sup>4</sup> NHMRC Dietary Guidelines for Children and Adolescents (incorporating Infant Feeding Guidelines for Health Workers) (2003)

<sup>5</sup> New Zealand Ministry of Health, *Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2): A Background Paper*, (2008).

As Proposal P274 has been on hold since 2008, FSANZ recommenced the project with targeted consultation, and are providing an additional round of public consultation, to enable stakeholders to provide updated information and identify any further issues that have arisen over the five years since Preliminary Final Assessment.

## **2.2 Current regulations**

### **2.2.1 Standard 2.9.2 – Foods for Infants**

Standard 2.9.2 provides the compositional and labelling requirements of foods intended and/or represented for use as foods for infants, excluding infant formula products 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
- where the food is recommended for infants between the age of 4–6 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, expressed or implied, that the food is suitable for infants less than four months old (subclause 5(2)).

### **2.2.2 International regulations**

There is a range of regulations and recommendations internationally relevant to the age labelling of infant food. These are outlined in SD2.

## **2.3 Applicable Ministerial Policy Guidelines**

Proposal P274 is consistent with the Ministerial Policy Guideline on the Intent of Part 2.9 of the Code. Details are provided in SD2.

## **2.4 Reasons for preparing the Proposal**

The Proposal was originally prepared in 2003 at the request of the then Ministerial Council, because the youngest minimum age labelling required by Standard 2.9.2 was not consistent with the 2003 Australian infant feeding recommendations. The Standard also remained inconsistent with the 2008 revision of the New Zealand Infant Feeding Guidelines. Similarly, the labelling did not support World Health Organization (WHO) recommendations on exclusive breastfeeding. This situation had the potential to create confusion for caregivers and did not support health education messages, as the labelling requirements for infant foods conflicted with the recommended timing for the introduction of solid food to infants.

As the current recommendations in the 2013 Australian Infant Feeding Guidelines, and the 2008 New Zealand Infant Feeding Guidelines continue to recommend solid food at 'around 6 months' of age, this inconsistency and potential confusion remains.

## **3. Consultation**

### **3.1 Preliminary Final Assessment Report**

A Preliminary Final Assessment Report (PFAR) was released for public consultation in 2008 that proposed to amend the youngest minimum age labelling permitted on infant foods 'from 4 months' to 'around 6 months' of age to align with the infant feeding recommendations of both Australia and New Zealand.

Twenty submissions were received: 4 from the food industry, 5 from health professionals, 6 from jurisdictions, 4 from individuals or consumer groups, plus 1 academic submitter. Overall, a majority generally supported amending Standard 2.9.2 to reflect the respective national infant feeding guidelines; whereas others supported retaining the current age requirements; and some recommended delaying any amendments until further evidence was available regarding the optimum time to introduce solid foods.

FSANZ has considered the issues raised by submitters and provides a response in supporting documents and particularly in the Table in SD3.

### **3.2 Targeted consultation 2013**

Since recommending the Proposal, FSANZ has held targeted consultations with key stakeholder groups i.e. infant food manufacturers, jurisdictions and some health professional representatives. The updated information gathered has informed this Consultation Paper and is included in SD2.

## **4. Summary of the assessment**

### **4.1 Risk assessment**

FSANZ's previous Risk Assessment concluded in 2008 that the available evidence on the relationship between the timing of solid food introduction and infant growth, kidney function and iron and zinc status shows that there are unlikely to be any adverse health effects from a delay in the introduction of solid foods to 6 months of age. While the Infant and Child Scientific Advisory Group (ICSAG) members noted that a delay in the introduction of solids (to as late as 6 months) in preterm 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.

Allergies and the age of first solid food was an area of emerging evidence at PFAR and was contentious at that time. In reviewing the 2003 Australian Infant Feeding Guidelines, the NHMRC considered evidence up to 2008 relating to this issue.

The evidence regarding the development 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 7 months. ICSAG members supported these preliminary findings.

The full risk assessment at PFAR is available on the FSANZ website<sup>6</sup>. Issues raised by submitters at that time are included in SD3, along with FSANZ's response to these issues. SD1 provides a review of evidence since 2008 undertaken by FSANZ, in relation to both the development of allergies and general health factors associated with introducing solid food to infants.

#### **4.1.1 FSANZ's Risk Assessment conclusion (2013)**

The appropriate timing for the introduction of solid food to infants, also termed complementary feeding, is considered important in meeting an infant's nutritional requirements in the first year of life. Infants should be introduced to solid foods when breastfeeding (or formula) no longer provides sufficient nutrients and when developmental cues indicate a readiness to receive solid food. However, the ideal time period in terms of various long- and short-term health outcomes has been debated over the past few years.

A number of international expert bodies including the WHO, the European Society for Paediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN), and the European Food Safety Authority (EFSA) have reported views on the timing of complementary feeding.

The main purpose of this risk assessment is to determine whether any food-related safety risks would be linked to introducing foods at 'around 6 months' of age, compared to 'from 4 months'.

Long and short-term health outcomes examined in relation to the timing of complementary feeding, include nutritional adequacy (including energy intake), growth and overweight, developmental effects (including food preferences), renal function, infectious morbidity, and allergic diseases or syndromes. Because of the many differences and variables in study designs, it is difficult to link the specific timing (i.e. defined in months of age) to an adverse health outcome. The strength of evidence for many of these associations is inconclusive due to studies where interpretation is complicated by study objectives which are separate to complementary feeding, such as duration of breastfeeding.

Because of the increase in the numbers of children observed with food allergy, sensitisation and anaphylaxis over the past 10–15 years, there is a lot of interest currently in the association between allergic diseases and the timing of solid food introduction. In 2008, FSANZ reviewed the risk of allergy and other immune-mediated diseases in relation to timing of introduction of solid foods and concluded that, although preliminary information suggests that a small window may exist between 4 and 6 months of age to minimise allergy risk, conclusive evidence is still lacking. In 2009, reports published by EFSA and ESPGHAN made similar conclusions.

This risk assessment has focused on reports and data published since 2008. Food allergy risks were reviewed in detail because of current concerns which are particularly relevant to the time periods being considered in this Proposal.

The main conclusions of this assessment are summarised as follows:

- Solid food introduced at 'around 6 months', compared to 'from 4 months' of age, effectively means that introduction of solid foods could be delayed by as much as up to 2 months.

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<http://www.foodstandards.gov.au/code/proposals/Pages/proposalp274reviewofminimumagelabellingoffoodsforinfants/Default.aspx>



Based on several key review articles, no health effects are clearly linked with adverse outcomes if solid food introduction is delayed to 'around 6 months' compared to 'from 4 months' of age.

- Allergy risk appears to be associated with solid foods introduced to infants at less than 4 months of age based on several cohort studies. This association, combined with evidence that risk of infectious morbidity is also increased with this time period, supports the current recommendations from ESPGHAN, EFSA, and NHMRC that from 4 months of age is the appropriate youngest minimum age at which solid foods are introduced.
- Since 2008, there is increasing evidence that the timing of solid food introduction may be related to the development of food-related allergy. The critical period to minimise the risk of allergy development seems to be between the ages of 4 and 7 months. However, because of unclear and inconsistent definitions of age categories, measurement bias in many studies and the contribution of various other factors in the development of allergic disease, the evidence is not conclusive.

Currently, there are randomised controlled trials (RCTs) underway which aim to determine whether exposure to food allergens, and not avoidance, is critical during this period to minimise the risk of developing food-related allergy and to determine the optimal timing for introduction of solid foods.

Therefore, based on current recommendations and the analysis presented in this risk assessment, the timing of 'around 6 months' as the appropriate age for the introduction of solid food to infants, would have minimal effect on the risk of adverse health outcomes, when compared to 'from 4 months' of age.

## **4.2 Risk management**

The supporting document SD2 provides detail on several background matters, and the issues considered in developing and assessing the regulatory options for Proposal P274. Section 4.2 provides a summary of those matters.

### **4.2.1 Matters considered**

When assessing this Proposal and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters:

- the objectives and matters listed in section 10 of the FSANZ Act (as was in force prior to 1 July 2007); and
- whether costs that would arise to bodies or persons from a food regulatory measure developed or varied as a result of the application outweigh benefits that would arise to the public from the measure or variation; and
- whether there are any alternatives (available to FSANZ or not) which are more cost-effective than a food regulatory measure developed or varied as a result of the proposal; and
- any relevant New Zealand standards; and
- any other relevant matters.

The regulatory options considered in 2013 remain the same as at PFAR and are outlined in SD2. The cost/benefit analysis has indicated that an overall net benefit is achieved through amending Standard 2.9.2 to reflect the national infant feeding guidelines of Australia and New Zealand. Details are provided in SD2.

There are no other measures which could achieve the same level of cost effectiveness other than amendments to Standard 2.9.2

Standard 2.9.2 applies to New Zealand and there are no relevant New Zealand only Standards.

#### **4.2.2 Other relevant matters considered**

To determine the most appropriate requirements in relation to the youngest minimum age permitted on infant food labels, and strategies to manage any potential risks, the following matters have been considered:

- the current New Zealand and Australian infant feeding guidelines
- international recommendations, regulations or guidelines
- previous stakeholder submissions (see SD3)
- FSANZ's risk assessment – updated from 2008 (see also SD1)
- Ministerial Policy Guidance
- consumer use and understanding of food labels (see also Attachment 1 to SD2)
- approach to labelling requirements
- options for amending the Code
- impacts on stakeholders
- transitional arrangements
- any consequential effects of the proposed approach including for infant foods other than those represented for the youngest minimum age.

These matters are either discussed in SD2, or in this Paper as indicated above. All the above considerations have informed the proposed regulatory approach for the labelling of infant foods.

#### **4.2.3 Proposed approach**

The proposed approach is to amend Standard 2.9.2 so that the youngest minimum age labelling permitted on the label of infant food would be prescribed as 'around 6 months' on infant food that is intended to be introduced in the first stage of weaning an infant i.e. a 'first food'. See Section 5 below. This approach, and the rationale for it, is discussed in SD2. The draft variation is provided at Attachment 1.

#### **Questions for submitters**

SD2 (and also summarised in Attachment 2 to SD2) contains questions for submitters relating to the proposed approach:

- concept and definition of 'first food'
- consequential use of the age number 6 on infant food
- proposed changes to location and wording of mandatory advisory statements
- request for cost estimate information.

While any feedback on the Consultation Paper is welcome, a response to the specific questions is particularly helpful to FSANZ.

#### **4.2.4 Addressing FSANZ's objectives for standards setting**

During the assessment, FSANZ has also considered the three objectives in section 10 of the FSANZ Act (as was in force prior to 1 July 2007) and considers that the proposed approach achieves these objectives.

##### *4.2.4.1 Protection of public health and safety*

FSANZ has updated its 2008 risk assessment in the PFAR to consider literature since that time until now, particularly on the contentious issue of allergies. This updated assessment includes a review of NHMRC's assessment underpinning the 2013 Australian Infant Feeding Guidelines. FSANZ's updated risk assessment is provided at SD1 and is summarised in Section 4.1 above.

##### *4.2.4.2 The provision of adequate information relating to food to enable consumers to make informed choices*

The labelling amendments proposed for infant food include (among other things) prescribed wording of 'around 6 months' to be required on foods intended as a first solid food; the age in numbers is to be displayed on the front of an infant food; two warning statements have been retained but shortened; and the warning statement 'not before 4 months' is now not required to be in association with the age statement. These amendments are to provide consistent information on the minimum age of infants for whom the food is recommended, describe the consistency of the food, provide clarity and avoid confusion, and provide a warning that infant food is not recommended for infants less than 4 months of age. These statements are mandatory to ensure sufficient information is provided for consumers to make informed choices. FSANZ's and other consumer research helped inform these information requirements.

##### *4.2.4.3 The prevention of misleading or deceptive conduct*

The requirements are drafted in Standard 2.9.2 so that they are clear for both manufacturing and enforcement purposes, and for consumers.

##### *4.2.4.4 Subsection 10(2) considerations*

FSANZ has also had regard to the matters listed in subsection 10(2) (as was in force prior to 1 July 2007):

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ has reviewed the evidence in the most recent risk assessment. Refer to SD1 and Section 4.1 above.

- **the promotion of consistency between domestic and international food standards**
- **the desirability of an efficient and internationally competitive food industry**

These matters are discussed in SD2. While recognising that some international standards may differ from the proposed labelling requirements for infant foods, amending the youngest 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 and only a small proportion is exported. Also, this is a proposed amendment to an existing requirement rather than a new requirement.

- **the promotion of fair trading in food**

The proposed amendments would apply to all ‘first food’ for infants, so would impact on all manufacturers equally (see SD2 for a definition of ‘first food’).

- **any written policy guidelines formulated by the Ministerial Council<sup>7</sup>**

Policy Guidance on the Intent of Part 2 of the Code – Special purpose foods, has been considered in this Proposal, and is discussed in SD2.

### **4.3 Risk communication**

FSANZ’s communication and education strategy for Proposal P274 aims to increase awareness among target groups of the proposed changes to the youngest minimum age labelling of infant foods and the infant feeding recommendations which support these changes. Target audiences identified are health professionals providing caregiver 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 caregivers of infants.

The need for education strategies for health workers and caregivers about the labelling changes was previously raised by some 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 education to caregivers.

#### **4.3.1 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 commented that the proposed regulatory approach would mean infant feeding labelling in Australia and New Zealand would 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 youngest 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).

## **5. Conclusion and proposed approach**

As requested by the (then) Ministerial Council, FSANZ has reviewed the youngest minimum age labelling requirements for infant food to resolve an inconsistency with the respective NHMRC, and New Zealand Ministry of Health Infant Feeding Guidelines.

The Guidelines both recommend exclusive breastfeeding for ‘around’ the first 6 months of life and the introduction of solid foods at ‘around 6 months’, and while continuing breastfeeding.

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<sup>7</sup> Now known as the COAG Legislative and Governance Forum on Food Regulation

FSANZ's proposed approach is to amend the youngest minimum age labelling requirements in Standard 2.9.2 by varying the minimum reference age to 'around 6 months' of age, to align with the recommendations which, as indicated by our analysis, would have an overall net benefit for the affected parties.

### **Proposed approach**

*Amend the youngest minimum age labelling required on infant foods in Standard 2.9.2 from 4 months to 'around 6 months' of age in accordance with the infant feeding recommendations of Australia and New Zealand.*

*Provide a definition of a 'first food' for the purposes of Standard 2.9.2.*

*Prescribe the words 'around 6 months' as the age labelling requirement for a 'first food' as defined in Standard 2.9.2.*

*Require the minimum age to be placed on the front of an infant food.*

*Amend the scope of the prohibition on age references (expressed or implied) on a label on infant food to not less than 'around 6 months' (rather than 'not less than four months').*

*Require a warning statement on the label of food that is represented for infants at 'around 6 months', rather than 'between the ages of 4-6 months'. Amend the warning statement to 'not before 4 months of age'. The warning statement is no longer required to be placed 'in association with' the age statement.*

Consequential amendments are needed in relation to:

- *the prescribed words of the warning statement related to food containing more than 3 g/100 kJ protein to reflect the changes to the other warning statement*
- *the requirement for a 'first food' to have a soft and smooth consistency (to replace the current provision relating to texture and the accompanying editorial note)*
- *the permission for addition of vitamins and minerals to cereal-based food (containing more than 70% cereal on a moisture free basis) to apply to infants over the age of around 6 months instead of over 6 months*
- *the permission for cereal-based food (containing more than 70% cereal on a moisture free basis) and promoted as suitable for infants from 4 months of age to contain added vitamins and minerals – clause to be deleted as no longer relevant.*
- *list only one RDI for iron with the value of 9 mg.*

This approach is proposed because it:

- provides consistency with the respective infant feeding recommendations in Australia and New Zealand thereby providing consistency, and reinforcing caregiver education and infant health promotion
- continues to protect the health and safety of infants
- provides caregivers with sufficient information in relation to the timing and consistency of infant foods so they can make appropriate choices
- allows for flexibility and recognition of the natural variability of the developmental needs of individual infants in relation to infant food choices
- maintains the harmonisation of regulations for Australia and New Zealand
- provides for minimum effective regulation and provides net benefits to affected parties.

The following 'before and after' schematic shows the changes to the relevant labelling requirements for infant food labelled with the youngest minimum age and with the next minimum age.

## Current Standard

### Aged under 6 months – Minimum age 4 months

Placement of minimum age **anywhere** on label. E.g. 'From 4 months', '4+ months'.

Warning statement: **anywhere** on label '*Not recommended for infants under the age of 4 months*'

Iron content claim 0.3 mg iron/serve (10% RDI 3 mg)

### Aged 6 months and above

Placement of minimum age **anywhere** on label. E.g. 'From 6 months'

Requirement for warning statement unclear

Iron content claim 0.9 mg iron/serve (10% RDI 9 mg)



## Proposed Standard

### First food – defined – 1<sup>st</sup> stage weaning

No statement permitted that suitable for infants aged less than around 6 months.

Placement of minimum age **on front** of label. E.g. From 'around 6 months' 'around 6 months +'

Warning statement: **anywhere** on label: '*Not before 4 months of age*'

Iron content claim 0.9 mg iron/serve (10% RDI 9 mg)

Possible additional voluntary labelling to differentiate from products labelled with older ages

### Non-first food

No statement permitted that suitable for infants aged less than around 6 months.

Placement of minimum age **on front** of label. E.g. 'From around 6 months' 'around 6 months +'

The following warning statement not required:

*'Not before 4 months of age'*

Iron content claim 0.9 mg iron/serve (10% RDI 9 mg)

## 6. Draft variation

The draft variation is provided at Attachment A, and the draft Explanatory Statement is at Attachment B.

## 7. Implementation and transitional arrangements

Following the consultation period for this assessment, draft variations to the Code will be prepared for consideration by the FSANZ Board. Notification of the Board's decision will be made to the Forum for consideration. Subject to any request from the Forum for a review, the variations will be gazetted, taking effect on the date of gazettal.

To allow time for manufacturers to use existing label stocks and to reformulate if necessary, FSANZ is proposing transition arrangements over three years as it is expected this would reduce the cost to infant food manufacturers. This extended period would include a two-year transition period from gazettal to allow manufacturers to comply with the new requirements in Standard 2.9.2 for manufacturers to manufacture and lawfully sell stock that complies with either the current requirements or the amended requirements. In addition, at the end of that two-year transition period, a 12-month stock in trade period would apply to allow stock that is already manufactured for sale at the end of the two years to be lawfully sold for a further 12 months.

### Attachments

- A. Draft variation to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement



## Attachment A – Draft variation to the *Australia New Zealand Food Standards Code*



### Food Standards (Proposal P274 – Review of Minimum Age Labelling of Foods for Infants) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer  
Delegate of the Board of Food Standards Australia New Zealand

**Note:**

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

## 1 Name

This instrument is the *Food Standards (Proposal P274 – Review of Minimum Age Labelling of Foods for Infants) Variation*.

## 2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies the Standards in the *Australia New Zealand Food Standards Code*.

## 3 Commencement and transitional provisions

The variation commences on the date of gazettal.

### SCHEDULE

[1] **Standard 1.1.1** is varied by omitting “paragraph 5(3)(c)” from the definition of warning statement in clause 2, substituting “subclause 5A(2)”.

[2] **Standard 2.9.2** is varied by

[2.1] omitting the heading of the Standard “Foods For Infants” and substituting “Food For Infants”

[2.2] inserting in clause 1 in alphabetical order

“**first food** means a food for infants that is intended for use in the first stage of weaning an infant.”

[2.3] inserting after clause 1

#### “1A Transitional and stock in trade arrangements for certain food for infants

(1) For the matters regulated by the provisions in this Standard amended by the *Food Standards (Proposal P274 – Review of Minimum Age Labelling of Foods for Infants) Variation*, a food for infants must comply with:

- (a) those provisions as amended by the variation; or
- (b) those provisions as if the variation had not commenced,

but not a combination of both (a) and (b).

(2) Subclause 1A(1) ceases to have effect two years after its commencement.

(3) A food for infants is taken to comply with each variation made by *Food Standards (Proposal P274 – Review of Minimum Age Labelling of Foods for Infants) Variation* for a period of 12 months after subclause 1A(1) ceases to have effect, if that food otherwise complied with this Code when subclause 1A(1) ceases to have effect.

(4) To avoid doubt, subclause 1(2) of Standard 1.1.1 does not apply in relation to any variation made by *Food Standards (Proposal P274 – Review of Minimum Age Labelling of Foods for Infants) Variation*.”

[2.4] omitting from paragraph 2(2)(b) “lactic acid producing cultures” and substituting “lactic acid producing microorganisms”

[2.5] omitting subclause 2(5)

[2.6] omitting the Editorial note to subclause 2(5)

[2.7] omitting the word “foods” from the heading of clause 3, and substituting “food”

[2.8] omitting from subclause 3(1)

“is promoted as suitable for infants over the age of 6 months”

and substituting

“is claimed to be suitable for infants over the age of around 6 months”

[2.9] omit subclause 3(2)

[2.10] omitting the word “foods” from the heading of clause 4, and substituting “food”

[2.11] omitting the word “foods” where first occurring in clause 4, and substituting “food”

[2.12] omit clause 5, substituting

#### **“4A Additional compositional requirements for a first food**

A first food must have a soft and smooth consistency.

### **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 around 6 months of age.

(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 on the front of the food indicating the minimum age, expressed in numbers, of the infants for whom the food is recommended; and
- (c) where the added sugars content of the food for infants is more than 4 g/100 g, the word –  
  
‘sweetened’; and
- (d) where honey has been used as an ingredient, the words –  
  
‘sterilised honey’.

#### **5A Labelling requirements for a first food**

(1) For the purposes of paragraph 5(3)(b), a first food must have a statement on the package on the front of the food with the words –

‘Around 6 months’.

(2) A first food must have a statement on the package of the food with the words -

‘Not before 4 months of age’.”

[2.13] omitting from subclause 6(2)

“Not suitable for infants under the age of 6 months”

and substituting

“Not before 6 months of age”

[2.14] omitting the word “recommendation” from subclause 7(2), and substituting “a claim, whether express or implied,”

[2.15] omitting from Table 1 to clause 8 “Niacin\*”, and substituting “Niacin”

[2.16] omitting from Table 2 to clause 8

“

Iron	9 mg, in the case of infants from 6 months
Iron	3 mg, in the case of infants under 6 months

”

and substituting

“

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

”

[2.17] omitting after Table 2 to clause 8

“# - These figures represent US Adequate Intake Levels”

[2.18] updating the Table of Provisions to reflect these variations.

## **Attachment B – Draft Explanatory Statement**

### **1. Authority**

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards.

FSANZ prepared Proposal P274 to review the youngest minimum age labelling requirements for food for infants in Standard 2.9.2 – Foods for infants.

### **2. Purpose and operation**

The Authority has approved a draft variation to Standard 2.9.2 to amend the labelling and other requirements for food for infants.

The Standard requires that a label of a food for infants must include a statement indicating the consistency of the food and the minimum age, expressed in numbers, of the infants for whom the food is recommended. Currently, the label must not include a recommendation, expressed or implied, that the food is suitable for infants less than 4 months of age. This minimum age requirement is no longer consistent with the infant feeding recommendations of both Australia and New Zealand which recommend that solid food be introduced at 'around 6 months' of age. The purpose of the draft variation is to amend Standard 2.9.2 to reflect these infant feeding recommendations.

### **3. Documents incorporated by reference**

The variations to food regulatory measures do not incorporate any documents by reference.

### **4. Consultation**

The Authority's consideration of Proposal P274 has included both public and targeted consultation since the Proposal commenced in 2003. Targeted consultation with key stakeholders was undertaken on recommencement in 2013 after the Proposal was put on hold in 2008. A further round of public consultation is now being undertaken on an updated assessment and revised draft Standard.

Representatives from the industry sector, the relevant State and Territory government agencies, health professional and consumer organisations have provided ongoing advice to the Authority throughout the standard development process.

An impact assessment has been prepared for this round of consultation.

### **5. Statement of compatibility with human rights**

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 44(1) of the *Legislative Instruments Act 2003*

## **6. Variations**

### *6.1 Standard 1.1.1*

Item [1] of the Schedule amends the definition in clause 2 of Standard 1.1.1 of the term ‘warning statement’. The reference in the definition to paragraph 5(3)(c) of Standard 2.9.2 is replaced with a reference to subclause 5A(2) of that Standard.

### *6.2 Standard 2.9.2*

Item [2.1] corrects a typographical error in the heading to Standard 2.9.2.

Item [2.2] inserts a definition of the term ‘first food’ into clause 1 of the Standard. The term is defined to mean a food for infants that is intended for use in the first stage of weaning an infant. Particular labelling and texture requirements are prescribed for ‘first foods’. These requirements relate to consistency of an infant food and the labelling of the youngest minimum age that are appropriate to the range of infant foods introduced during the first stage of a progressively diversified infant diet. The term ‘weaning’ as used in the definition is to be given its ordinary meaning (i.e. in the sense of accustoming a child to food other than breast milk). As a subset of food for infants, a ‘first food’ does not include infant formula products.

Item [2.3] inserts a new clause 1A after clause 1 of Standard 2.9.2. Clause 1A details the transitional arrangements that would apply to food for infants over a period of 3 years from the date that the variations to Standard 2.9.2 commence. These arrangements include a 2-year transition period from the date of commencement to allow manufacturers time to comply with the new requirements. During this period, manufacturers would be able to manufacture and lawfully sell stock that complies with either the current requirements or the amended requirements but not both. Following this 2-year transition period, a 12-month stock in trade period would apply to allow for the sale of existing stock that complies with the current requirements at the end of the 2 years.

Item [2.4] amends paragraph 2(2)(b) of the Standard to update the reference to microorganisms.

Items [2.5] and [2.6] omit subclause 2(5) and the Editorial Note to subclause 2(5) to reflect the insertion into the Standard of new clause 4A.

Item [2.7] corrects a typographical error in the heading to clause 3 of the Standard.

Item [2.8] amends subclause 3(1) of Standard 2.9.2 to provide that the clause’s requirements apply to food that is claimed to be suitable for infants from ‘around 6 months’ of age, rather than to food for infants over the age of 6 months. The subclause prescribes compositional requirements for cereal-based food for infants containing more than 70% cereal on a moisture free basis. The amendment reflects the amendments to the minimum age labelling requirements in Standard 2.9.2.

Item [2.9] omits subclause 3(2) from Standard 2.9.2. This omission is required as the Standard, as amended, no longer permits food to be represented as suitable for infants from 4 months of age.

Items [2.10] and [2.11] correct typographical errors in clause 4 and in the heading to that clause.

Item [2.12] omits clause 5 of the Standard and replaces it with new clause 4A, an amended clause 5 and a new clause 5A.

New clause 4A requires a 'first food' to have a soft and smooth consistency. This is required to reduce the risk of choking, as these foods are intended to be introduced in the first stage of a transition from solely liquid nourishment to the family diet.

Subclause 5(2) of the Standard has been amended to prohibit labels on food for infants from representing the food as suitable for infants aged younger than 'around 6 months'. This requirement replaces provisions which permit age labelling from 4 months of age. The new requirement reflects the current infant feeding guidelines of both Australia and New Zealand that recommend first solid food be introduced to infants at 'around 6 months' of age.

Paragraph 5(3)(b) of the Standard now requires the minimum age statement on a label to be on the front of the package. This is to assist purchasers because age is considered to be a key piece of information that guides purchasing decisions and is easily visible when displayed on the front of the package.

Paragraph 5(3)(d) requires that, if honey has been used as an ingredient, the words 'sterilised honey' must be on the label.

New clause 5A prescribes the specific labelling requirements for a 'first food'.

Subclause 5A(1) prescribes the mandatory minimum age statement on a 'first food' to be 'around 6 months'. The wording reflects the exact wording used in the infant feeding recommendations of Australia and New Zealand that advise first solid food should be introduced at around 6 months of age. Additional words or symbols are not precluded from being used in conjunction with this age statement to indicate that the age is a minimum, such as 'from' or '+'. Confining the labelling of 'around 6 months' to a 'first food' clarifies that other food for infants with a texture and formulation intended for infants from 6 months of age can continue to be produced. This approach also does not preclude a manufacturer from voluntarily providing other stage-based information on a label of food for infants.

Subclause 5A(2) requires the label of a 'first food' also to bear a warning statement indicating that the food must not be fed to infants under 4 months of age. This statement has been shortened for ease of labelling and reinforces the advice in the infant feeding guidelines of both Australia and New Zealand about the health risk from premature introduction of infant food. The warning statement is no longer required to be in association with the mandatory minimum age statement.

Item [2.13] amends the warning statement required by subclause 6(2) of Standard 2.9.2. The subclause requires a warning statement on a food for infants that contains more than 3 g/100 kJ of protein. This statement has been shortened for ease of labelling and has been framed to be consistent with the warning statement in subclause 5A(2).

Item [2.14] amends subclause 7(2) of the Standard to provide that a claim must not be made, whether expressed or implied, that food for infants can be added to bottle feeds of infant formula product.

Item [2.15] amends Table 1 to clause 8 of Standard 2.9.2 to remove the asterisk attached to the entry for 'niacin' in Column 1 of the Table. This is because there is no footnote linked to the asterisk.

Item [2.16] amends Table 2 to clause 8 of Standard 2.9.2 to omit the Recommended Dietary Intake (RDI) for iron in the case of infants under 6 months of age. The RDI of 9 mg is considered appropriate for all infants from a minimum age of 'around 6 months' and would apply to the nutrition labelling of all food for infants that claim iron content.

Item [2.17] corrects a typographical error in the note that follows Table 2 to clause 8 of the Standard.

Item [2.18] amends the Standard's Table of Provisions to reflect the changes made by the variations.

### *6.3 Commencement*

Clause 2 of the instrument provides that the variations commence on the date of that instrument's gazettal.