

Supporting document 2

Risk Management Considerations – Proposal P274

Review of Minimum Age Labelling of Foods for Infants

Executive summary

FSANZ is considering amending the *Australia New Zealand Food Standards Code* (the Code) to align with the infant feeding recommendations of both Australia and New Zealand.

In the Code, Standard 2.9.2 – Foods for Infants, requires infant food to be labelled with a statement indicating the minimum age, expressed in numbers, of the infants for whom the food is recommended. The provisions allow for age labelling from 4 months of age.

When assessing the regulatory options under Proposal P274, and to determine the most appropriate age labelling requirements on infant food, and strategies to manage any risks, the following factors have been considered:

- the current New Zealand (2008) and Australian (2013) infant feeding guidelines
- international recommendations, regulations or guidelines
- previous stakeholder submissions
- FSANZ's updated risk assessment (2008)
- Ministerial policy guidance on Part 2.9 of the Code
- consumer research on use and understanding of food labels
- approach to labelling requirements
- options for amending the Code
- impacts on stakeholders and the net benefit to the community
- transition arrangements
- any consequential effects of the proposed approach.

Both the current Australian and New Zealand infant feeding guidelines recommend that solid food be introduced to infants at 'around 6 months', while acknowledging the individual variation in an infant's readiness. Overseas regulations and guidelines have various labelling requirements such as the youngest minimum age labelling of 'not less than 6 months' including World Health Organization (WHO), Canada, Codex Alimentarius cereal-based infants food standard (Codex). Some others have no age requirements, for example the United States of America (USA), and Codex canned baby foods standard; whereas others such as the European Commission (EC) require '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 a majority of submitters generally supported amending Standard 2.9.2 – Foods for Infants, to reflect the respective national infant feeding guidelines of Australia and New Zealand.

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 food.

Key issues raised during consultation, 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 on products suitable for ‘around 6 months’ to indicate they were a ‘first food’; and some concern was raised regarding the impact of having one RDI for iron relevant for infants above 6 months of age.

Both the FSANZ 2008 risk assessment and the 2013 NHMRC review of the Australian infant feeding guidelines, primarily considered evidence until 2008. Therefore FSANZ has reviewed literature since that date.

The main purpose of this risk assessment was to determine whether any food-related safety risks, including the risk of allergies, would be linked to the introduction of solid food at ‘around 6 months’ compared to ‘from 4 months’ of age. Based on the analysis and current recommendations, it is 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 impact 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’s consumer research found that caregivers valued age and consistency information, particularly for deciding when to move from one stage of solids to the next.

After considering the above factors, FSANZ is proposing to amend Standard 2.9.2 so that the requisite youngest minimum age on a label of infant food is prescribed as ‘around 6 months’. This would be required on an infant food that is intended to be introduced in the first stage of the weaning process i.e. a first food.

Also, we are proposing that that the age (expressed as a number) must be displayed on the front of the food label. Mandatory statements indicating solid foods are not recommended for infants under the age of 4 months of age have been shortened. In addition, it is proposed that only one RDI for iron will be listed in Standard 2.9.2 i.e. the RDI for infants over 6 months of age.

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 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
- 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 manufacturers to comply with the new requirements, plus a 1-year 'stock in trade' provision. This is expected to minimise costs to industry.

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1. Introduction

This Supporting Document provides detail on the background and issues considered in developing and assessing the regulatory options for Proposal P274.

2. Background

In April 2003, Food Standards Australia New Zealand (FSANZ) was requested by the then Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council)¹ to review the youngest 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 request sought to resolve an inconsistency with the revised National Health and Medical Research Council (NHMRC) *Dietary Guidelines for Children and Adolescents* (incorporating *Infant Feeding Guidelines for Health Workers*)². The NHMRC guidelines recommended exclusive breastfeeding for ‘around’ the first 6 months of life and the introduction of solid foods at ‘around 6 months’ of age. In addition, Ministers asked that a review of minimum age labelling also consider and accommodate New Zealand Infant Feeding Guidelines.

FSANZ prepared a Proposal and released a Draft Assessment Report in 2004, however work was then delayed due to other Ministerial Council priorities.

The New Zealand *Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2 years)* were revised, and finalised³ in May 2008. These Guidelines recommend exclusive breastfeeding for around the first 6 months of life and the introduction of complementary solid foods at ‘around 6 months’ of age. The Guidelines also recommend that complementary solid foods should be introduced when an infant is at the appropriate stage of development, which will vary from infant to infant.

In 2008, FSANZ provided a Preliminary Final Assessment Report (PFAR) on the basis of issues raised through consultation, the release of the New Zealand Guidelines, updated cost information provided by industry, and FSANZ’s updated risk assessment, particularly with regard to allergies and timing of the introduction of solid food. However, also in 2008, the NHMRC began a review of the Australian Guidelines. Because this was expected to consider the emerging evidence relating to the development of allergies in infants, P274 was put on hold to await the outcome of the NHMRC Review.

The revised NHMRC Guidelines were released in February 2013, so Proposal P274 was recommenced to further consider aligning the labelling requirements in Standard 2.9.2 with the current infant feeding recommendations.

¹ The Australia and New Zealand Food Regulation Ministerial Council has been renamed to be the Legislative and Governance Forum on Food Regulation (the Forum)

² NHMRC Dietary Guidelines for Children and Adolescents (incorporating Infant Feeding Guidelines for Health Workers) (2003) <http://www.eatforhealth.gov.au/guidelines>

³ New Zealand Ministry of Health, *Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2): A Background Paper* (2008) [Food and Nutrition Guidelines for Healthy Infants and Toddlers \(Aged 0 to 2 years\) - A Background Paper \(May 2008\)](#)

2.1 Current standard – Australia New Zealand Food Standards Code

Standard 2.9.2 – Foods for Infants, requires infant food to be labelled with a statement indicating the minimum age, expressed in numbers, of the infants for whom the food is recommended.

Also, the label must not expressly recommend or imply that the food is suitable for infants less than 4 months of age.

If the food is recommended for infants between 4-6 months of age, the warning statement – *Not recommended for infants under the age of 4 months* is also required on the label. A statement regarding the consistency of the food is also required.

Other requirements in the Standard that relate to the age labelling include compositional requirements for iron; vitamins and minerals in cereal-based food for infants; protein levels; and making claims about the vitamin and mineral content of infant food.

3. Consideration of issues

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 points have been considered, and are discussed below:

- the current New Zealand (2008) and Australian (2013) infant feeding guidelines
- international recommendations, regulations or guidelines
- previous stakeholder submissions (also see SD3)
- FSANZ's updated risk assessment (2008) (also see SD1)
- Ministerial policy guidance on Part 2.9 of the Code
- consumer research on the use and understanding of food labels
- approach to labelling requirements
- options for amending the Code
- impacts on stakeholders and the net benefit to the community
- transitional arrangements
- any consequential effects of the proposed approach.

3.1 Current infant feeding recommendations

3.1.1 Australia

The revised 2013 Australian Guidelines recommend the introduction of solid food to infants at 'around 6 months' of age, but before 7 months. This continues the previous 2003 recommendations and also continues to align with the 2008 New Zealand Guidelines.

In addition, it is recommended that:

- Infants should be fed exclusively on breast milk to 'around 6 months' of age, with breastfeeding continued up to 2 years or beyond.
- When the infant is ready, appropriate complementary food should be introduced, with continued breastfeeding. Developmental cues should be used to determine if the infant is ready for solids. The infant will most likely be ready at around 6 months of age but

some infants may be ready sooner. However, infants should not be given complementary foods before 4 months of age.

The Guidelines also note that although exclusive breastfeeding 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 recommendation⁴.

3.1.2 New Zealand

The 2008 New Zealand Guidelines revised the recommended age for the introduction of complementary solid foods to 'around 6 months' of age. Previously, they had recommended appropriate solid foods be introduced at around 4 to 6 months. The Guidelines also recommend that solid foods should be introduced when an infant is at the appropriate stage of development, which will vary from infant to infant.

These Guidelines also reflect the WHO population-level recommendations that infants be fed exclusively on breast milk for 6 months, *with the introduction of complementary foods and continued breastfeeding thereafter*.

3.1.3 Aligning the Code with national recommendations

A requirement in the Code that the youngest minimum age reference on a label of infant food is 'around 6 months' would align with the infant feeding recommendations of both Australia and New Zealand. This would provide consistent information for consumers and support health professional messages to caregivers.

Further support for this approach was noted in FSANZ's previous interviews with health professionals where a number of respondents considered that the term 'around 6 months' of age allows for the introduction of solids prior to 6 months if required to meet individual need.

⁴ NHMRC Dietary Guidelines for Children and Adolescents (incorporating Infant Feeding Guidelines for Health Workers) (2002), page 48

3.1.4 International and overseas regulations and recommendations

Table 1: Comparison of regulations/recommendations for age of complementary feeding

Overseas or expert body	Regulations and/or recommendation
WHO (2003)⁵	Recommends infants start receiving complementary foods at 6 months of age in addition to breast milk
Codex Alimentarius	Processed Cereal-based Foods for Infants and Young Children ⁶ This standard includes the requirement for <i>the label to indicate clearly from which age the product is recommended for use. This age shall not be less than 6 months for any product.</i>
Codex Alimentarius	Canned Baby Foods ⁷ This standard does not have a minimum age labelling requirement.
European Commission	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: <i>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 4 months for any product.</i>
Canada	Division 25 of the Canadian <i>Food and Drug Regulations 1954</i> 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 6 months of age (B25.061 (1)).
United States of America	The <i>Code Of Federal Regulations</i> 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).
ESPGHAN (2009)	Complementary feeding should not be introduced in any infant before 17 weeks and all infants should start complementary feeding by 26 weeks.
European Food Safety Authority (EFSA) (2009)	Complementary food introduced between the age of 4 and 6 months is safe and does not pose a risk for adverse health effects.

⁵ The WHO defines complementary feeding as foods or liquids that are provided along with breast milk and thus, infant formula is categorised as a complementary food. The intention of the WHO definition is to encourage exclusive breast feeding until 6 months, particularly in developing countries where risk of infection from unsanitary food and water is significant (WHO 2003). In contrast, ESPGHAN and ESFA and others define complementary foods as all solid food and liquid foods other than breast milk or infant formula and follow-on formula. This assessment for P274 follows the ESPGHAN/EFSA definition.

⁶ Codex (2006) Standard for Processed Cereal-Based Foods for Infants and Young Children. CODEX STAN 74-1981. Revised 2006 www.codexalimentarius.org/input/download/standards/290/cxs_074e.pdf accessed 19 October 2012

⁷ Codex (1989) Standard for Canned Baby Foods. CODEX STAN 73-1981. www.codexalimentarius.org/input/download/standards/.../CXS_073e_u.pdf accessed 19 October 2012

3.2 Consultation

3.2.1 Response to PFAR (2008)

In August 2008, FSANZ released a PFAR for public consultation. It proposed, among other things, to amend Standard 2.9.2 so that:

- the youngest minimum age permitted on a label on infant food was 'around 6 months' of age
- food labelled as suitable for 'around 6 months' must carry a statement to indicate the food was not recommended for infants under 4 months of age.

In addition, the Recommended Dietary Intake (RDI) for iron for infants under 6 months of age would be removed from Standard 2.9.2 as it was no longer considered necessary. The RDI for infants from 6 months was retained.

Twenty submissions were received in response to PFAR; 4 from the food industry, 5 from health professionals, 6 from jurisdictions, 4 from individuals or consumer groups, and 1 academic submitter. In general, a majority supported amending Standard 2.9.2 to reflect the respective national infant feeding guidelines; 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.

SD3 tables the issues raised by submitters at PFAR and FSANZ's response. Key issues raised are discussed below:

- **Allergies:** allergy experts raised the potential window of opportunity to reduce allergic responses in infants by the introduction, not avoidance, of solid foods, between 4 and 6 months of age. They considered maintaining the current age labelling requirements (from 4 months) would be consistent with this emerging evidence. Some other submitters recommended delaying labelling changes until further studies on allergies are undertaken and reported. See Section 3.3 below and SD1.
- **Stages versus age:** the New Zealand Ministry of Health and New Zealand Food Safety Authority (now Ministry of Primary Industries) recommended mandatory wording of first (complementary) food on food labelled 'around 6 months', to reflect the 2008 New Zealand Guidelines. Standard 2.9.2 mandates only age and consistency. See Section 4.1.4 below.
- **Harmonisation:** some submitters noted current EU requirements retain the 4–6 months provisions. It was considered that this would limit the opportunity for import, export and competition. See Section 5.2.1.2 below.
- **Iron:** it was noted that removing the RDI for iron for infants under 6 months of age (and using the higher RDI for infants from 6 months) might lead to increased levels of iron in a first food resulting from the desire to maintain a 'good source' label claim. This was suggested to pose a health risk for younger infants who might consume infant foods before they are 6 months old, and also have implications for preterm infants. Sections 4.2.2 and 4.2.2.1 below discuss this issue.

3.2.2 Targeted consultation in 2013

When Proposal P274 was recommenced in 2013, targeted consultation was undertaken with key stakeholders, including infant food manufacturers, jurisdictions and some health professional representatives.

Information was updated, issues raised previously were discussed and new issues identified. Information gathered has helped inform the Consultation Paper.

Infant food manufacturers provided current information on the market and on the impact of the proposed changes to the youngest minimum age labelling requirements i.e. the impact on costs, timeframes, transition arrangements and flow-on effects to other products intended for infants over 6 months of age. Manufacturers discussed options to incorporate 'around 6 months' onto the labels of their relevant products.

Jurisdictions raised the importance of consistency with national recommendations, the need to support health professionals' education and provide consistent messages for caregivers. They also considered that youngest minimum age labelling of 'around 6 months' would support recommendations for exclusive breastfeeding until that age.

Two health professionals from the FSANZ Consumer and Public Health Dialogue⁸ also considered that labelling requirements of 'around 6 months' would support the current recommendations; provide one consistent message; and provide a population approach which reflected the current evidence base. They considered it important that labelling indicates that solid food is not recommended before 4 months of age.

3.3 Risk assessment conclusion

The appropriate timing for the introduction of solid foods to infants, also termed complementary feeding, is considered to be an important aspect of 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.

As noted above, Australia and New Zealand both recommend solid food is introduced at 'around 6 months. A number of international expert bodies including WHO, the European Society for Paediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN), and the EFSA have reported views on timing of complementary feeding.

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

Long- and short-term health outcomes that have been examined in relation to the timing of complementary feeding include nutritional adequacy (including energy intake), growth and

⁸ The Consumer and Public Health Dialogue was established by FSANZ to provide advice on public health matters. The CPHD is made up of representatives from peak consumer and public health bodies and public health academics.

See: <http://www.foodstandards.gov.au/about/committees/Pages/default.aspx>

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 a 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 seen over the past 10–15 years, the association between allergic diseases and the timing of solid food introduction is of much current interest. 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 to minimise allergy risk, conclusive evidence is still lacking. In 2009, reports published by EFSA and ESPGHAN gave similar conclusions.

As part of Proposal P274, this risk assessment was undertaken to review the evidence for the appropriate timing for solid food introduction, focussing on reports and data published since 2008. The main objectives were to identify adverse health outcomes associated with timing of solid food introduction relevant to the proposed change for the labelling of infant foods as appropriate for infants ‘around 6 months’. Food allergy risks were reviewed in detail because of current concerns which are particularly relevant to the time periods covered in this Proposal.

The main conclusions of this assessment are summarised as follows:

- Solid foods introduced at ‘around 6 months’ compared to ‘from 4 months’ effectively means that introduction of solid foods could be delayed by as much as up to 2 months. Based on several key review articles, there are no health effects that are clearly linked with adverse outcomes if solid food introduction is delayed to ‘around 6 months’ compared to ‘from 4 months’.
- Allergy risk appears to be associated with solid foods introduced to infants at less than 4 months 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 and EFSA that ‘from 4 months’ of age is the appropriate 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 foods for infants would have minimal effect on the risk of adverse health outcomes compared to 'from 4 months' of age.

3.4 Assessment against Ministerial Policy Guidance

During the assessment of a Proposal, FSANZ must consider the three objectives in subsection 18(1) of the FSANZ Act. These are discussed in Section 4.2.4 of the Consultation Paper. When developing or modifying regulatory measures, FSANZ must also have regard to the lower order Section 18(2) objectives, which include having regard to Ministerial Policy Guidelines provided by the Forum (or formerly by the Ministerial Council).

There is one Ministerial Policy Guideline that applies to this Proposal i.e. the Intent of Part 2.9 – Special purpose foods. This includes specific policy principles as below:

Food Standards contained within Part 2.9 of the Code should maintain a clear distinction between special purpose foods and other foods, as regulated elsewhere in the Code.

In particular:

- Special purpose foods should be targeted only to those population groups satisfying the definition presented in the Scope/Aim section.
- The composition of special purpose food should be consistent with the intended purpose.
- Adequate information should be provided, including through labelling and advertising of special purpose foods, to:
 - *assist consumer understanding of the specific nature of the food, the intended population group and intended special purpose of the food; and*
 - *provide for safe use by the intended population and to help prevent inappropriate use by those for whom the special purpose food is not intended.*
- Consideration, where appropriate, should be given to application of controls to restrict access to a special purpose food on the basis of risk to public health and safety.

Proposal P274 is consistent with the Ministerial Policy Guideline on the Intent of Part 2.9 of the Code. This Proposal does not change the intended purpose of an infant food, the assessments undertaken recognise the vulnerability of infants; the proposed labelling requirements, including mandatory warning statements, are clearly targeted to carers of infants; provide adequate information for caregivers to make appropriate choices; promote safe use and help avoid inappropriate use.

3.5 Summary of the impact of infant food labels on caregivers

As assessment of carers' understanding and use of labels on infant food is at Attachment 1 and summarises:

- the relevant literature on factors that influence the introduction of solids to infants, focusing on factors that are likely to influence the efficacy of a change to the youngest minimum age permitted on infant food labels
- the 2004 FSANZ consumer research on the labelling of infant foods
- the likely impact of the proposed labelling change on caregivers.

The available research, as discussed in Attachment 1, 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, the FSANZ consumer research found that caregivers did value age and consistency information, particularly for deciding when to move from one stage of solids to the next.

The FSANZ research and published literature did suggest that the youngest minimum age displayed on infant foods may influence the small proportion of caregivers who are in specific situations that may lead them to read infant food labels before they plan to introduce solid foods to their infant.

Based on the published literature on infant feeding, the following factors are likely to temper the influence of the 'around 6 months' youngest minimum age on infant food labels:

- the influence of family or friends, who tend to encourage earlier introduction
- caregivers' perceptions that their infants' behaviour indicates they desire or need solid foods at an earlier age
- some caregivers' disagreement with the guidelines
- caregivers' perceptions that the guidelines (although generally appropriate) are not suitable for their child
- the use of homemade foods as first solid which are not accompanied by a label with a minimum age
- caregivers' experience of introducing solids before 6 months with a previous child
- the experience, for some caregivers, of the first solids meal being an important milestone that is looked forward to.

Aligning the youngest minimum age on infant food labels may have the following benefits for caregivers:

- reducing confusion about the recommended age for introducing solids, particularly for caregivers who have received differing advice from different sources
- providing some indication of an appropriate age for solids for caregivers who have not received formal advice on the topic or who do not have a clear understanding of the recommendations
- aiding caregivers who are experiencing pressure from family or friends to introduce solids earlier than they would like.

4. Proposed approach to amending Standard 2.9.2

4.1 Labelling

SD3 provides responses to labelling issues previously raised at PFAR. Key issues are further discussed below.

4.1.1 Alignment of labelling with infant feeding recommendations

In the PFAR, FSANZ proposed to amend the youngest minimum age permitted on infant food labels in Standard 2.9.2 from '4 months' to 'around 6 months' in accordance with the respective infant feeding recommendations of Australia and New Zealand.

FSANZ's current assessment indicates that the approach proposed in 2008 is still appropriate. It meets the objectives of the FSANZ Act (see Consultation Paper Section 4.2.4), reflects current national infant feeding recommendations, is unlikely to pose a risk to the health and safety of infants, aligns with Ministerial policy guidance, and provides consistent information for caregivers.

FSANZ's risk assessment concludes that '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.

Currently, there is insufficient conclusive evidence, in relation to potentially reducing the risk of developing allergies in a subgroup of the infant population that would support retaining labelling permissions that do not reflect national recommendations. Randomised control trials investigating this issue are underway and may provide more clarity. However, the timeframe for completion is unknown and the outcomes cannot be assumed.

FSANZ also notes that labelling requirements provide a population approach, and recognises that individual infants and subgroups of the population may have varying needs. Use of 'around 6 months' on a label allows for the variation in infants' readiness for solid food. In addition, use of 'around 6 months' as the minimum age on infant food, supports national recommendations for exclusive breastfeeding to 'around 6 months'.

At the previous consultation, a majority of submitters supported aligning Standard 2.9.2 with the respective national infant feeding guidelines. However, some stakeholders considered that the term 'around 6 months' could be open to interpretation.

FSANZ has considered how best to incorporate the term 'around 6 months' into regulation.

4.1.1.1 Consumer understanding and interpretation of 'around'

Neither the Australian nor New Zealand guidelines define 'around 6 months'. The term is a general recommendation for the infant population. FSANZ's previous consumer research indicated that consumers view this statement to mean 2–3 weeks either side of 6 months. This understanding would support the guidelines which acknowledge some infants may require solids sooner than 6 months, and that solids should not be delayed later than 7 months. The consumer research also indicated that labelling of 'around 6 months' (rather than from 4 months as currently permitted) has the potential to influence the age of introduction of solids towards 6 months of age. This is in line with the intent of the current infant feeding recommendations.

4.1.1.2 Prescribed wording of youngest minimum age; and food intended as a first food

The phrase 'around 6 months' could be interpreted by manufacturers in a variety of ways and lead to a range of labelling statements e.g. '5–7' or 'by 6', or 'before 7' months. To avoid any variation in interpretation by manufacturers, and to ensure consistent labelling messages for consumers, FSANZ proposes to prescribe the words 'around 6 months' as the youngest minimum age permitted on infant food.

However, since the term 'around 6 months' is deliberately vague, the Standard needs to provide greater certainty for manufacturers. To manage this issue, we propose to introduce a definition of a *first food* into Standard 2.9.2 (see Attachment A to the Consultation Paper). The proposed definition is: a *first food means a food for infants that is intended for use in the first stage of weaning⁹ an infant.*

⁹ The ordinary meaning of weaning is relied on in this situation as provided in the Macquarie dictionary i.e. 1. *weaning* is to accustom (a child or animal) to food other than its mother's milk; and *phrase* 2. wean off (or from), to induce to give up dependence on (a substance, habit, or activity).

It is proposed that the prescribed words ‘around 6 months’ for youngest minimum age would be required only on those foods intended to be used as a first food having the appropriate consistency and formulation.

Question for submitters

1. Is the concept and definition of first food a useful way to apply certain labelling and formulation requirements?
2. Is the definition of ‘first food’ enforceable?

4.1.1.3 Impact on labelling of other infant food

Currently, there are infant foods on the market recommended ‘from 6 months’ or ‘6–7’ or ‘6+’ months of age, for example. The statement ‘around 6 months’ could overlap with these currently-used age recommendations. This could cause confusion for caregivers, or pose difficulties for manufacturers in formulating and differentiating products.

Manufacturers have advised that factors such as texture, flavours, complexity of the food matrix (e.g. different types of grain), additional ingredients (e.g. sugar, protein), and the stage labelling of products could be affected. For example, foods currently manufactured as suitable ‘from 4 months’ may be rice based, whereas food suitable from 6 months may be wheat based; also, current stage 1 foods may overlap with current stage 2 foods. Manufacturers have indicated they are considering a range of options for the formulation, staging and labelling of their products, to ensure clarity for caregivers and appropriate product formulation for the different stages of an infant’s development.

FSANZ is considering whether it is necessary, or not, to regulate the use of the age/number 6 used in other ways on a label of infant food, such as 6+ or ‘from 6’. A prohibition on the use of the age/number 6 other than in conjunction with the word ‘around’, would avoid potential confusion. However, permitting the use of other such statements containing the number 6 would allow manufacturers some flexibility. It also may be possible for manufacturers to use other labelling elements to sufficiently differentiate ‘around 6 months’ from 6+ or ‘from 6’.

Question for submitters

Should the use of the age/number 6 on labels of infant food be prohibited, other than in conjunction with the word ‘around’? Please explain your view.

4.1.2 Mandatory advisory statements on product use before a certain age

There are requirements in Standard 2.9.2 for infant food labels to display the warning statements listed in Table 2 below, if certain conditions are met.

Table 2: Warning statement requirements in Standard 2.9.2

Warning statement	Conditions
Not recommended for infants under the age of 4 months	Where the food is recommended for infants between the ages of 4–6 months
Not suitable for infants under the age of 6 months	Infant food contains more than of 3 g/100 kJ of protein

FSANZ intends to modify the conditions for the ‘not recommended under the age of 4 months’ statement (under 4 months statement) so that they only apply to products that are

represented for use at a minimum age of ‘around 6 months’. This change will ensure that the under 4 months statement applies only to first food, which was the original intent of the conditions for this statement. FSANZ does not intend to apply the under 4 month warning statement to products that are represented ‘from 6 months’, ‘6 + months’ or higher minimum ages, as these products are not represented for use as a first food in an infant’s diet.

FSANZ is also proposing to shorten and amend the prescribed wording (without changing the intent) of these statements as shown in Table 3 below, so that it is easier for manufacturers to display this information on their labels.

On the basis of the above, FSANZ is proposing the following modified warning statements on product use before a certain age:

Table 3: Modified warning statement requirements in Standard 2.9.2

Warning statement	Conditions
Not before 4 months of age	Where the food is represented for infants ‘around 6 months’ of age
Not before 6 months of age	Infant food contains more than of 3 g/100 kJ of protein

Questions for submitters

1. Do the changes to the wording of the warning statements change the intent of these statements? If so, please explain why.
2. Should the ‘not before 4 months of age’ statement apply only to first food represented for infants ‘around 6 months’ of age? If not, please describe which foods should carry this warning statement and the reasons why.

4.1.3 Location of mandatory statements on infant food labels

Proposal P274 is proposing to change two mandatory age-related statements in Standard 2.9.2 to the following:

- The youngest minimum age for which the product is suitable is to be no younger than ‘around 6 months’
- A shortened warning statement of ‘not before 4 months of age’ to reflect the recommendation that solid foods should not be introduced prior to 4 months of age.

We are also proposing to retain the requirement for a statement on the textural consistency of infant food that is first food.

Standard 2.9.2 currently does not mandate the placement of any of the above three statements on a label. FSANZ is concerned about this arrangement for the following reasons:

- FSANZ’s 2004 consumer research found that the information on a recommended age and the product’s textural consistency were very important for participants, particularly when choosing to move from products in one age range to those in another. Participants mentioned that they would pay the most attention to the front of the label when selecting a product.
- Standard 2.9.2 requires the current ‘under 4 months’ statement (see 4.1.2) to be displayed *in association with* the relevant minimum age statement. However, FSANZ’s

2004 consumer research has identified the potential for the 'under 4 months' statement to be misinterpreted as a result of this requirement.

When asked to consider the relevant minimum age and 'under 4 months' warning statements together, some participants became confused about how to interpret this information. The researchers noted that participants viewed this information as an encouragement to introduce solid foods closer to 4 or 5 months of age. Moreover, the researchers also identified that such misinterpretation could be mitigated if the minimum age statement was displayed by itself on the front of the label.

- Consultations with industry and health professionals in 2013 indicated support for requiring the minimum age, the 'under 4 months' statement, and textural consistency statement to be placed on an infant food label. However, these stakeholders also commented that caregivers could be confused about when to introduce a product to their infant if 'around 6 months' was co-located close to the 'under 4 month' statement on the label.

FSANZ is aware that most of the infant foods currently on the market display the relevant minimum age and 'under 4 months' warning statement on separate parts of the label (front and back of the label respectively). We consider that this practice, while in contrast to the current requirements of Standard 2.9.2, may help caregivers correctly interpret the two mandatory statements.

FSANZ is therefore proposing changes to Standard 2.9.2 to address the placement of the mandatory statements on the label of an infant food.

1. The current requirement to display the 'under 4 months' warning statement *in association with* the relevant minimum age is to be removed from Standard 2.9.2. This will allow manufacturers to place the two mandatory statements on separate parts of the label.
2. The addition to Standard 2.9.2 of a requirement that the minimum age statement should always be placed on the front of the label will help draw caregiver's attention to the age-related information to assist decision making about when to introduce the product into an infant's diet.

Questions for submitters

1. Is it important for minimum age to be always displayed on the front of a product? Please give your reasons. If not, are there any other labelling measures that should be mandated?
2. Will the removal of the association between the relevant minimum age statement and the under 4-month warning statement reduce the risk of caregiver confusion on the age of introducing solid foods?

4.1.4 Age versus stage labelling

FSANZ has previously canvassed various options for minimum age labelling, including a system that introduces different foods based on phases or stages of development. FSANZ's preferred approach at PFAR was to modify the youngest minimum reference age to 'around 6 months', and not to require infant food labels to display phase/stage information.

There were divergent views among submitters who commented on age versus stage forms of labelling information. The Department of Human Services Victoria, Department of Health and Human Services Tasmania, and the Dietitians Association of Australia (DAA) supported FSANZ's proposed use of a reference age for information on the introduction of solid food.

The New Zealand Food Safety Authority (NZFSA – now NZ Ministry of Primary Industries) requested that FSANZ introduces mandatory stage-based information on foods for infants to ensure that infant food labels remain consistent with New Zealand policy.

However, FSANZ is proposing not to mandate stage-based labelling because:

- The complexity of information on developmental cues and ‘readiness’ would be such that the majority of products on the market would not be able to accommodate the volume of this information on their labels.
- Infant food manufacturers are currently required to label infant foods with a statement indicating the consistency of the food. This statement already ensures that caregivers have access to information on the nature of the product to make an informed choice that is safe and meets the developmental needs of their infants.
- All major infant food manufacturers in Australia and New Zealand have voluntarily incorporated stage labelling and/or colour coding in addition to mandatory age labelling on infant foods. This includes indicating which foods should be introduced first into an infant’s diet. Although the voluntary stage information is not consistent across brands, it still provides information that allows caregivers to make informed choices on the suitability of a product for their infant.
- FSANZ’s consumer research has shown that carers use the age and texture information on infant foods when deciding to progress from one texture or age range to the next. The study found no clear preference among participants tested in the focus groups for keeping or excluding the stage-based labelling. In contrast, participants reported that age and texture information were both valuable.
- They also commented that it would be difficult to meaningfully communicate on infant food labels the physiological signs of readiness for solids (although feedback from manufacturers to FSANZ in 2013 indicated that it is possible to include this information on current labels).

Therefore, FSANZ’s preferred approach is to retain a mandatory age reference and not to mandate a stage-based system of labelling requirements (such as an indicator that the product is a ‘first food’). Manufacturers would be able to provide other stage-based information voluntarily on infant food labels.

4.1.5 Summary of approach to labelling

In summary, FSANZ is proposing to mandate that the label on a package of infant food must include (among other things):

- the minimum age, expressed in numbers, of the infants for whom the food is recommended
- the age (number) must be on the front of the package
- the youngest minimum age permitted is ‘around 6 months’ and is to be applied to ‘first foods’ as defined in Standard 2.9.2
- ‘around 6 months’ is prescribed wording
- shortened wording for warning statements relating to product use below 4 or 6 months of age respectively
- the ‘before 4 months of age’ warning statement applies only to infant foods represented for use at the youngest minimum age of ‘around 6 months’.

Other labelling options would remain voluntary e.g. first foods labelling, information and/or colours indicating stages.

4.1.6 Nutrition and health claims

4.1.6.1 Reference Iron Recommended Dietary Intake

Currently Table 2 to Clause 8 in Standard 2.9.2 provides the Recommended Dietary Intakes (RDIs)¹⁰ as the basis for permitted claims about vitamins and minerals. The Table contains two values for iron – one for *under 6 months* (3 mg/day), and one *from 6 months* (9 mg/day). The proposed amendment to the youngest minimum age labelling of infant foods to ‘around 6 months’ has consequences for these two RDIs for iron claims on foods for infants.

At PFAR, FSANZ proposed to remove the 3 mg/day iron RDI from Table 2 to clause 8, and apply the 9 mg/day iron RDI to all foods for infants. Submitters had mixed views on this change. Queensland Health and La Leche New Zealand indicated that they both supported the removal of the iron RDI for infants under 6 months. The Australian Food and Grocery Council (AFGC) and Heinz Australia did not support this change, and indicated that manufacturers might need to add iron to their ‘first food’ products to be able to meet the 9 mg/day RDI requirement for good source of iron claims. Heinz also mentioned that the small serving sizes (5g) of their first foods range makes this reformulation difficult, as a good source claim would require at least 47 mg iron per 100 g, which is very close to the maximum limit on iron (50 mg/100 g on a moisture free basis) specified in paragraph 2(4)(a) of Standard 2.9.2.

Heinz is also one of two manufacturers of infant foods that use a serving size as low as 5 g. The majority of other foods that are targeted to infants aged around 6 months on the Australian and New Zealand markets use serving sizes ranging from 7–15 g (dry weight for cereal products as sold).

Manufacturers can make good source of iron claims (no less than 25% RDI/serve) on the label at these higher serving size recommendations, while having concentrations of iron below 33 mg/100 g and without the need to add any further iron to the product.

FSANZ recognises the importance of promoting sources of iron during the introduction of solid foods. At PFAR, we proposed the use of 9 mg/day iron as the RDI for all infant foods to ensure that infants would receive a sufficient intake of iron from foods introduced around 6 months of age, and we are proposing to reaffirm this position. See also Section 4.2.2.

4.1.6.2 Health claims about foods for infants

Standard 1.2.7 – Nutrition, Health and Related Claims was gazetted in the Code in January 2013, with a 3-year transition period. This standard applies to foods for infants. Standard 1.2.7 permits health claims about foods for infants, subject to the requirements of the Standard. Standard 1.2.7 includes some pre-approved health claims for certain vitamins and minerals (including iron) which can be made about a food for infants if the product meets the requirements for a content claim in Standard 2.9.2. Alternatively, a manufacturer of a food for infants can self-substantiate general level health claims by carrying out a systematic review of the relevant food-health relationships.

¹⁰ FSANZ previously released a consultation paper considering how to implement the 2006 Australian and New Zealand Nutrient Reference Values (including RDIs) into the Code. The 1991 values will remain in place until further work is undertaken.

4.2 Compositional and claims requirements

As a consequence of a change to ‘around 6 months’ as the youngest minimum age permitted on infant food labels, compositional and claims requirements in Standards 2.9.2 have been reviewed and amendments proposed.

4.2.1 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 suitable for infants over the age of 6 months, to contain thiamin, niacin, vitamin B6, vitamin C, folate and magnesium¹¹ added to restoration levels, and it mandates a minimum amount of iron (20 mg/100 g on a moisture free basis).

In contrast, subclause 3(2) permits cereal-based food containing more than 70% cereal manufactured and marketed *as suitable for infants from 4 months of age* the voluntary addition of iron and vitamin C only. There is no mandatory requirement for the addition of iron. This subclause is no longer considered necessary as it relates to foods marketed for infants from 4 months of age.

Attachment A to the Consultation Paper provides the proposed variations to the labelling requirements in Standard 2.9.2

4.2.2 Iron

As discussed in Section 4.1.6.1, FSANZ is proposing to apply 9 mg/day as the RDI for iron to all infant foods in Standard 2.9.2. Some submitters raised a concern that this amendment could potentially lead to higher levels of iron in foods that may be consumed by younger infants i.e. by infants younger than 6 months of age.

We have considered this issue and estimated a daily iron intake based on a 4-month old infant (boy) consuming 21.4 g of iron-fortified infant cereal plus the balance of energy intake from infant formula, assuming four month old infants only eat infant cereal and infant formula and no other foods. The cereal was assumed to contain iron at two levels: the maximum permitted level; and in an amount consistent with a ‘good source’ content claim for a serve size of 7 grams of infant cereal as sold.

Table 4: Energy and iron content and amounts consumed of infant formula and iron-fortified infant cereal

Data element	Amounts	Basis
Energy requirement/intake of 4-month old infant (boy) of median body weight	2,380 kJ/day	Recommended energy intake for a four-month-old boy (FAO, 2004) at the 50th percentile weight (WHO, 2007)
Infant cereal consumption for a 4-month-old infant	21.4 g/day, 310 kJ/day	Average of 2.3 serving occasions of infant cereal per day and an average serving size of 9.3 grams*. Dry infant cereal energy content of 1,459 kJ/100 grams as derived from AUSNUT 2007 (for “ <i>Infant cereal, dry, mixed grain, fortified</i> ”) (FSANZ 2008).
Infant formula intake	710 mL, 2070 kJ	Amount calculated to meet the balance of energy requirements for a four-month

¹¹ The permitted forms for vitamins and minerals added to infant foods are listed in Schedule 1 of Standard 2.9.1 – Infant Formula Products

		old boy
Iron concentration of infant formula	0.35 mg/100 kJ	Midpoint of range in Standard 2.9.1 – Infant Formula Products
Iron concentration of infant cereal	i) 46.5 mg/100 g as sold ii) 32 mg/100 g as sold	i) maximum limit 50 mg/100 g on moisture free basis as per Standard 2.9.2 – Foods for Infants ii) an amount consistent with a ‘good source’ content claim for a serve size of 7 g

* Derived from Nourish Study, as provided by the Queensland University of Technology and the University of South Australia.

Table 5: Estimated total iron intake from infant formula and iron-fortified infant cereal

Iron concentration level in infant cereal	Calculation of total iron intake from consumption of infant formula and infant cereal	Total iron intake
i) 46.5 g/100g as sold (iron at maximum limit)	$\frac{[2,070 \times 0.35] + [46.5 \times 21.4]}{100}$	= 17.2 mg/day
ii) 32 g/100g as sold (iron at level consistent with a ‘good source’ content claim)	$\frac{[2,070 \times 0.35] + [32 \times 21.4]}{100}$	= 14.1 mg/day

4.2.2.1 Comparison with UL

The iron intake of a 4-month old male infant of median body weight consuming 21.4 grams of infant cereal per day (2.3 serves per day, at 9.3 grams per serve) at either a moderate or high iron concentration and the balance of energy requirement from infant formula is below the upper level (UL) for iron of 20 mg/day established by the National Health and Medical Research Council and the New Zealand Ministry of Health for infants and young children less than 4 months of age (NHMRC/MOH 2006).

On this basis, FSANZ is not intending to amend the current maximum limit for iron of 50 mg/100 g on a moisture free basis in cereal-based food in Standard 2.9.2.

5. Cost Benefit Analysis

5.1 Regulatory Options

FSANZ has identified two regulatory options for this proposal:

Option 1 – Reject Proposal and maintain the *Status Quo* in Standard 2.9.2

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 ‘from 4 months’.

The current labelling requirements for a warning statement, and for the consistency of the food, would also remain unchanged in Standard 2.9.2.

Option 2 – Amend the youngest minimum age labelling requirements in Standard 2.9.2 so that the minimum reference age permitted on infant food is ‘around 6 months’

With this Option, the requirement to label an infant food with an age reference would remain, although the youngest minimum reference age permitted would be changed to 'around 6 months', and be prescribed wording. Also, the age reference (expressed in numbers) on infant food, would be required to be on the front of a product label.

Under Option 2, the warning statement would be retained but amended to a shortened statement, 'not before 4 months of age'. Also, it would not be required to be *in association with* the reference age on a label. The current requirement to label infant foods with a statement indicating the consistency of the food would remain. In addition, other consequential amendments to Standard 2.9.2 would occur to reflect the variation of the minimum age reference.

5.2 Background

This analysis is updating the cost analysis that was provided with the PFAR in 2008. Following consultation, a decision regulatory impact statement (RIS) will be prepared, taking into account feedback received from submitters on the updated cost analysis.

In 2013, FSANZ undertook some targeted consultation with key stakeholders to update market information, discuss issues previously raised, and identify any new issues.

Information received from infant food manufacturers has helped us update the cost analysis, which has resulted in some alternations to transitional arrangements to reduce costs to industry. This is further discussed in Section 5.2.1.1 below.

5.2.1 Issues raised in submissions at PFAR

5.2.1.1 Transition period

Subclause 1(2) of Standard 1.1.1 provides transitional arrangements for 12 months after the commencement of a variation to the Code, to allow for 'stock in trade' to continue being sold.

At PFAR, FSANZ recommended an 18-month transition period from gazettal, for industry to comply with the proposed new labelling requirements.

However, FSANZ is now proposing transition arrangements over 3 years as it is expected this will reduce the cost to infant food manufacturers. This extended period will include a 2-year period from gazettal to allow manufacturers time to comply with the new requirements in Standard 2.9.2. It is intended that, during this period manufacturers will be able to manufacture and lawfully sell stock and labels that comply with the current requirements and/or the new requirements as gazetted.

In addition, at the end of that 2-year transition period, a 1-year stock in trade period will apply to allow stock that is already manufactured at the end of the 2 years, to be lawfully sold for a further year (in effect a total of 3 years).

Manufacturers have advised that the shelf-life of some products is 2 years so this transition period will reduce the financial impact for them. This extended transition period is based on the shelf life of infant foods, the scale of the costs associated with a 1-year period only, and the impost on a relatively small number of companies. This is further discussed in the Section 5.3.2.1 below.

5.2.1.2 Potential barrier to trade

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.

The proposed draft variation to Standard 2.9.2 supports the infant feeding guidelines of both Australia and New Zealand, and maintains consistency of standards for trade purposes between the two countries. The proposed minimum age amendment to Standard 2.9.2 aligns with the Codex standard for cereal-based foods which requires that the age on a label of infant food '*shall not be less than 6 months for any product*' (see section 3.1.4).

Also the proposed amendment does not introduce a new 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 to accord with the current infant feeding guidelines. While companies may need to re-label products, this is an amendment to the current situation and therefore should not create new or additional trade barriers.

FSANZ considers it unlikely that this Proposal will create trade barriers and therefore should not affect international trade.

5.3 Impact Analysis (Costs and Benefits)

FSANZ is required, in the course of developing or varying food standards, to consider the impact of the proposed options on affected parties. The parties who are potentially affected by this Proposal include, but are not limited to:

- caregivers; particularly those who use food labels to provide information to make informed choices in feeding their infants
- manufacturers and/or importers of infant food that supply the Australian and New Zealand markets
- Governments of New Zealand, the States and Territories and Australia, including enforcement agencies and health advisors.

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

5.3.1 Caregivers

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

However, maintaining the current labelling may confuse caregivers who receive advice from health professionals based on current infant feeding guidelines that recommend the introduction of solids at 'around 6 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 caregivers 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. Again, infant health may be compromised.

Under **Option 2**, if labelling was changed as proposed, caregivers 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 therefore more likely to minimise potential caregiver confusion. 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.

5.3.2 Industry

Maintaining the *status quo* in **Option 1** could present an inherent risk to industry. Caregivers and health professionals may perceive industry as acting irresponsibly and undermining infant feeding recommendations, if labelling is not adjusted. Caregivers may consider product labels to be misleading which may lead to lack of confidence in manufacturers and a distrust of their products, and potentially 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 estimated at around A\$2,702 per SKU¹² using cost estimates provided by manufacturers. Details of how these estimates were calculated are included in Section 5.3.2.1 below. These labelling changes include complete label redesign and production costs. Revision of advertising and educational material, product and label write off could be additional costs. It is noted that some companies have already adopted 'around 6 months' as an infant feeding age reference in their educational material which reflects the proposed approach. However the proposed requirements to use the specific wording 'around 6 months' on labels will incur additional costs for a number of businesses.

In addition, the proposed amendments to Standard 2.9.2 with regard to the RDI for iron, may affect the ability of infant food manufacturers to make 'good source' claims in some instances. Should infant food manufacturers choose to reformulate any products to enable 'good source' claims, additional costs may be incurred. However, by changing labelling to be more consistent with infant feeding recommendations, there may be a benefit to industry as a result of 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 proposed reduced text requirement for the mandatory warning statements, given the restraints on space on the labels for infant foods.

5.3.2.1 Labelling cost estimate for Option 2

In June and July 2013, FSANZ conducted targeted consultation with key infant food manufacturers¹³ to update cost estimates provided in the PFAR.

Three large infant food manufacturers provided their estimated direct costs of making labelling changes. The costs involved are different for different types of packaging. Infant food is produced in 4 different types of packaging – flexible (pouch/bag), fibre (corrugated and folding carton), metal (can) and glass (jar, caps).

¹² SKU – refers to stock keeping unit, a unique identifier for each distinct product and service that can be purchased in business

¹³ A large divergence in industry costs was noticed during consultation, in relation to similar changes to labels. Further investigation and possible expert advice will need to be sought ahead of the decision RIS to ensure that a common understanding of what is being costed, exists.

Direct costs (i.e. for label design and printing costs) are estimated at around A\$2,702 for a single SKU (see Table 6). This average cost has been calculated using the individual estimates that have been provided by the manufacturers. These are the direct monetary impacts that industry has identified to meet the regulatory requirements of the proposed change in the youngest minimum age labelling of infant foods 'from 4 months' to 'around 6 months' of age.

Based on the information received from 3 infant food manufacturers, that together represent around 80% of the Australian and New Zealand market, the number of SKUs that currently carry a label 'from 4 months, 4+ or 4-6 months' varies from 2 to 110 SKUs, depending on the manufacturer.

Table 6: Labelling cost estimate for Option 2

Based on the information received from three infant food manufacturers, which together represent around 80% of the Australian and New Zealand market.				
Material	Flexible	Fibre	Metal	Glass
Type of packaging	Pouch/bag	Corrugated and folding carton	Can	Jar/Caps
Number of SKUs affected	49	39	20	33
Total number of SKUs affected	141 SKUs			
Total costs of a change	A\$381,050.00			
Total cost has been calculated using all the individual estimates that have been provided by infant food manufacturers				
Average cost per single SKU	A\$2,702			

Through targeted consultation, manufacturers reported that further anticipated costs of the proposed change may include: realignment of marketing material (websites, digital assets, print advertising and marketing collateral); public relations and communications in relation to consumer education; barcode verification for retailers; loss of sales due to a possible diminished market due to consumer perception; reformulation; write-off costs; consumer research on how to communicate and express the new age statement; and flow on effects e.g. labelling of related tableware.

In addition, the proposed amendment to Standard 2.9.2 may also have a 'flow on' effect on the labelling of later stages (e.g. from 6 months, from 8 months and from 10 months) in relation to the age reference and texture of products.

FSANZ is therefore proposing a 2-year period from gazettal to allow manufacturers time to comply with the new requirements in Standard 2.9.2.

In addition, at the end of that 2-year transition period, a 12 month stock in trade period will apply to allow stock that is already manufactured at the end of the 2 years, to be lawfully sold for a further year (a total of 3 years). Information received from the infant food manufacturers indicates, depending on the type of packaging, they typically reorder their labels/packaging 2 to 5 times a year. Also, voluntary charges to labels or packaging happen every 2 to 5 years. Infant food manufacturers have said that if proposed labelling changes in Standard 2.9.2 could be made at the same time as making a voluntary change, the additional cost of making a change to meet the proposed changed regulatory requirements would be negligible.

Industry has been aware of this proposed change for some time. With the early notice and extended transition period of 2 years plus 12 months, industry will either completely avoid or

significantly reduce any anticipated costs associated with the proposed change in the minimum age labelling of infant foods. For example, it is very unlikely with appropriate planning that any stock or labels would need to be written off.

Based on that FSANZ cost estimates for the proposed change in the Standard 2.9.2 would be somewhere between 3/5 of the A\$381,050.00 to A\$0 if the changes can be made at the same time as voluntary changes (see Table 7).

Table 7: FSANZ cost estimate based on the extended transition period

Total costs of a change	A\$381,050.00
Total cost has been calculated using all the individual estimates that have been provided by infant food manufacturers	
Based on the 36-months transition period FSANZ internal costs estimates	from 3/5 of the total cost provided by industry to A\$0 or from A\$228.630 to A\$0
Number of SKUs affected by the proposed change (provided my industry)	141 SKUs
Based on the 36-months transition period FSANZ internal costs estimates per single SKU	From A\$1621.5 to A\$0

Questions for manufacturers are provided at Attachment 2.

If you have previously supplied any of this information to FSANZ, there is no need to provide it again.

However, please note the **additional question*** in the table i.e. could industry please provide evidence of which additional costs will be incurred and quantified estimates of the size of these costs? Would these costs be less if they were incurred at the same time as other voluntary labelling changes? If so, to what degree would they be reduced?

5.3.3 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. No additional monitoring costs are likely to be incurred by state or territory enforcement agencies.

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 caregivers 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.

5.4 Comparison of Options

FSANZ's objectives include that regulations, such as labelling requirements, should reflect the most up-to-date science and also provide caregivers with adequate and appropriate information to guide decisions.

A comparison of the two Options presented at PFAR indicates that maintaining the *status quo* could present a number of disadvantages for caregivers, infants, industry and government. These disadvantages would result from the inconsistency between infant feeding recommendations for the age of introduction of solids and the youngest minimum age labelling on infant foods. This could lead to consumer confusion and inappropriate, and potentially harmful, decisions on the introduction of solids for their infant. The inconsistency may also cause a loss of consumer confidence in manufacturers and their products, with consequential effects on sales for infant food manufacturers. Government education efforts in promoting infant feeding recommendations may also be affected by the inconsistency which could reduce the public health gains desired from implementation of the infant feeding guidelines.

In comparison, **Option 2** is consistent with FSANZ's objectives and benefits caregivers; governments and industry by ensuring infant food regulations are consistent with national infant feeding recommendations.

Option 2 will minimise customer confusion, caregivers 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 reinforce government health authorities' infant feeding recommendations and caregiver education, and therefore contribute to the promotion and protection of infant health and safety. Under **Option 2**, industry is likely to benefit from increased caregiver confidence, thus sales of infant foods are likely to be maintained; possible innovation in the provision of additional information on infant food labels, including space gained through the reduced warning statements; and continued harmonisation of regulations for Australia and New Zealand. However, under **Option 2**, industry would incur additional costs due to the labelling changes required. As noted above some companies already use 'around 6 months' of age on some educational material reflecting the new recommendations. This initiative suggests an industry desire to provide uniform, consistent and accurate messages to caregivers.

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 caregivers, infants, government and industry.

5.5 Proposed approach

The proposed approach is Option 2 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 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

- provides net benefits to affected parties and is in line with minimum effective regulation.

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Attachment 1

Impact of Infant Food Labels On Caregivers

This Attachment provides:

- a summary of the relevant literature on factors that influence the introduction of solid foods to infants, focusing on factors that are likely to influence the efficacy of a change to the youngest minimum age permitted on an infant food label
- a summary of the 2004 FSANZ consumer research on the labelling of infant foods
- conclusions on the likely impact of the proposed labelling change on caregivers.

1. Literature review

1.1 Literature search strategy

FSANZ undertook a targeted literature search for articles that examined the following factors that may influence the timing of introduction of solids to infants:

- caregivers' knowledge of infant feeding guidelines, including:
 - developmental cues
 - age of the infant
- caregivers' perceptions of infant feeding guidelines
- sources of information on infant feeding for caregivers, including:
 - which sources of information caregivers are exposed to
 - which sources are influential in the decision to introduce solids
- the impact of different information sources (i.e. do some information sources which encourage introduction of solids closer to the guidelines?)
- the role of infant food labels, including:
 - caregivers' reactions to or perceptions of infant food labels
 - whether the age recommendations on infant foods influence caregivers' knowledge of infant feeding guidelines
 - whether the age recommendations influence when caregivers introduce solids to infants.

These factors were chosen as they are likely to influence whether the proposed labelling change is likely to have any impact on the age at which caregivers introduce solids. For example, if caregivers are unsure of the recommended age for introducing solids, the proposed change to infant food labels may assist them. Conversely, if caregivers rely heavily on informal information sources and pay little attention to infant food labels, then this will limit the effects of the labelling change.

FSANZ searched conducting searches in the following databases:

- Health Source: Nursing/Academic Edition
- Academic Search Premier
- E-Journals
- Medline
- Food Science Source
- Food Science & Technology Abstracts.

In addition, the following sources were used:

- Google Scholar
- the reference lists of relevant articles
- citation searches using relevant articles
- the Health Canada website (as Canada has infant food labelling regulations similar to the proposed amendments to Standard 2.9.2)
- the United Kingdom Food Standard Agency's website (as the agency has conducted extensive research on how consumers use food labels).

The review focused on primary research published in peer-reviewed journals and research produced by government agencies (references are provided below).

1.2 Literature review findings

A range of social factors influence caregivers' decision on when to introduce solid food to their infants. This overview of the literature explores the influence of infant feeding guidelines (caregivers' awareness and perceptions of the guidelines), caregivers' sources of information for deciding when to introduce solids, and the role of commercial infant food labels (in particular the age recommendations on labels).

1.2.1 Knowledge of guidelines

Guidelines on infant feeding practice include information for health professionals and caregivers on the appropriate age for introducing solids. Depending on the country, guidelines on the introduction of solids to infants tend to focus on the age of the infant and developmental cues. Compliance with guidelines depends both on caregivers' awareness of them and also their perception of them.

1.2.2 Developmental cues

It is recommended that caregivers consider developmental cues when deciding to introduce solid foods. The New Zealand infant feeding guidelines outline the developmental cues that infants exhibit at around 6 months when they are ready for solid foods to be introduced to their diet (Ministry of Health 2008). However, research with caregivers suggests that they tend to focus on other infant behaviours when considering introducing solids. In particular, caregivers report interpreting infant distress as a sign of hunger and become concerned that breast milk or infant formula are not sufficient to satisfy their infant (Heinig et al. 2006; Scott et al. 2009; Redsell et al. 2010; Arora et al. 2012). Some caregivers also believe that introducing solid foods will help their infant sleep, and so may decide to introduce solids in an attempt to fix disturbed sleeping patterns (Crocetti et al. 2004; Caton et al. 2011). Allcutt and Sweeney (2010) found in their study conducted in Ireland that some of these beliefs may be promulgated to caregivers by health professionals. However, McAndrew et al. (2012) have found that mothers who introduced solid foods after 5 months were more likely to mention appropriate developmental cues, such as the baby being able to sit up and hold food in its hand, as influencing their decision to introduce solids. This suggests that an understanding of appropriate developmental cues may encourage the introduction of solids closer to 6 months.

1.2.3 Age guidelines

The relationship between knowledge of infant feeding guidelines and later introduction of solids (closer to guidelines) is not clear, with the literature revealing mixed findings. For example, Spillman (2012) found that the few caregivers in her study who did wait until 6 months were aware of the guidelines. In contrast, neither Anderson et al. (2001) nor Crocetti

et al. (2004) found a relationship between knowledge of the guidelines and the age of introduction of solids.

Research by Arden (2010) found that caregivers felt conflicted by the WHO recommendations to introduce solid foods at around 6 months, and the perceived importance of responding to signs of readiness from infants. Arden found that caregivers who placed more importance on the WHO recommendations introduced solids foods later (closer to 6 months) than those who responded to signs such as the baby's weight, hunger or advice from family.

1.2.4 Perceptions of guidelines

As well as knowledge of infant feeding guidelines, caregivers' perceptions of guidelines will affect the influence they have on infant feeding decisions. For example, Alder et al. (2004) found that caregivers who disagreed with guidelines on the introduction of solids tended to introduce them earlier. Horodyski et al. (2007) found that many of the mothers in their study did not believe the guidelines on introducing 'solid' foods applied to thinned or semisolid foods, such as cereal in a bottle or applesauce thinned with breast milk. The researchers also found that some of the mothers in the study who were aware of the guidelines and thought they were generally appropriate, felt that their baby had different needs and required solids at an earlier age (Horodyski et al. 2007) e.g. because the infant was large or perceived as very hungry.

Anderson et al. (2001) and Olson et al. (2010) have found that, for some caregivers, the introduction of solids was perceived as a milestone or achievement that was looked forward to. This may explain why, as noted by Hetherington et al. (2011), caregivers tend to introduce solid foods before government sanctioned guidelines recommend. Recent research in Australia (Brodrigg and Miller 2013), Ireland (Tarrant et al. 2010) and the United Kingdom (McAndrew et al. 2012) has found a trend towards later introduction of solid foods (closer to 6 months) in recent years. This may indicate that the change in guidelines is having an effect on the average age of introduction.

Guidelines may exert an influence not only through caregivers wishing to avoid the potential risks of early or late introduction, but also through social pressure. Hamilton et al. (2012), found that the age at which caregivers introduced solids to their infant was not related to their beliefs in a range of health benefits that would occur from doing so. Normative beliefs about what their partner or doctor believed they should do, and the belief that there were commercially available foods for infants under the age of 6 months, were the only factors found to independently predict when solids would be introduced. The belief that their doctor would want them to introduce solids at 6 months was slightly more influential than the same belief about their partner.

1.2.5 Information sources

Caregivers receive advice from many information sources including family and friends, health professionals, books and brochures, as well as drawing on their own previous experience (Crocetti et al. 2004; Walker et al. 2006; Spillman 2012). These different information sources tend to provide conflicting advice on the appropriate age for introducing solids (Anderson et al. 2001; Horodyski et al. 2007; Arden 2010; Olson et al. 2010; Spillman 2012). In particular, health professionals and written sources of information are more likely to be informed by government guidelines (although this is not always the case) (Olson et al. 2010).

Family members and friends, on the other hand, are more likely to suggest introducing solids at an earlier age than guidelines recommend (Wright et al. 2004; Tarrant et al. 2010). This

may, in part, be due to changes in recommendations which, over time, have increased the recommended age (Synnott et al. 2007).

Gage et al. (2012) have found that between the birth of their infant and 8 months later, the information sources mothers rely on tends to shift, with family and friends having greater influence on infant feeding decisions when the infant is older compared to at birth.

1.2.6 Advice from health professionals

Even among health professionals, caregivers may find that they receive conflicting advice from nurses, nutrition educators and paediatricians (Olson et al. 2010). Scott et al. (2009) have argued that health professionals need to ensure consistent advice on infant feeding is provided to caregivers to increase compliance with guidelines. A consistent guideline from a credible authority may be a useful counter argument for caregivers resisting pressure to introduce solids early. Health professionals in a study by Olson et al. (2010) reported that some mothers were able to draw on the credibility of the American Academy of Pediatrics' recommendations to justify to their friends and family, their stance on waiting until 4-6 months to introduce solids.

1.2.7 Reliance on information sources

The extent to which particular information sources are relied upon by caregivers tends to vary by social factors. For example, teenage (Bentley et al. 1999) and low income mothers (Heinig et al. 2006; Horodynski et al. 2007; Olson et al. 2010) rely more heavily on the advice provided by family members, particularly their own mothers. Mothers with higher levels of education and income are more likely to rely on written sources of information than mothers with less education or income (Gage et al. 2012). Synnott et al. (2007) have found information sources relied upon by caregivers tends to vary by country, with caregivers from Scotland more likely to rely on their caregivers' advice and those from Sweden, Spain and Germany more likely to dismiss advice from their caregivers as out of date.

1.2.8 The influence of information sources

Studies which examine the influence of different information sources have mixed findings on whether the provision of professional advice impacts on the age at which solids are introduced. Savage et al. (1998) and Kuo et al. (2011) both investigated the effect of receiving professional advice on feeding solids. Savage et al. (1998) found that those who had received professional advice tended to wait longer to introduce solids than those who had not. In contrast, Kuo et al. (2011) found no relationship between advice and age of introduction, possibly due to the high proportion of respondents who had received advice (92 per cent).

Caregivers who report being influenced to a greater extent by professional sources of advice tend to introduce solids closer to the recommended age than those who are more influenced by family members. Wright et al. (2011) and Tarrant et al. (2010) have found that caregivers who report using a family member as a principal source of advice tend to introduce solid foods earlier than those who rely on a health professional's advice. McAndrew et al. (2012) had similar findings among mothers in the United Kingdom, with those who relied on either advice from a health professional or written sources of information being more likely to introduce solids closer to 6 months of age.

1.2.9 Infant food products

Researchers have examined the potential effect of infant food labels on the decision to introduce solid foods in a small number of studies (Alder et al. 2004; Arora et al. 2012; Hamilton et al. 2012; Spillman 2012).

In a survey of 70 caregivers of infants aged 6-18 months conducted in the United Kingdom, Spillman (2012) gave respondents the opportunity to provide additional comments on the infant feeding guidelines and their experiences in introducing solids to their infant. A small proportion of respondents (less than ten per cent) noted that labels on infant foods in the United Kingdom conflict with guidelines. Alder et al. (2004) conducted a survey of 338 first-time mothers in Scotland to examine factors associated with introducing solids before 12 weeks.

The researchers found women who had received free samples of manufactured infant foods were more likely to have introduced solids to their infant than other mothers before 12 weeks (odds ratio 4.38; 95 % CI 2.03, 9.45). Depending on the samples received, this relationship may have been due to age recommendations on the labels which can be younger than government guidelines.

An Australian study by Arora et al. (2012) used a survey of 187 mothers and qualitative interviews with 15 mothers to investigate factors associated with infant feeding decisions. The researchers noted that some of the reasons given by mothers for introducing solids included the infant showing interest in food, signs of hunger from the infant, and advice from friends or advertising e.g. for one respondent, the 'from 4 months' on infant food labels was used as evidence to support a recommendation from a friend that solid foods could be introduced at 4 months, "I was advised by a friend that I can start her on baby food from 4 months. You see when you go to Woolworths, they have labels on baby foods from 4 months" (Arora et al. 2012, pg. 470). Similar to Arora et al.'s (2012) study, Arden et al.'s (2010) online survey of mothers in the United Kingdom found at least one caregiver was confused by the difference between guidelines and infant food labels: ". . . Also labels on baby food still say from 4–6 months so this is also inconsistent. All in all very confusing – even if you are trying to do the right thing – it's not clear what that is." (Arden 2010, pg. 164).

Hamilton et al. (2012) used a prospective study to examine how beliefs about infant feeding (measured when the infant was aged around three months) predicted the age at which Australian mothers introduced solids (measured at seven months). The survey, using a Theory of Planned Behaviour framework, included questions on behavioural, normative and control beliefs. Behavioural beliefs included benefits mothers believed would occur if solids were introduced at 6 months. Normative beliefs were the perception that people, such as a child health nurse or partner, would think they should introduce solids at 6 months. Control beliefs were factors that would prevent them from introducing solids at 6 months (and thereby encourage earlier introduction), such as the belief that they were "able to access commercial baby foods that are suitable *before* 6 months". Regression analysis was conducted to determine which factors were key beliefs that independently contributed to predicting when solid foods were introduced.

The three key contributing beliefs were: that the partner/spouse would think that they should introduce at 6 months; that their doctor would think they should introduce at 6 months; and that being able to access commercial baby foods that are suitable before 6 months would prevent them from introducing solids at 6 months.

These findings suggest that the availability of commercial infant foods carrying 'from 4 months' on the label may encourage earlier introduction of solids than labels carrying a minimum age of 'around 6 months'.

1.3 Summary of literature review

1.3.1 Knowledge of guidelines

- Caregivers who are aware of appropriate developmental cues (that signal an infant's readiness for solids) may be more likely to introduce solids closer to 6 months of age.
- However, many caregivers focus instead on their infant's eating and sleeping patterns when deciding on when to introduce solids. caregivers who focus on these behaviours tend to introduce solids at an earlier age than those who focus on the recommendation to introduce solids at around 6 months.
- Caregivers' compliance with infant feeding guidelines also depends on:
 - their understanding of the guidelines
 - whether they feel they are applicable to their infant
 - whether they believe their family members and doctors would want them to follow the guidelines.

1.3.2 Information sources

- Caregivers receive advice on infant feeding from many sources, including family and friends, and health professionals.
- Family members generally encourage earlier introduction of solids than health professionals.
- Caregivers who rely on the advice of health professionals or written sources of information are more likely to introduce solids closer to 6 months than those who rely on family members.

1.3.3 Infant foods

- There is some (limited) research that suggests some caregivers may be influenced by infant foods labelled 'from 4 months'.
- Qualitative evidence suggests that a small number of caregivers may find the difference between guidelines (to introduce solids at around 6 months of age) and the 'from 4 months' on food labels confusing.
- One Australian study found that the availability of commercial infant foods labelled 'from 4 months' may make it more difficult for some caregivers to wait till their infant is around 6 months of age to introduce solids.

2. FSANZ research

In January 2004, FSANZ commissioned a qualitative research¹⁴ study with primary caregivers in Australia and New Zealand to assist in the assessment of Proposal P274. Although undertaken in 2004 and reported at PFAR, this research is included in this assessment for completeness and as it provided relevant information specific to the issues being considered under Proposal P274.

¹⁴ A copy of the full report *A Qualitative Consumer Study Related to Food Labelling of Infant Foods* is available in Attachment 3 to the Draft Assessment Report at <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp274reviewofminimumagelabellingoffoodsforinfants/Default.aspx>

The purpose of the study was to:

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

This section expands on the research findings previously discussed in the PFAR.

2.1 How caregivers make decisions about introducing solids to their infants

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 by participants 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 4 months or just before, compared to about a quarter of Australian participants, with half introducing solids at 5 months. Australian participants were generally aware that 6 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 4-6 months, yet acknowledged that 6 rather than 4 was recommended. At the time the research was conducted, the New Zealand Ministry of Health still recommended introduction of solids at ‘around 4 to 6 months’ whereas the Australian National Health and Medical Research Council recommended introduction at around 6 months of age. This difference in guidelines at the time of the research may explain some of the difference in findings between the two countries.

2.2 The influence of current labels

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 of when to start introducing solid foods.

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 information on labels 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
- colour coding.

2.3 Exposure to infant food labels

Most caregivers in the study reported that they hadn't explored infant food labels until they first decided to start using solid foods.

However, there were three small groups of caregivers who were exceptions to this: curious caregivers, caregivers who were given infant foods when their infant was young; and caregivers experiencing pressure to introduce solids at an earlier age.

The researchers found that there were a few curious caregivers who, when their infants were 2–3 months old, had examined some infant foods. These caregivers were not necessarily planning to start solids at that time. As a result of their exposure to the labels, the researchers reported this had one or both of two consequences for the curious caregivers:

- the age information ensured that they delayed introducing solids
- the 'from 4 months' age recommendation was cemented as a target age.

Some caregivers had received infant food products from friends, in hospital, from retailers' online baby clubs, or from baby expos. Although these were set aside for later use, the caregivers who had received these products experienced the 'from 4 months' on the label as a frequent reminder to introduce solids. Some of these caregivers perceived the 'from 4 months' as a target for introducing solids to their infants.

The last group were caregivers who had experienced pressure from family members or friends to introduce solids before 4 months. In these instances, caregivers were able to use the minimum age on the label to argue their case to delay introducing solids until at least 4 months. It is not clear from the research whether the family members or friends promoting the early introduction of solids exposed the caregivers to infant food labels (for example, by giving them a commercial infant food product), or whether the caregivers sought these out as a result of pressure from friends and families and then saw the labels.

2.4 Labelling information on infant foods

Some potential labelling scenarios were discussed with study participants.

2.4.1 'Around 6 months'

When presented with mock-ups of the proposed labels, participants said they interpreted 'around 6 months' as aiming to introduce solids at 6 months of age, with 2–3 weeks leeway on either side.

Participants felt that if 'around 6 months' was the youngest age shown on infant food labels, that they would be unlikely to consider introducing solids at 4 months.

Some participants who were unsure as to how they would apply this to their own infant, noted that they would seek out further information (for example, from health professionals or friends). Compared to 'from 4 months', the research found that the 'around 6 months' minimum age would encourage the introduction of solids to infants at closer to 6 months of age.

2.4.2 'Not recommended for infants under the age of 4 months'

Participants were shown mock-ups of the proposed labels, carrying the 'around 6 months' on the front and the warning statement 'not recommended for infants under the age of 4 months'. Caregivers tended to interpret this as a warning that there were health or safety issues when solids are introduced to infants before 4 months of age.

When caregivers were asked to compare the minimum age ('around 6 months') and the warning statement, many participants interpreted the warning statement as suggesting that introduction of solids from 4 months was 'OK', but not obligatory. The researchers noted that there would be some risk that the warning statement may be used by caregivers to rationalise introducing solids closer to 4 months of age. However, participants mentioned that when purchasing infant foods they noticed information on the front of the package first and paid most attention to this. Without a researcher encouraging them to compare the minimum age and the warning statement, this suggests that most caregivers will not read the two statements together. However, if the minimum age and the warning statement are located next to one another on the label, this may encourage caregivers to consider them together and encourage the introduction of solids to infants closer to 4 months of age.

2.4.3 Stage labelling

Over the whole study, there was no clear preference for keeping or excluding the 1st, 2nd, 3rd Stage reference. Generally first-time caregivers 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 caregivers, such as being an easy way to direct husbands and relatives to shop for the right food for their infant, as well as assisting sleep and time deprived caregivers to quickly select products from the supermarket shelf. While the stage information was useful for some caregivers, most participants found the clarity and structure of the age and texture information more useful. There was no agreement on the usefulness of the word 'stage' relative to the age and texture information in the label concepts.

2.5 Summary of FSANZ research

The overall findings of the FSANZ research were:

- most participants used signs of hunger to indicate an infant's readiness for solids
- labels had little if any influence on the decision of when to start introducing solid foods
- those who did use labels found the age and texture information the most useful
- a small number of caregivers who are exposed to infant foods labels prior to introducing solid food, may be influenced by the age on the label
- 'around 6 months' was interpreted by participants to mean aiming to introduce solids at 6 months of age, plus or minus 2–3 weeks
- the use of 'around 6 months' was considered likely to move the introduction of solid food closer to 6 months
- participants understood the warning statement, 'not recommended for infants under the age of 4 months' to indicate earlier introduction of solids was unsafe
- there is potential for confusion among caregivers if the warning statement is co-located with the statement 'around 6 months'
- labelling of 'stages' was generally considered of little additional benefit, although some participants did consider this to be of some use.

Overall, this research suggests that, for caregivers, mandating age and texture on a label would provide adequate information to enable an informed choice and protect the health and safety of infants.

3. Research findings summary and conclusion

The FSANZ consumer research had many similar findings to the published literature, in relation to factors that influence caregivers' decisions on when to introduce solids to their infants e.g. the research found the most important or trusted sources of information were the child health nurse, books and magazines, and other mothers (via mothers groups). This was similar to the published literature; however the published literature also identified other family members as important. Similarly, the research found caregivers often interpreted disturbed sleeping patterns or hunger as a sign that their infant wanted or needed to have solid foods. In the published literature, caregivers who relied on (what they interpreted as) signs from their infant that they were ready for solids, were found to introduce solids earlier than caregivers who focused more on age guidelines.

However the FSANZ consumer research showed a greater focus on developmental cues than was apparent in the published literature. Awareness of developmental cues (e.g. the tongue extrusion reflex) was more common among the New Zealand than the Australian participants. This may be due to a greater focus on developmental cues by health professionals in New Zealand. The difference between the FSANZ research and the published literature could also be related to the discussion guide used by the researchers which may have explored developmental cues in greater depth.

The published literature and FSANZ's research both suggested there are many factors encouraging parents to introduce solids to their infants closer to 4 months of age. For example, family members often encourage early introduction and caregivers often interpret their infant's behaviour as indicating they need solids when the infant is around 4 months. The FSANZ research found that the proposed change to the youngest minimum age on infant food labels is unlikely to override all of these influences. However, it may cause some caregivers to reconsider introducing solids around 4 months of age when they go to buy infant food products and find 'around 6 months' is the youngest minimum age on a label.

The FSANZ research found three groups of caregivers who were exposed to infant food labels when their infant was young and may have been influenced by them. These were curious caregivers, caregivers who were given commercial infant foods when their infant was young; and caregivers experiencing pressure to introduce solids at an earlier age. The researchers noted that all of these groups were small. However, they echo some of the findings from the published literature on infant foods. For example, the study by Alder et al. (2004) found that caregivers who had received free samples of infant food tended to introduce solid foods at an earlier age. This aligns with the experiences of the caregivers in the FSANZ consumer research who had received free samples and perceived the age on these as a target.

For a small proportion of caregivers, 'from 4 months' labels may cause some confusion about the recommendations. For example, a small number of United Kingdom respondents reported that the conflicting advice on labels and guidelines was confusing. In another case the label reinforced advice from a friend that the appropriate age for solids was 'from 4 months'. It was also found that the availability of food marketed for infants under the age of 6 months may make it more difficult for some caregivers to wait until 6 months to introduce solids.

The FSANZ research and published literature did suggest that the youngest minimum age displayed on infant foods may influence the small proportion of caregivers who are in the following situations:

- caregivers who are curious about solids foods and decide to look at infant food labels

- caregivers who receive free samples of infant foods and keep these for later use
- caregivers who are pressured by family and friends to introduce solids food earlier than they would like.

3.1 Conclusion

Available research 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, the FSANZ consumer research found that caregivers did value age and consistency information, particularly for deciding when to move from one stage of solids to the next.

The FSANZ research and published literature did suggest that the youngest minimum age displayed on infant foods may influence the small proportion of caregivers who are in specific situations that may lead them to read infant food labels before they plan to introduce solid foods to their infant.

Based on the published literature on infant feeding, the following factors are likely to temper the influence of the 'around 6 months' minimum age on infant food labels:

- the influence of family or friends, who tend to encourage earlier introduction
- caregivers' perceptions that their infants' behaviour indicates they desire or need solid foods at an earlier age
- some caregivers' disagreement with the guidelines
- caregivers' perceptions that the guidelines (although generally appropriate) are not suitable for their child
- the use of homemade foods as first solid foods. Where infants' very first solid foods are prepared at home they will not be accompanied by a label with a minimum age
- caregivers' experience of introducing solids before 6 months with a previous child
- the experience, for some caregivers, of the first solids meal being an important milestone that is looked forward to.

Aligning the youngest minimum age on infant food labels may have the following benefits for caregivers:

- reducing confusion about the recommended age for introducing solids, particularly for caregivers who have received differing advice from different sources
- some indication of an appropriate age for solids for caregivers who have not received formal advice on the topic, or who do not have a clear understanding of the recommendations
- support for who experience pressure from family or friends to introduce solids earlier than they would like.

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Attachment 2

Questions for submitters

4.1.1.2 Food intended as a first food

1. Is the concept and definition of first food a useful way to apply certain labelling and formulation requirements?
2. Is the definition of 'first food' enforceable?

4.1.1.3 Impact of labelling on other infant food:

1. Should the use of the age/number 6 on labels of infant food be prohibited, other than in conjunction with the word 'around'? Please explain your view.

4.1.2 Mandatory advisory statements

1. Do the changes to the wording of the warning statements change the intent of these statements? If so, please explain why.
2. Should the 'not before 4 months of age' statement apply to food is represented for infants 'around 6 months' of age only? If not, please describe which foods should carry this warning statement, and the reasons why.

4.1.3 Location of mandatory statements on infant food labels

1. Is it important for minimum age to be always displayed on the front of a product? Please give your reasons. If not, are there any other labelling measures that should be mandated?
2. Will the removal of the association between the relevant minimum age statement and the 4-month warning statement reduce the risk of caregiver confusion on the age of introducing solid foods?

5.3.2.1 Labelling cost estimate

Questions for manufacturers are provided in the table below. If you have previously supplied any of this information to FSANZ, there is no need to provide it again.

However, please note the **additional question*** in the table i.e. could industry please provide evidence of which additional costs will be incurred and quantified estimates of the size of these costs? Would these costs be less if they were incurred at the same time as other voluntary labelling changes? If so, to what degree would they be reduced?

Questions for manufacturers of infant foods (if information not previously provided - please note additional question below*):

Material	Flexible	Fibre			Plastic			Metal		Glass	
Packaging	Pouch/bag	Liquid paperboard carton	Corrugated carton	Folding carton	Tub	Bottle	Jar	Aluminium can	Steel can	Jar	Bottle
Number of SKUs ¹⁵ that carry a label- Appropriate for 4 months, 4+ or 4-6 months (in number)											
How often do you reorder labels or packaging with age for consumption recommendation printed onto it (in months)											
How often do you voluntarily change labelling for marketing or other purposes (in months)											
What is the direct cost of a labelling change for a single SKU? (in \$)											

<p>If you were to make a labelling change to meet the recommended changes at the same time as making a voluntary change, what would the additional cost of making the change to meet the proposed changed regulation requirement be?¹⁶ (in \$)</p>											
<p>* Could industry please provide evidence which additional costs will be incurred and quantified estimates of the size of these costs? Would these costs be less if they were incurred at the same time as other voluntary labelling changes? If so by how much?</p>											

¹⁵ Stock Keeping Unit - refers to a stock-keeping unit, a unique identifier for each distinct product and service that can be purchased in business

¹⁶ We are seeking the marginal cost of making the change if we were to wait until you were making another change in the future. We are trying to establish if by setting a transition period whether industry costs can be reduced.