

**7 October 2014**  
**[20–14]**

Rejection – Proposal P274

## Review of Minimum Age Labelling of Foods for Infants

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Food Standards Australia New Zealand (FSANZ) has assessed a proposal prepared by FSANZ to review the labelling requirements in Standard 2.9.2 – Food for infants, in light of the Australian and New Zealand infant feeding guidelines.

On 20 October 2004, FSANZ sought submissions on a draft variation. FSANZ received 12 submissions. Stakeholder views were also sought in 2007, 2008 and 2013 on the proposal to amend the Standard to increase the minimum age permitted on labels of infant food to ‘around 6 months’.

Pursuant to paragraph 18(1)(c) of the *Food Standards Australia New Zealand Act 1991* (as was in force prior to 1 July 2007), FSANZ rejected the draft variation on 18 September 2014. The Australia and New Zealand Ministerial Forum on Food Regulation<sup>1</sup> (Forum) was notified of FSANZ’s decision on 3 October 2014.

Information on the reasons for FSANZ’s decision is contained in this Report.

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<sup>1</sup> convening as the Australia and New Zealand Food Regulation Ministerial Council

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## Supporting documents

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

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

SD1 Risk Assessment  
SD2 Summary of submitter comments to October 2013 Consultation Paper

## Executive summary

In Australia, the National Health and Medical Research Council (NHMRC) 1995 Dietary Guidelines for Children and Adolescents advised that the general timetable for introducing foods starts at 4–6 months. Four months is also the minimum (youngest) age permitted on infant food labels by Standard 2.9.2 – Foods for Infants.

This Proposal commenced in 2003 after the (then) Ministerial Council asked FSANZ to prepare a proposal to undertake a review of Standard 2.9.2, following release of the 2003 NHMRC Infant Feeding Guidelines for Health Workers which recommended for the first time that solids be introduced at ‘around 6 months’ of age. FSANZ was asked to take account of inconsistencies between Standard 2.9.2 and the 2003 guidelines and their impact as part of the review. The Ministers also asked that the corresponding New Zealand guidelines be accommodated. Completion of the project has been delayed twice, firstly in 2004 due to competing priorities, and more recently in 2008 while awaiting review of the 2003 NHMRC (Australian) infant feeding guidelines, which were subsequently released in 2013.

Several public consultations were held over the life of the Proposal, each time proposing to amend Standard 2.9.2 by raising the minimum age on infant foods from 4 months to ‘around 6 months’ in keeping with recommendations from both the Australian infant feeding guidelines (2003, 2013) and the New Zealand Food and Nutrition Guidelines for Healthy Infants and Toddlers (Ministry of Health 2008).

The proposed amendment to Standard 2.9.2 was more strongly supported in the earlier consultations before 2008. By 2013, stakeholder views had divided into two clear groups i.e. industry and allergy specialists did not support a change whereas jurisdictions and other health professionals and health groups supported changing the labelling requirements. However, in 2014 when the possibility of retaining the status quo was discussed, some stakeholder views changed within some groups. This divergence of views over time partly related to emerging evidence linking the timing of introduction of solids and allergy prevention. Also, over time, the food industry identified further details of impacts and costs of the proposed change that might arise from amending the standard.

FSANZ prepared risk assessments relating to the appropriate age for introducing solid foods in 2004 and again in 2008, 2013 and 2014. Although the risk assessment in 2008 covered a broad range of health effects, the 2013 assessment focussed largely on the main area of new evidence (development of food allergies), and the 2014 assessment primarily addressed new matters raised in response to the 2013 consultation.

After weighing all the relevant available evidence across a range of health outcomes, including growth and development, allergy development, nutrient deficiencies and infections, FSANZ considered that in Australia and New Zealand, there is no difference in risk of harm from the introduction of solids from ‘4 months of age’, relative to introducing solids at ‘around 6 months’ of age.

In 2014, FSANZ liaised with NHMRC to identify commonalities in the assessments undertaken by the two agencies and to understand the reasons for apparent differences in how the respective assessments were used. As a result, FSANZ considered that there was no inconsistency in the assessment of the evidence underpinning the labelling age (from 4 months), and the infant feeding guidelines (‘around 6 months’), even though different points in the age range 4–<7 months were chosen by the two agencies for their advice. Apparent differences between the two agencies’ use of the assessments reflect the different purposes of their work. Food regulations must provide a high degree of certainty to protect public health and safety, whereas population guidelines directed to health workers can be more flexible to take account of the needs of individual infants.

Given the assessed lack of difference in health risk, FSANZ reconsidered the basis of the problem and how best to approach the labelling of infant food. The Office of Best Practice Regulation (OBPR) in Australia advised that it does not regard inconsistency between national guidelines and labelling as a problem unless there is harm arising from any such inconsistency.

FSANZ concluded that the current age requirements for labelling of infant food prescribed in subclauses 5(2) and 5(3) of Standard 2.9.2 (refer to section 1.2) were unlikely to result in harm to infants.

On that basis, amending the age labelling requirements in Standard 2.9.2 in the manner proposed in the draft variation was not considered warranted, having regard to the applicable statutory objectives and considerations. The draft variation was therefore rejected.

# 1 Introduction

In Australia, the National Health and Medical Research Council 1995 Dietary Guidelines for Children and Adolescents (NHMRC 1995) noted that *traditionally the period between 4–6 months of age has been viewed as suitable for infants to begin to adapt to different foods* and also *the general timetable for the introduction of foods starts with iron enriched foods at 4–6 months*. Standard 2.9.2 – Foods for Infants, which derives from that time<sup>2</sup> and its Australian predecessors, prohibited infant food from being labelled with an age younger than 4 months. This allowed labels to provide information for carers on the suitability of the food for infants aged from 4 months.

In 2003, the then Australia and New Zealand Food Regulation Ministerial Council<sup>3</sup> asked FSANZ to prepare a proposal to undertake a review of Standard 2.9.2, following release of the 2003 NHMRC Dietary Guidelines for Children and Adolescents in Australia which incorporated the Infant Feeding Guidelines for Health Workers (NHMRC 2003). These infant feeding guidelines recommended for the first time that solids be introduced at ‘around 6 months’ of age. FSANZ was asked to take account of possible inconsistencies with the minimum (youngest) age on infant food labels and their impact, as part of the review. The Ministers also asked that corresponding New Zealand guidelines be considered and accommodated.

At the time of the 2003 request, the New Zealand guidelines for infant feeding recommended introducing solids from 4–6 months of age. In 2008, revised New Zealand Food and Nutrition Guidelines for Healthy Infants and Toddlers (Ministry of Health 2008) were released and generally recommended the introduction of solids at ‘around 6 months’. As these guidelines were directed to health workers, an individual infant’s developmental readiness for solid foods was also recognised e.g. *the emphasis is on using the developmental stages and skills to guide the age for introducing complementary foods to the individual child, and while the ideal is to wait until the infant is around six months of age, the timing of the developmental stages and skills that signal readiness vary from infant to infant*.

In 2013, NHMRC released a new edition of the Infant Feeding Guidelines (NHMRC 2012a) where it was again recommended that solids be introduced at ‘around 6 months’ of age. It is noted in the disclaimer to these guidelines that *this document is a general guide to appropriate practice, to be followed subject to the clinician’s judgement and patient’s preference in each individual case*. The 2013 Australian Dietary Guidelines (NHMRC 2013) also note that *it is important, however, that health professionals manage all infants on an individual basis, no matter how they are fed, so that any faltering growth or other adverse outcomes do not go unnoticed*.

## 1.1 History of the Proposal

The Proposal was prepared in 2003 and a draft assessment released for public consultation in 2004. FSANZ then deferred finalising the assessment of the Proposal due to competing priorities until 2007, then consulted on the Proposal in 2007 and 2008, deferred again and next consulted in 2013. The reason for the Proposal’s deferral in 2008 was to await the outcome of the 2008–12 review of the NHMRC infant feeding guidelines which considered emerging evidence in relation to allergy and reaffirmed the previous general recommendation to introduce solids at ‘around 6 months’. The Proposal re-commenced in 2013.

Issues considered over the life of the Proposal included:

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<sup>2</sup> Standard 2.9.2 was gazetted on 20 December 2000.

<sup>3</sup> Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

- the importance of the timing of the introduction of solid foods to an individual infant
- ongoing evidence relevant to the introduction of solid foods
- consistency of labelling with Australian and New Zealand infant feeding guidelines
- parents'/carers' use of label information
- managing risks associated with early introduction of solids
- the effect of current regulations and any change on affected parties
- the benefits and costs of amending the current labelling requirements
- the current regulatory environment.

As shown in Table 1, FSANZ had previously proposed to amend Standard 2.9.2 to align labelling requirements with the general recommendations in the Australian infant feeding guidelines and in the revised New Zealand guidelines. In response to public consultation in 2013 and targeted consultation in 2014, stakeholder views were more strongly divided than previously on whether the minimum age labelling requirements for foods for infants should be amended.

In 2014, due to the diversity of views and provision of more detailed information in submissions and subsequent targeted consultation, FSANZ reconsidered the basis for the problem and how best to approach the labelling of infant food. We reviewed and updated the evidence base and further consulted with relevant parties, including the NHMRC and the Office of Best Practice Regulation (OBPR).

## 1.2 The current Standard

Standard 2.9.2 – Foods for Infants provides for the compositional and labelling requirements of foods intended or represented for use as foods for infants, excluding infant formula products regulated by Standard 2.9.1 – Infant Formula Products. An infant is defined in the Code as a person up to the age of 12 months.

In relation to minimum age labelling, subclause 5(2) requires that:

- (2) *The label on a package of food for infants must not include a recommendation, whether express or implied, that the food is suitable for infants less than four months old.*

Also, paragraphs 5(3)(a)–(c) of Standard 2.9.2 require the label on a package of a food for infants to include –

- (a) *a statement indicating the consistency of the food; and*
- (b) *a statement indicating the minimum age, expressed in numbers, of the infants for whom the food is recommended; and*
- (c) *where the food is recommended for infants between the ages of 4–6<sup>4</sup> months, in association with the statement required by paragraph (b), the words –*

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

## 1.3 Reasons for preparing the Proposal

The Proposal was originally prepared in 2003 at the request of the then Ministerial Council, because of the apparent inconsistency between the minimum age labelling required by Standard 2.9.2 (4 months) and the revised recommendation on the timing of introduction of solids in the 2003 NHMRC infant feeding guidelines of 'around 6 months' which had the potential to create community confusion.

<sup>4</sup> Under Proposal P1025 – Code Reform, this will likely become "if the food is recommended for infants *under the age of 6 months*—in association with the statement required by paragraph (b), the words 'Not recommended for infants under the age of 4 months'"

Since 2008, both the Australian and the New Zealand infant feeding guidelines have recommended introducing solids at 'around 6 months' of age. Since NHMRC reaffirmed this recommendation in 2013, FSANZ continued to assess whether a variation to Standard 2.9.2 was warranted.

## 1.4 Decision

FSANZ's decision was to reject the draft variation. This decision relates to the draft variation to Standard 2.9.2 which was first released for public consultation with the Draft Assessment Report in 2004 (provided at Attachment A).

## 2 Summary of findings

### 2.1 Summary of views from submissions (2003–13)

Table 1 provides an overarching summary of stakeholder views from 2003–13. Refer to FSANZ website for previous reports and submissions at <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp274reviewofminimumageoflabellingoffoodsforinfants/Default.aspx> and Supporting Document (SD2) for a summary of submitter comments to the 2013 Consultation paper.

**Table 1: Overall summary of Stakeholder views**

Year	Consultation	Proposed approach	Submissions	General views of stakeholders
2003	Initial Assessment Report		34	Majority supported amending Standard 2.9.2 to align with the 2003 Australian infant feeding guidelines.
2004	Draft Assessment Report including draft variation	Amend the minimum reference age in Standard 2.9.2 to 'around 6 months'	12	Majority supported change to align with the 2003 Australian infant feeding guidelines.
2007	Public Consultation Paper on recommencement of P274	Amend the minimum reference age in Standard 2.9.2 to 'around 6 months'	20	Over half supported the proposed approach. New Zealand government also supported labelling with 'first stage' (of introducing solid food). Others supported status quo. Medical/allergy specialists suggested delaying decision to wait for results of allergy research. Most jurisdictions, infant health and breastfeeding organisations supported the approach. Industry views were divided.

Year	Consultation	Proposed approach	Submissions	General views of stakeholders
2008	Preliminary Final Assessment Report with draft variation, and targeted consultation	Amend the minimum reference age in Standard 2.9.2 to 'around 6 months'	20	Range of views. Majority generally supported alignment with guidelines; others supported retaining current requirements; some preferred labelling that refers to the progressive stages of introducing solids. Allergy specialists opposed change on the basis of emerging evidence for timing of introduction of solids and allergy prevention.
2013	Public Consultation Paper, plus targeted consultation with industry and Jurisdictions.	Amend the minimum reference age in Standard 2.9.2 to 'around 6 months'	41	Views more divergent – industry and allergy specialists opposed change; health professional (non-allergy) organisations, health groups and jurisdictions supported change. Evidence was still emerging, randomised control trials in progress. Further details of impacts and costs of proposed change were provided by industry.

Stakeholders' views became more strongly divergent over time due to the emergence of new scientific evidence and more detailed information about costs of the proposed change from the food industry. As a result, FSANZ undertook further targeted consultation in 2014. This included discussions with NHMRC regarding the evidence base supporting the 2013 infant feeding guidelines; and with the OBPR in Australia regarding requirements for changing regulation in the Australian context. The possibility of retaining the status quo and the accompanying rationale was also raised with some stakeholder groups. Industry stakeholders, allergy specialists and some jurisdictions did not support changing the labelling requirements, whereas other public health stakeholders and at least half of the jurisdictions were supportive of change. Within these groups, some parties had changed their view over time.

## 2.2 FSANZ risk assessments and evidence base

In 2004, FSANZ prepared a risk assessment on the timing and introduction to solid foods for infants as part of the Draft Assessment. More recently, FSANZ prepared risk assessments relating to the appropriate age of introduction of solid foods on three occasions: 2008, 2013 and 2014. These assessments were produced with a tiered approach, that is, the risk assessment in 2008 covered a broad range of health effects, the 2013 assessment focussed largely on the main area of new evidence (development of food allergies) and the 2014 assessment primarily addressed new matters raised by submitters in response to the 2013 Consultation paper.

The content of these more recent assessments, and the conclusion of each, is summarised in Table 2. Please refer to SD1 for details of the assessment undertaken during 2013–4 and a summary of the previous 2008 assessment.



**Table 2: Summary of issues considered in FSANZ risk assessments relating to the age of introduction of solid foods**

Date of assessment	Issues considered	Conclusions
<b>August 2008</b>	Potential for displacement of breast milk and/or formula, any changes in energy intake, and whether growth outcomes are adversely affected	Intervention studies show introduction of solids at 3–4 months of age reduces breast milk intake but does not significantly affect the rate of increase in weight and length of the infant.
	Capacity of infant kidneys to deal with the higher solute load of solid foods prior to 6 months of age	Unable to identify any studies that directly assessed changes in renal solute load or water balance with introduction of solid food, but greatest risk of negative water balance is during illness. However, the capacity of infants to reduce intake of solid foods during illness is likely to mitigate potential risk.
	Impact on iron and zinc status, particularly in pre-term infants	Evidence from 2 studies provides some indication that exclusive breastfeeding to 6 months does not increase risk of iron deficiency at a later age. Expected that the outcomes on zinc status would be similar to, and no worse than, those for iron, as infants have a better storage of zinc compared to iron in the first 6 months of life.
	Influence of feeding practices in infancy on later food preferences	Emerging evidence suggesting that the timing of solid food introduction can influence later dietary outcomes and preferences, but it is too early to draw conclusions about the effect this might have on recommended infant feeding practices.
	Risk of allergy and other immune-mediated diseases	Evidence regarding the timing of the introduction of solids and risk of allergy and other immune-mediated diseases, such as coeliac disease and Type 1 diabetes, is emerging and no firm conclusions can be drawn at this time. However, preliminary indications are that the risk of allergy may be minimised if breastfeeding is maintained throughout the period of introducing solids, whereas the risk may increase if the introduction of solids is delayed beyond 7 months
	<b>Conclusion</b>	<b>Delaying introduction of solid foods to ‘around 6 months’ of age is unlikely to have any discernible positive or negative effect on the nutritional or developmental outcomes of infants.</b>

Date of assessment	Issues considered	Conclusions
October 2013	Risk of iron and zinc deficiencies in preterm infants with delayed introduction of solids	Unable to identify any studies addressing this question.
	Allergy risk – <4 completed months (~17 weeks of age)	Allergy risk appears to be associated with solid foods introduced at <4 months. This association, combined with evidence that risk of infectious morbidity is also increased with this time period (as related to the protective effects of breastfeeding), supports the current recommendations from ESPGHAN, EFSA, and NHMRC (see SD1) that from 4 months of age is the appropriate minimum age at which solid foods should be introduced.
	Allergy risk – 7months or above	Since 2008, there is increasing evidence that the timing of solid food introduction may be related to the development of food-related allergy. Critical period to minimise the risk of allergy development seems to be between 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.
	<b>Conclusion</b>	<b>‘Around 6 months’ as the appropriate age for the introduction of solid food to infants would have minimal effect on the risk of adverse health outcomes, relative to ‘from 4 months’ of age.</b>
January 2014	Proportion of infants being introduced to solids at <4 months	The Australian national average proportion of infants who were receiving solids before 4 completed months of age was 4–10%, noting that within this range there was some variation according to maternal age and SES (2010 Infant Feeding Survey). New Zealand data (2011/12) indicates that the proportion of infants introduced to solids before 4 months was 10%, which was lower than previous survey (2006/07) of 16%.
	Introduction of solids and cessation of breast feeding	Data on infant feeding practices in Australia indicate there is little association between the introduction of solid foods and continuation of breastfeeding. Between 4–6 months of age, the prevalence of any breastfeeding declined from 69% to 60% while the prevalence of feeding solids rose from around 10% to over 90%. Similarly, before 4 months of age, the decline in prevalence of breastfeeding was double the prevalence of introducing solids (2010 Infant Feeding Survey).

Date of assessment	Issues considered	Conclusions
	<b>Conclusion</b>	<b>Current evidence indicates that in developed countries with generally hygienically prepared foods, there is no additional in risk from delaying introduction of solids until around 6 months or, conversely, from introducing solids closer to the 4-month end of the window between 4 and &lt;7 months.</b>
<b>July 2014</b>	Gastrointestinal infection	Large UK cohort study identified no association between age of introduction of solids and hospitalisation for gastrointestinal or respiratory tract infections in the first 8 months of life.
	<b>Overall conclusion</b>	<b>In Australia and New Zealand, there is no overall difference in risk between introducing solids from 4 months of age relative to around 6 months (ie within window from 4 months to &lt;7 months of age).</b>

In these assessments, FSANZ has stressed the limitations of the available data in this area of research and the challenge of differentiating the health effects for infants solely due to the introduction of solid foods, rather than to the introduction of infant formula at around the same time, or other changes. Distinguishing the effects (if any) of introducing solid food from those of infant formula is particularly important in these assessments, as this Proposal relates only to packaged solid foods and these foods may be consumed by both breastfed and formula-fed infants, whether or not these children are cared for in the home or in child care centres.

A major challenge to this process was that much of the available evidence is confounded or complicated by unclear and conflicting definitions of what constitutes complementary foods and exclusive breastfeeding, confusion over the exact age of infants studied, and concurrent changes from breastfeeding to formula feeding with introduction of solid foods. Data in populations of comparable socio-economic and health status to Australia and New Zealand are also limited.

### 2.2.1 Conclusion

Despite these caveats and after weighing all the relevant available evidence across a range of health outcomes, including growth and development, allergy development, nutrient deficiencies and infections, FSANZ's conclusions have not changed. We consider that in Australia and New Zealand, there is no overall difference in risk between introducing solids from 4 months of age relative to 'around 6 months' of age, that is within the window of 4-<7 months of age.

## **2.3 Risk management**

### **2.3.1 The problem**

#### **2.3.1.1 Inconsistency with NHMRC guidelines**

An inconsistency between the infant feeding guidelines and the labelling on infant food as suggested by the 2003 Ministerial Council could possibly cause consumer confusion, and not support health education messages regarding the introduction of solid foods. In 2014, FSANZ liaised with NHMRC to identify commonalities in the assessments undertaken by the two agencies and to understand the reasons for apparent differences in how the respective assessments were used (SD1, Attachment 4).

As a result, FSANZ considered that there was no inconsistency in the assessment of the evidence underpinning the labelling age (from 4 months), and the infant feeding guidelines ('around 6 months'), even though different points in the age range 4–<7 months were chosen by the two agencies for their advice. Apparent differences between the two agencies' use of the assessments reflect the different purposes of their work. Food regulations must provide a high degree of certainty to protect public health and safety, whereas population guidelines directed to health workers can be more flexible to take account of the needs of individual infants. FSANZ therefore considers that the apparent inconsistency between government guidelines and food regulation is not a problem as originally thought in 2003.

#### **2.3.1.2 Potential harm to infants**

OBPR has advised that inconsistency between national guidelines and labelling is not regarded as a problem unless there is harm arising from such inconsistency. For example, receiving solid foods at inappropriate ages may cause adverse health effects for infants.

FSANZ's risk assessment of the current evidence determined that, in developed countries with generally hygienically prepared foods, there is no difference in risk of harm to the health of infants from introducing solid food from 4 months relative to 'around 6 months' of age. Based on this evidence, there is unlikely to be any harm to infants in Australia and New Zealand as a result of the current labelling.

However, some stakeholders expressed concern about infants who received solids *before* 4 months of age (currently from 4–10% (Australian Institute of Health and Welfare 2011; Ministry of Health 2012)), which is not recommended. Stakeholders considered that continuing to label infant food 'from 4 months' (rather than raising to 'around 6 months') would not help reduce the current prevalence of premature introduction of solids which, it was suggested, might be indirectly achieved if the minimum age permitted on a label was raised.

FSANZ notes that Standard 2.9.2 requires a mandatory warning statement on the label of infant foods for infants between 4–6 months to mitigate any potential risk i.e. 'Not recommended for infants under the age of 4 months'. This mandatory warning requirement will continue to be required.

In addition, we note that 10% or fewer infants are introduced to solids before 4 months of age in both Australia and New Zealand. This proportion appears to have declined compared to earlier surveys e.g. for Queensland, the proportion of infants receiving solids before 4 months dropped from 48.5% (2003) to 12.3% (2008) to 5.9% (2010). In New Zealand, the proportion of infants receiving solids before 4 months dropped from 16% in 2006/07 to 10% in 2011/2012 (see SD1). Over these years, the permission in Standard 2.9.2 to label infant food from '4 months' did not change. This suggests that the infant feeding guidelines and education are having an influence on carers of that age group.

This issue was not considered further under Proposal 274, as it was not the purpose of the original request, and the warning statement continues to reflect the evidence base for the Australian and New Zealand guidelines.

### **2.3.2 Cost benefit analysis**

The assessment of this Proposal indicates that no regulatory response is necessary and that the status quo should be maintained. This conclusion has been reached on the basis of no difference in risk of harm from introducing solids from 4 months of age, when compared to introducing solids at 'around 6 months' of age; also that the current labelling regulations are compatible with the evidence base for the NHMRC infant feeding guidelines. As the decision to retain the current labelling requirements has been made on the basis that no benefits are likely from a change from the status quo, no consideration of the costs or more complex economic analysis is necessary.

### **2.3.3 Risk management conclusion**

FSANZ's assessment of the evidence does not support amending Standard 2.9.2. The assessment has not demonstrated an inconsistency between the evidence for the Australian (NHMRC) and New Zealand infant feeding guidelines, and the minimum age labelling requirements on infant food, so there is no problem that requires a regulatory solution.

Therefore, the current regulatory requirements remain appropriate and no additional risk management measures are required.

The current labelling requirements as prescribed in Standard 2.9.2 will be retained, including (among other things) that the label on a package of food for infants:

- must indicate the minimum age, in numbers, of the infants for whom the food is recommended
- must not recommend that the food is suitable for infants <4 months old
- must indicate the consistency of the food e.g. smooth, puréed
- must include (if the food label refers to infants between the ages of 4–6 months), the warning statement 'Not recommended for infants under the age of 4 months', in association with the age (of the infants for whom the food is recommended).

## **2.4 Risk communication**

### **2.4.1 Communication strategy**

FSANZ prepared a communication strategy for this Proposal. FSANZ communicated about the Proposal both directly with stakeholders and through our website, publications, social media and notification emails. All calls for submissions were notified through these channels and the Notification Circular and were announced through media releases.

The process by which FSANZ considers standard matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on the draft variation to the Code. FSANZ places all related Proposal documents and submissions on the FSANZ website. All public comments received for this Proposal were reviewed and considered by the FSANZ Board.

This Report with supporting documents is available to all interested parties on the FSANZ website. Decisions about applications and proposals are also notified to interested stakeholders through email notifications and more broadly through Food Standards News.

## 2.4.2 Consultation

Consultation is a key part of FSANZ's standards development process. This Proposal has involved considerable consultation over the years, both through public papers, and targeted meetings and communications with key stakeholder groups. Issues raised are discussed within the relevant Proposal reports available on the FSANZ website. In addition, SD2 provides a summary of submitter comments in response to the Consultation paper in 2013.

FSANZ acknowledges the time taken by individuals and organisations to provide information and make submissions on this Proposal. All comments are appreciated and contribute to our assessment.

## 2.5 FSANZ Act assessment requirements

FSANZ has considered the objectives in subsection 10(1) and 10(2) of the FSANZ Act (as was in force prior to 1 July 2007) during the assessment of this Proposal as follows.

### 2.5.1 Subsection 10(1) considerations

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

FSANZ's risk assessment, including reference to the NHMRC assessment, has considered the health and safety of infants. As the evidence indicates no increase in risk of harm to the health of infants from introducing solid foods from '4 months' of age relative to around '6 months' of age, maintaining the status quo will continue to protect the health and safety of infants in the age group relevant to this Proposal.

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

As there will be no change to the current Standard, infant food labels will continue to provide adequate information to parents/carers so they can make an informed choice in relation to the age suitability and consistency of an infant food product, as summarised in Section 2.3.3 above. The warning statement: *not recommended for infants under 4 months of age*, will be retained to provide additional information, where the food is recommended for infants between the ages of 4–6<sup>5</sup> months.

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

Retaining the status quo will continue to provide clear labelling requirements for both manufacturers and enforcement agencies to avoid misleading or deceptive conduct.

### 2.5.2 Subsection 10(2) considerations

FSANZ has also had regard to the objectives set out in subsection 10(2) of the FSANZ Act (as was in force prior to 1 July 2007):

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

FSANZ prepared four risk assessments between 2003 and 2014.

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<sup>5</sup> Under Proposal P1025 – Code Reform, this will likely become “if the food is recommended for infants *under the age of 6 months*—in association with the statement required by paragraph (b), the words ‘Not recommended for infants under the age of 4 months’”

The 2013 and 2014 assessments focussed largely on new evidence and new matters raised during consultation. In addition, the assessment undertaken by the NHMRC as the basis of the 2013 infant feeding guidelines for Australia has been considered. Our ongoing assessment over time ensured the best available evidence was considered.

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

As no amendment to Standard 2.9.2 is proposed, there is no impact on the food industry.

- the promotion of fair trading in food.

Not relevant.

- any written policy guidelines formulated by the Ministerial Council<sup>6</sup>

There are no specific policy guidelines for infant food.

### **2.5.3 Any other relevant matters**

No other matters are relevant to rejection of the draft variation.

#### **2.5.3.1 Any relevant New Zealand standards.**

There is no relevant New Zealand only standard.

## **3 Rights of review**

The *Food Standards Australia New Zealand Act 1991* (as in force prior to 1 July 2007) does not provide a right of review in relation to a decision by the Board under section 18 to reject a draft variation arising out of a proposal.

## **4 References**

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## **Attachments**

A. Draft Food Regulatory Measure (at Draft Assessment – 2004)



# Attachment A – Draft variation to the Australia New Zealand Food Standards Code (At Draft Assessment – 2004)

## To commence: on gazettal

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

(d) Paragraph 5(4)(b) and subclause 6(2) of Standard 2.9.2; and

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

[2.1] *omitting subclause 2(4).*

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

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

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

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

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

(c) may contain added thiamin, niacin, vitamin B<sub>6</sub>, vitamin C, folate, magnesium in the forms permitted in Schedule 1 of Standard 2.9.1; and

(d) may contain added vitamin C to a maximum level of 90 mg/100 g on a moisture free basis.

[2.4] *omitting subclause 3(2).*

[2.5] *omitting clause 5, substituting –*

## 5 Labelling

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

(2) The label on a package of food for infants must not include a representation, whether express or implied, that the food is suitable for infants less than 4 months.

(3) The label on a package of food for infants must include –

(a) a statement indicating the consistency of the food; and

(b) a statement indicating from which age, expressed in numbers, the food is suitable; and

(c) where the added sugars content of the food for infants exceeds 4 g/100 g, the word –  
‘sweetened’; and

(d) where honey has been used as an ingredient, the words-

‘sterilised honey’.

In addition to the requirements in subclause (3), where the food is suitable for infants aged between 4 and 6 months the label on a package of food for infants must include the following statements –

- (a) 'Around 6 months'; and
- (b) 'Not recommended for infants under the age of 4 months'; and
- (c) words to the effect that the decision to begin feeding solids should be made in consultation with a health professional.

**Editorial note:**

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

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