

Supporting document 3

Key outstanding issues raised by submitters at Preliminary Final Assessment – Proposal P274

Review of Minimum Age Labelling of Foods for Infants

In August 2008, FSANZ released a Preliminary Final Assessment Report (PFAR) for public consultation. The following table summarises the key outstanding issues raised by submitters in this consultation; it is not a comprehensive summary of the submissions received. These include submissions from the following stakeholders:

- Australian Food and Grocery Council (AFGC)
- Dietitians Association of Australia (DAA)
- Australasian Society of Clinical Immunology & Allergy (ASCIA)
- Food Technology Association of Australia (FTAA)
- New Zealand Dietetics (NZDA)
- New Zealand Food Safety Authority and The New Zealand Ministry of Health (NZFSA & NZ MoH)
- Nestlé
- New Zealand Food and Grocery Council (NZFGC)
- Food Safety Unit, Department of Human Services Victoria (Victoria DHS)
- H.J. Heinz Company Australia Limited (Heinz)
- La Leche League New Zealand (LLLNZ)
- Food Safety Policy and Regulation Section, Environmental Health Unit, Queensland Health (QLD Health)
- Department of Human Services Tasmania (Tasmania DHS)
- New South Wales Food Authority (NSW FA)
- South Australia Department of Health (SA Health)
- Institute of Food, Nutrition and Human Health, Massey University (Massey Uni)
- Royal Children’s Hospital, Melbourne (RCH, Melbourne)

Issue	Raised by	FSANZ Response
<p>Allergy/Evidence</p> <ul style="list-style-type: none"> • New evidence available regarding allergies suggest that delaying the introduction of complementary foods to six months or later may increase the risk of food allergy. • In considering the role of diet in development of allergic disease, expert groups consider there is no evidence to support delaying introduction of solids beyond 4-6 months of age. Current available literature would support retaining current labelling practices. • In light of emerging evidence in the allergy field, believe the proposed ‘around 6 months’ for the introduction of solids will pose an increased health risk to infants – so is not in line with FSANZ objective of protecting health and safety. • The evidence for a ‘window’ (for reducing risk of allergy) is not yet conclusive. • Studies quoted refer to delaying allergens, not all solids, beyond 7 months. Current guidelines recommend delaying allergenic foods until 8-12 months (NHMRC 2003) so changing labelling to ‘around 6 months’ will have no bearing on these allergens. • Further studies concerning the recommended age for solids to reduce the risk of allergic disease need to be undertaken and reported to support and change to the status quo. • Considers there is little evidence on age of introduction of solids in formula fed infants 	<p>DAA, AFGC, ASCIA, Heinz</p> <p>ASCIA, Heinz,</p> <p>Nestlé</p> <p>Tasmania DHS</p> <p>Victoria DHS</p> <p>AFGC, FTAA, NZDA, QLD Health, SA Health</p> <p>Heinz</p>	<p>Following PFAR, FSANZ put P274 on hold – as we expected that NHMRC would consider the age of introduction of solid foods to infants in relation to the emerging evidence around the impact on allergies. The NHMRC reviewed evidence up until 2008.</p> <p>FSANZ has now reviewed literature on this issue since 2008. An updated risk assessment is provided in SD1.</p>
<p>National recommendations and consistency of information</p> <p>The information on food labels should be consistent with current infant feeding recommendations/ guidelines. Parents and health professionals main concern in seeking nutrition advice is consistency of message.</p> <p>Recognises that the Standard is inconsistent with the national feeding guidelines in Australia and New Zealand, however does not consider that this is sufficient argument alone, and in the face of conflicting and contradictory advice on public health and safety concerns over delaying the introduction of solids until six months. Rejects the argument that the FSANZ standard must align with the guidelines, as the guidelines are flawed.</p>	<p>Massey Uni, RCH Melbourne</p> <p>AFGC</p>	<p>A majority of submitters supported aligning with the national infant feeding guidelines, in principle.</p> <p>Others supported retaining the current age requirements; some recommended delaying any amendments until further evidence was available regarding the optimum time to introduce solids.</p>

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<p>Review of NHMRC guidelines</p> <p>The optimal time for introduction of foods into the diets of children is controversial and undergoing review e.g. by NHMRC, ASCIA & American Academy of Paediatrics, 2008. Review is due for completion by 2010. This may change the benchmark.</p> <p>Changing the minimum age labelling for food for infants at this time would be unwise. Recommended retain the status quo, delay labelling changes and review once the NHMRC guidelines are revised.</p> <p>Guidelines fail to take into account the needs of infants who require infant formula and are not breastfed, including <i>pre-term babies</i>.</p>	<p>DAA, AFGC, Heinz, NZDA, Nestlé, FTAA</p>	<p>Following PFAR, FSANZ decided to place Proposal P274 on hold until after the NHMRC review of the infant feeding guidelines. The review was released in February 2013, hence P274 has recommenced.</p>
<p>Harmonisation with international regulations</p> <p>Current EU and USA requirements retain the 4-6 months provisions. Being inconsistent with major trading partners will limit the opportunity for import, export and competition. This is a barrier to fair trade - any food importer in Australia and NZ would not be able to directly import baby food from these countries without the additional costs of maintaining a separate SKU with separate labels.</p> <p>FSANZ acknowledges that amending the standard as proposed will introduce significant costs in changes to labels and will result in increased barrier to the entry of new manufacturers into the Australian market.</p> <p>Imposing more restrictive labelling regulations in Australia / NZ than is currently required in Europe and USA will not meet the FSANZ objective of an efficient and internationally competitive food industry. Notes FSANZ has identified that EU and USA regulations do not impose the restriction on minimum age labelling as proposed by Option 2. Consider Option 2 does not promote consistency between domestic and international food standards.</p> <p>Considers this is a barrier to fair trade as any food importer in Australia and NZ would not be able to directly import baby food from these countries without the additional costs of maintaining a separate SKU with separate labels. This will restrict the availability of products onto the Australian / NZ market which are currently produced in Europe or USA with a reference to suitability for infants from 4 months on their labels.</p>	<p>AFGC</p> <p>Nestlé</p> <p>FTAA</p> <p>AFGC</p> <p>Nestlé</p>	<p>See SD2</p>

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<p>Age, stage, 'first foods'</p> <p>Absence of a stage-based approach remains inconsistent with the NZ guidelines. Requests that FSANZ include this approach in its final considerations. Noted NZ infant formula manufacturers and Australian branch support mandatory first stage labelling in addition to age i.e. intended as a first complementary food.</p> <p>Considers information regarding age may be more practical to caregivers than stage in terms of feeding milestone information. More research on how parents interpret food labels and infant feeding recommendations would be good to see.</p> <p>Age and consistency information should both be provided. Stating the consistency allows carers to choose appropriate products based on their child's development.</p>	<p>NZFSA/MoH</p> <p>DAA</p> <p>Victoria DHS</p>	<p>See SD2. FSANZ does not propose to mandate any stage labelling. This will remain a voluntary option for manufacturers.</p>

Issue	Raised by	FSANZ Response
<p><i>'Around 6 months' wording on labels</i></p> <p>Mandating 'around 6 months' creates ambiguity for carers and advisors. 'Around 6 months' is indefinite and less clear for consumers, than '4-6 months'. Also, it is critical that 'around 6 months' is NOT interpreted by jurisdictions to mean that manufacturers cannot provide advice about developmental cues seen younger than 6 months but older than 4 months. Considers the FSANZ proposal implies that manufacturers should be prohibited from providing consumer advice.</p> <p>Notes the ranges of interpretations of the term among health professionals reported by FSANZ. Parents need clear and concise information and queries if health professionals are confused, how are parents expected to make informed choices. Considers labelling of 'around 6 months' and 'not for infants under the age of 4 months' is a complex message. Believes the statement 4-6 months is less confusing and delivers the same message.</p> <p>As there is wide variation as to when infants are ready for solids, the proposed labelling changes would be confusing and counterproductive.</p> <p>The term 'around 6 months' is indefinite and could be interpreted as 4,5,7, or 8 months. Readiness for solids varies and the carer makes a judgment based on many more factors than a label.</p> <p>Notes evidence from Queensland Health CATI study supports FSANZ consumer research and suggests that 'around six months' impacted the age of introduction of solids.</p> <p>'Around 6 months' is silent on context and without qualification. Suggests 'suitable for around 6 months'.</p>	<p>AFGC, FTAA</p> <p>Heinz</p> <p>FTAA</p> <p>SA Health</p> <p>QLD Health, DHS Tasmania</p> <p>NSW FA</p>	<p>See SD2</p>
<p><i>Warning statement</i></p> <p>Considers this needs to be retained to discourage early introduction of solids. Believes using 5 months rather than four months may partially address this problem.</p>	<p>LLL NZ</p>	<p>See SD2</p>

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<p>FSANZ consumer research</p> <p>Research is outdated (2004), has a small sample size and not representative of NZ consumers. Considers FSANZ’s consultation supports a stage approach. The research has been used to justify the ‘age ‘ approach – but considers it supports the NZFSA recommendation that the statement ‘around’ six months be accompanied with wording that it is intended as a first complementary food for an infant. Noted that a key (NZ) child health professional group was supportive of infant food labels including stages to guide health professionals.</p> <p>Would like to see more research in how parents interpret food labels and recommendations for infant feeding.</p>	<p>NZFSA/MoH</p> <p>DAA</p>	<p>See SD2, Attachment 1. SD2 also provides comments on a stage (1st complimentary foods) approach.</p>
<p>Iron declaration - Table 2 to Clause 8</p> <ul style="list-style-type: none"> • Removing the younger RDI for iron could result in iron levels being increased in a first stage food to maintain a claim as a ‘good source’. Concerned about the implications for preterm infants who will have different stage requirements for their age. • Notes that increasing the RDI from 3 to 9 mg for infants from between 4-6 months, where the serve size is 5 g, will significantly increase the risk of regulatory non-compliance for the manufacturer as this will require 49mg/ 100g on a moisture free basis. This will prohibit manufacturers from making a ‘good source’ claim due to difficulties in tolerance. • Impact of retaining one RDI for all infants (9mg per day) is unclear. Using an RDI three times the specified current level for a first food could cause health risks for the infant e.g. constipation and binding of other nutrients. Recommended further scientific study and discussion. • Also notes the NRVs from NHMRC for iron for infants 7-12 months is 11mg per day (RDI). Queries how FSANZ intends to adopt the NRVs for Standard 2.9.2 and how an infant ready for solids around 6 months (but not before 4) will be captured via the new NRVs which begin at 7 months. 	<p>AFGC</p> <p>AFGC</p> <p>Heinz</p> <p>Heinz</p>	<p>See SD2</p> <p>FSANZ is considering the regulatory NRVs as a separate project. It is out of scope of Proposal P274.</p>

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<p><i>Impact on nutritional status</i></p> <p>If complementary foods are introduced at 6 or 7 months, then introduced sequentially over time this could affect nutritional status e.g. meat based foods may be delayed until 9–10 months impacting negatively on iron and zinc intake.</p> <p>This could also affect energy intake, food variety and oral stimulation for language development.</p> <p>Considers the issue has not been addressed for exclusively infant formula fed infants (or fully breastfed infants) in the PFAR.</p>	<p>Heinz</p> <p>NZDA</p> <p>Nestlé</p>	<p>See SD1</p>
<p><i>Transition period</i></p> <p>Requested a 2-year transition period if a change to labelling be required. Does not support a 24-month period and recognises 18 months is a compromise.</p>	<p>Heinz, QLD Health</p>	<p>See SD2 and Section 7 of this Paper.</p>
<p><i>Education</i></p> <p>Considers education through health professionals on a 1-1 basis is a better use of funds.</p> <p>Recommends an education strategy for consumers and health professionals including information about the labelling changes.</p> <p>Suggests it would be more cost effective for the Commonwealth Department of Health and Ageing to produce (or contract out) consumer and health professional information nationally to avoid duplication of resources and effort.</p>	<p>FTAA</p> <p>DHS Tasmania</p>	<p>FSANZ will update any educational material about the Code (e.g. fact sheets). See section 6 of this Paper.</p>

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<p>Drafting</p> <p>Suggests that Clause 6(2) of Standard 2.9.2 is amended to remove the word 'suitable' - for consistency. That is, amend the clause to '<i>not for infants under the age of 6 months</i>'.</p> <p>Concerned that the proposed subclause (5)(a) requires labels to contain the words 'around 6 months' but is silent on context and is without qualification. This will be uninformative and will not assist the purchaser.</p> <p>Suggests the required statement should be 'suitable from around 6 months' or similar.</p> <p>If there is a situation where a food for infants 'around 6 months' contains more than 3 g/ 100 g protein, there may be some confusion over the required statements in Clause 5(5)(b) 'Not for infants under the age of 4 months' and 6(2) ' Not suitable for infants under the age of 6 months'. It would appear reasonable that if clause 6(2) is required then clause 5(5) (b) does not apply.</p> <p>The definition of infant formula in Standard 2.9.1 refers to infants aged <i>up to four to six months</i>. As infant feeding guidelines recommend complementary foods around 6 months it may be appropriate to change to 'up to six months' in the proposed review of Standard 2.9.1.</p>	<p>DHS Tasmania</p> <p>NSWFA</p> <p>DHS Tasmania</p>	<p>See SD2.</p> <p>See Attachment1 for proposed amendments to Standard 2.9.2.</p> <p>To be considered under the Review of Infant Formula project.</p>
<p>Warning statement 'Not recommended for infants under the age of 4 months'</p> <p>Current regulations require the warning statement 'not recommended for infants under the age of four months' to be included on the label of infant food for infants between four and six months. Furthermore, a recommendation on the label (expressed or implied) that an infant food is suitable for infants less than four months of age is not permitted.</p> <p>Submissions to the Preliminary Final Assessment strongly supported the continued inclusion of the requirement for the warning statement on labels. These submissions also supported the proposed removal of the word 'recommended' as a means of simplifying the regulatory requirement.</p>	<p>QLD Health, DHS Victoria, LLL NZ, DHS Tasmania, Heinz, RCH Melbourne</p>	<p>FSANZ is proposing to continue with the requirement for a warning statement, because of available evidence that demonstrates risks with the early introduction of solid foods, and support from submitters.</p> <p>FSANZ has proposed drafting changes to remove the word 'recommended' from the warning statement requirement, because it makes the warning statement more consistent with the available evidence, and stakeholders support this change. To further simplify the statement (to reduce wording while retaining the intent), we are proposing that the required warning statement is shortened to 'not for under four months'.</p>

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<p><i>Statement on consistency and the risk of choking</i></p> <p>Considers the wording of the PFAR is unclear and does not describe the intent of the proposed changes. Suggest this be reworded.</p>	<p>QLD Health, DHS Victoria, LLL NZ, NZFSA, NZDA</p>	<p>All of the submissions commenting on this issue indicated support for the retention of subclause 2(5) in a modified form. FSANZ will therefore continue with the proposed change to this part of Standard 2.9.2.</p> <p>Refer to Attachment 1 – draft variation.</p>
<p><i>Temporary solution</i></p> <p>Regards the PFAR decision as a sensible, pragmatic solution in light of the emerging evidence which may suggest changes in practice in the near future.</p> <p>Labelling standards have generally lagged well behind recommended practice, and a change in the standard may need to be addressed again in the relatively near future.</p> <p>Recommends a more streamlined process for amendments such that Guidelines in both countries and Food Standards are consistent.</p>	<p>RCH Melbourne</p>	<p>The approach proposed in this Consultation Paper remains as at PFAR, with regard to the minimum age labelling permissions.</p>