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Manager  
Application Assessments  
Food Standards Australia New Zealand  
PO Box 10559  
The Terrace  
Wellington 6143  
New Zealand

Email: [submissions@foodstandards.gov.au](mailto:submissions@foodstandards.gov.au)

Dear Sir/Madam

Attached are the comments that the New Zealand Food & Grocery Council wishes to present on the ***Consultation Paper for Proposal P274 – Minimum Age Labelling of Foods for Infants.***

Yours sincerely

Katherine Rich  
**Chief Executive**

**Food Standards Australia New Zealand**  
**PROPOSAL P274 – MINIMUM AGE LABELLING OF FOODS FOR**  
**INFANTS**

**Consultation Paper**

**12 November 2013**

The New Zealand Food & Grocery Council (the “NZFGC”) welcomes the opportunity to make a submission on the *Consultation Paper for Proposal P274 – Minimum Age Labelling of Foods for Infants*.

**New Zealand Food & Grocery Council**

The NZFGC represents the major manufacturers and suppliers of food, beverage and grocery products in New Zealand. Collectively this sector generates over \$28 billion in the New Zealand domestic retail food, beverage and grocery products market and over \$26 billion in export revenue from exports to 183 countries. Food and beverage manufacturing is the largest manufacturing sector in New Zealand representing 46% of total manufacturing income and 34% of all manufacturing salaries and wages.

Food and beverage manufacturing and wholesaling in New Zealand directly employs over 100,000 people (5% total employment) and, when taking the wider food and beverage value chain (including farming and food retailing/foodservice) into account, employment soars to almost 350,000 in over 85,000 enterprises. This represents around one in five people employed in our country.

No matter how you look at it, the New Zealand food, beverage and grocery sector makes a substantial contribution to the New Zealand domestic economy, to our exports and to the general economic well-being of the country.

**Proposal P274**

The NZFGC understands that Proposal P274 covers a wording change for the minimum age labelling on the complementary foods first given to infants by caregivers and compositional changes. NZFGC further understands that several factors have delayed proceeding with this Proposal which was initially raised in 2003. The original request, from the then Australia and New Zealand Food Regulation Ministerial Council, was for a review to address minimum age labelling and inconsistency with Australian Infant Feeding Guidelines and to ‘accommodate’ New Zealand infant feeding guidelines. More recently, work was delayed pending further research. FSANZ is proposing the labelling change such that the youngest minimum age declaration required on a label of an infant food is ‘around 6 months’.

**Executive Summary**

NZFGC considers there is no case for change and that there are compelling arguments to retain the status quo (Option 1). The most significant is that the risk assessment did not reconsider the case for change for labelling other than in relation to allergens. Rather, it covered the research since 2008 (when the last risk assessment was conducted) by way of

background. NZFGC considers such an approach unacceptable. Secondly, fundamental research will conclude over the next two-three years concerning allergies and infant feeding. No change should be made until that research is complete. Thirdly, NZFGC considers that the consumer research undertaken in 2004 and including ten New Zealanders is inadequate for determining the consumer impact of change and therefore benefit. Finally, the regulatory impact statement significantly underestimates the cost for change because of the flow on effects for other infant foods. Data relevant to costs were provided by industry but appears to have been misinterpreted. FSANZ has not demonstrated benefits exceeding costs. NZFGC considers the statement '4-6 months' on a food complemented by a 'first stage food' is 'not inconsistent with' national infant feeding guidelines as reflected in the specific policy principles in the Policy Guideline on Infant Formula Products.

As a result of these matters, NZFGC supports Option 1, status quo.

## Comments

### ***Adequacy of risk assessment***

The subject of the risk assessment (see 1.3 of the FSANZ Supporting Document 1 – SD1) is:

*“What conclusions can be drawn from the evidence on the association between the age of introduction of solid food and the development of food-related allergies and/or gluten intolerance in children?”*

This, on its own, is an appropriate aspect to assess. However, the case for changing the date from '4 to 6 months' to 'around 6 months' has not been reassessed. FSANZ provided a commentary on the research undertaken in this latter area as part of the background but the risk assessment in SD 1 simply sets out a restatement of the FSANZ conclusions from the risk assessment in 2008. That statement is that there are 'no health effects CLEARLY linked with adverse outcomes'. The more cautious position is that taken by European Food Safety Agency (EFSA) and others, that there is evidence to suggest at least some children would be affected if complementary feeding is not undertaken before 6 months. In this situation the statement 'around 6 months' is flawed because it actually does not mean 'later than 6 months'.

Considerable scientific work has been conducted since 2008 on this issue, most notably by the EFSA and the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN). Although the risk assessment purports to have assessed both those reports, the conclusion that “there are no health effects clearly linked with adverse outcomes if solid food is delayed to ‘around 6 months’” does not address the reasons why the EFSA opinion did not recommend moving to 'around 6 months' but rather continued with 4 to 6 months as the period for the introduction of complementary food and why ESPGHAN qualifies its comments on the same issue.

EFSA concluded, in its 2009 *Scientific Opinion on the Appropriate Age for Introduction of Complementary Feeding of Infants*, that “The needs for water, energy, protein, calcium and many other nutrients can be met by exclusive breast-feeding for six months. However, breast milk may not provide sufficient iron and zinc in some infants after the age of 4-6 months, and these infants require complementary foods.”<sup>1</sup> This led to the EFSA recommendation that “Overall, ... the introduction of complementary food into the diet of healthy term infants in the EU between the age of 4 and 6 months is safe and does not pose a risk for adverse health effects”<sup>2</sup>. This does not support 'around 6 months' (with the inference that complementary food can be delayed safely beyond 6 months) based on evidence.

<sup>1</sup> p25 EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), Scientific Opinion on the appropriate age for introduction of complementary feeding of infants (2009)

<sup>2</sup> p4 op sit

ESPGHAN stated in its 2009 *Breast-feeding: A Commentary by the ESPGHAN Committee on Nutrition* that “On the basis of available data, the Committee recently concluded that full or exclusive breast-feeding for around 6 months is a desirable goal. In exclusively or partially breast-fed infants, complementary feeding, such as any solid or liquid food other than breast milk or infant formula and follow-on formula, should not be introduced to the diet of any infant before 17 weeks or delayed after 26 weeks of age...”<sup>3</sup>. Again the ‘goal might be desirable’ but the reality is there is a window of between 17 and 26 weeks within which to introduce complementary feeding. ESPGHAN did not recommend exclusive breast feeding at ‘around 6 months’.

This raises the next issue of the interpretation of ‘around 6 months’. If the window for complementary feeding is 17 weeks to 26 weeks (just after four months to just after 6 months), then ‘around 6 months’ is interpreted differently for the period when complementary feeding might start and the period when such feeding must start. That is before 6 months ‘around’ means 7 weeks but after 6 months it means just 2 weeks. This is very confusing for consumers especially but also for health professionals.

It is also the case that EFSA concluded that “... breast milk may not provide sufficient iron and zinc in some infants after the age of 4-6 months, and these infants require complementary foods.”<sup>4</sup> and that “Consistent with these conclusions, presently available data on the risk of celiac disease and T1DM [type 1 diabetes mellitus] support also the timing of the introduction of gluten containing food (preferably while still breast-feeding) not later than 6 months of age.”<sup>5</sup> The New Zealand Ministry of Health states that: “Stores of iron and zinc are likely to be depleted by six months of age, so iron and zinc must be supplied by complementary food” [NZFGC emphasis]. While the risks of iron and zinc deficiency exist for some infants and reduced risks of coeliac disease suggest complementary feeding no later than 6 months, the more cautious approach for Australia and New Zealand would be to remain with a clear and unambiguous statement that first foods are for infants aged 4 to 6 months.

### **Ongoing research**

NZFGC understands that fundamental research will conclude over the next two-three years concerning the timing of the introduction of complementary feeding and the minimisation of the development of allergies or gluten intolerance in infants and children. For example, two randomised trials are now investigating early introduction of allergenic foods: the US Learning Early About Peanut Allergy (LEAP) study<sup>6</sup> and the UK Enquiring About Tolerance (EAT) trial<sup>7</sup> both due to conclude in July 2014. As well, a systematic review infant energy needs to six months and exclusive breast feeding conducted by Wells and Reilly is now under review.

This research has been ongoing for the immediate past three to four years. FSANZ might consider this would have been considered by the National Health and Medical Research Council of Australia (NHMRC) in publishing its position on the introduction of complementary feeding in 2013 (and prompting the reactivation of P274). However, it is important to note that the literature review used by the NHMRC reviewed no papers after 2010 suggesting the

<sup>3</sup> p114 ESPGHAN Breast-feeding: A Commentary by the ESPGHAN Committee on Nutrition (2009) *Journal of Pediatric Gastroenterology and Nutrition* 49:112–125 # 2009 by European Society for Pediatric Gastroenterology, Hepatology, and Nutrition and North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition

<sup>4</sup> p25 EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), Scientific Opinion on the appropriate age for introduction of complementary feeding of infants (2009)

<sup>5</sup> p27 op sit

<sup>6</sup> Learning Early About Peanut Allergy (LEAP) study <http://clinicaltrials.gov/ct2/show/NCT00329784>

<sup>7</sup> Enquiring About Tolerance (EAT) trial <http://www.controlled-trials.com/ISRCTN14254740>

literature review was conducted in late 2010 or early 2011 even though it was published in 2012. This was before a number of the studies that are currently nearing conclusion (or have recently concluded) had commenced.

NZFGC considers that the prospect of there being benefits in reducing allergies and coeliac disease for at least some infants from complementary feeding between 4 to 6 months justifies a decision to retain the current provisions. Such a position would:

- avoid potentially negative health consequences for some infants
- reduce the prospect of further confusion for consumers (if labelling had to be changed yet again in a few years time) and
- minimise or remove significant costs for manufacturers for labelling changes that might change again in the near future.

### **FSANZ Consumer Research**

The consumer research drawn on by FSANZ to support the case for change in labelling was conducted in 2004. It comprised focus groups totalling 55 caregivers. Of these, only 10 were from New Zealand. The research reflects a small group overall and a very small group in New Zealand and is almost a decade old.

NZFGC considers that the consumer research is inadequate for determining the consumer impact and therefore the risks and benefits of change. It is also inadequate when considering the extent of change in manufacturing terms that is likely to be involved. This is particularly the case for New Zealand.

### **Regulatory Impact Statement**

No regulatory impact statement has been prepared. An impact analysis has been included in SD2. This is insufficient for a change that may have significant impact on caregivers and industry, the former in terms of increased confusion of a vague label and the latter because of cost through re-categorisation and reformulation of products. The suggestion that caregivers might disregard both the labelling and guidelines and make inappropriate and potentially harmful decisions for their infant on the introduction of solid foods could have been empirically tested in either country when the messaging and guidelines have differed.

As well, the costs of change significantly underestimate the costs for industry because of the flow on effects for other infant foods if the entire range of infant foods has to be adjusted. In any event, there is no evidence of consumer perceiving industry as acting irresponsibly and undermining infant feeding recommendations. Had this been the case, industry would have moved to make changes to ensure ongoing confidence since this is an incredibly valuable factor for any branded product. In addition, such 'loss of confidence' could have been empirically tested during the lengthy period of difference between the infant feeding recommendations and labelling infant foods that has been in place.

### **Consistency with the current New Zealand and Australian infant feeding guidelines**

The *Recommended Policy Guideline on the Intent of Part 2.9 - Special Purpose Foods* provides that "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"<sup>8</sup>. The current labelling satisfies this Guideline. It is the only guideline referred to in the FSANZ Risk Management Considerations (SD 2) for P274. There is no mention of consistency with guidelines issued by the Australian or New Zealand governments.

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<sup>8</sup> p2 Australia and New Zealand Ministerial Council on Food Regulation *Recommended Policy Guideline on the Intent of Part 2.9 - Special Purpose Foods*

However, in the *Policy Guideline on the Regulation of Infant Formula Products*, a specific policy principle reads that “The regulation of infant formula products should not be inconsistent with the national nutrition policies and guidelines of Australia and New Zealand that are relevant to infant feeding.”<sup>9</sup> This principle accommodates, amongst other things, the inconsistencies that exist from time to time between New Zealand and Australian guidelines.

NZFGC contends that the current labelling provisions satisfy the requirements of both Ministerial guidelines. In the case of the *Policy Guideline on the Regulation of Infant Formula Products* are ‘not inconsistent’ with those guidelines in that the current provisions refer to 6 months and reflect the warning statement of not before 4 months. They are much clearer for consumers and manufacturers and obviate the need for additional explanation for what FSANZ admits is a ‘deliberately vague’ term.<sup>10</sup>

### **Legislative confusion**

The drafting proposes that wording in clause 3(1) of Standard 2.9.2 be amended where this refers to ‘6 months’. Instead of the legally clear and enforceable statement ‘is promoted as suitable for infants over the age of 6 months’ the proposed replacement is a confusing and legally obscure statement ‘is claimed to be suitable for infants over the age of around 6 months’. No explanation of what ‘over the age of around 6 months’ actually means is given.

### **World Trade Organization (WTO)**

FSANZ suggests that making the labelling changes for infant foods is not expected to have a significant effect on international trade and that in any case this is a change to an existing requirement and is not notified. New Zealand has generally notified changes to existing requirements but in any case, the compositional change has not been mentioned. This change could be considered a change to be notified under the Sanitary and Phytosanitary (SPS) Agreement and may well present as a barrier to change. In any event, New Zealand manufacturers are required to meet the compositional requirements of the Food Standards Code for exported product and this change brings with it costs for exports.

### **Questions for submitters**

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

NZFGC considers that if the term ‘around 6 months’ is so vague as to require a legislative definition for manufacturers to interpret then the rationale for the concept and definition of ‘first food’ is flawed. As well, since the definition is developed to clarify the term for manufacturers, there is little hope that consumers will understand and interpret the term. This is confirmed by the FSANZ limited research that indicated that “*caregivers did value age and consistency information, particularly for deciding when to move from one stage of solids to the next.*”<sup>11</sup>

Industry currently uses a range terms including ‘first food’ for the infant foods intended as the first complementary food for infants. If the definition proceeds, there may be difficulty in the sequencing of foods for the growing infant. Some manufacturers refer to ‘first foods’ for infants aged 4-6 months and to second foods as 6-7 or 8 months. The term ‘around 6 months’ simply does not deliver on this categorisation for either manufacturers or consumers. As well, foods for infants aged 4-6 months are not ‘weaning’ foods. They are complementary foods that deliver a range of nutrients but particularly iron and zinc which are minerals that breast milk may not be delivering adequate supplies of to the infant.

<sup>9</sup> p2 Australia and New Zealand Ministerial Council on Food Regulation *Policy Guideline on the Regulation of Infant Formula Products*

<sup>10</sup> p14 FSANZ P274 Proposal, SD2

<sup>11</sup> p39 op sit



*2. Is the definition of 'first food' enforceable*

If texture requirements are considered in conjunction with the definition of "first food", then NZFGC considers a definition as proposed is enforceable. Food texture linked to choking hazard is the principal consideration for industry with respect to age and staging of foods. This is currently reflected in Standard 2.9.2 of the Food Standards Code, clause 2(5) which states that "Food for infants intended for infants under the age of 6 months must be formulated and manufactured to a consistency that minimises the risk of choking". This has been an efficient and effective provision to date and NZFGC therefore does not support for specifically prescribing texture/sensory aspects (i.e. *soft and smooth*) of the infant food.

*3. 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.*

The use of the age/number 6 should not be prohibited. As noted above, infant foods intended to follow initial complementary foods also use the number 6 when referring to an age group of 6-8 months, from 6 months or 6+ months. Such products are very suitable from 6 months of age but not before. Again, the full range of complementary foods would be impacted by such a change.

*4. Do the changes to the wording of the warning statements change the intent of these statements? If so, please explain why.*

NZFGC considers the changes to the warning statements do not change the intent of the statements. However, the current provisions are likely to be more complete in terms of understanding by consumers than the proposed wording.

*5. 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.*

NZFGC considers that the 'not before 4 months of age' statement should apply to food represented for infants 'around 6 months' of age only. Foods staged or categorised for growing infants are clearly identified for such infants and there appears to be no evidence of consumer confusion on this point.

*6. 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?*

NZFGC considers that display on the front of the product provides a useful context for minimum age but since directions for use are on the back of the pack, there is no risk of caregivers missing the information.

*7. 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?*

See above.

### **Compositional requirements**

It is proposed that a textural/sensory description be applied to the definition of foods for infants of 'around 6 months'. NZFGC does not support this change as noted above and considers it unnecessary. This is also a change that potentially has significant regulatory impact yet the change is not addressed in SD 2 in the section on impact. This compositional change has not been emphasised in the consultation document which is described as relevant to labelling.

### **Conclusion**

NZFGC does not consider evidence is presented to support the proposed change in current labelling provisions that provide for first complementary foods to be labelled as 'suitable for 4-6 months' and replace this with 'around 6 months'. The risk assessment has not updated



the assessment of this change since 2008. A full regulatory impact statement has not been provided and the cost benefit analysis omits addressing a range of issues including the proposed compositional change. The 2004 consumer research is almost a decade old and involved only 10 New Zealanders.

As a result, NZFGC supports Option 1, status quo.

## References

Australia and New Zealand Food Regulation Ministerial Council. *Policy Guideline on the Regulation of Infant Formula Products* [n.d].

Australia and New Zealand Food Regulation Ministerial Council. *Recommended Policy Guideline on the Intent of Part 2.9 - Special Purpose Foods* [n.d].

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). "Scientific Opinion on the appropriate age for introduction of complementary feeding of infants". *EFSA Journal* 2009; 7(12): 1423 [38 pp.] doi:10.2903/j.efsa.2009.1423.

European Society for Pediatric Gastroenterology, Hepatology, and Nutrition and North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition. "Breast-feeding: A Commentary by the ESPGHAN Committee on Nutrition". *Journal of Pediatric Gastroenterology and Nutrition* 2009, 49:112–125