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16 July 2003

INITIAL ASSESSMENT REPORT

PROPOSAL P274

REVIEW OF MINIMUM AGE LABELLING OF FOODS FOR INFANTS

DEADLINE FOR PUBLIC SUBMISSIONS to FSANZ in relation to this matter:
27 August 2003
(See 'Invitation for Public Submissions' for details)

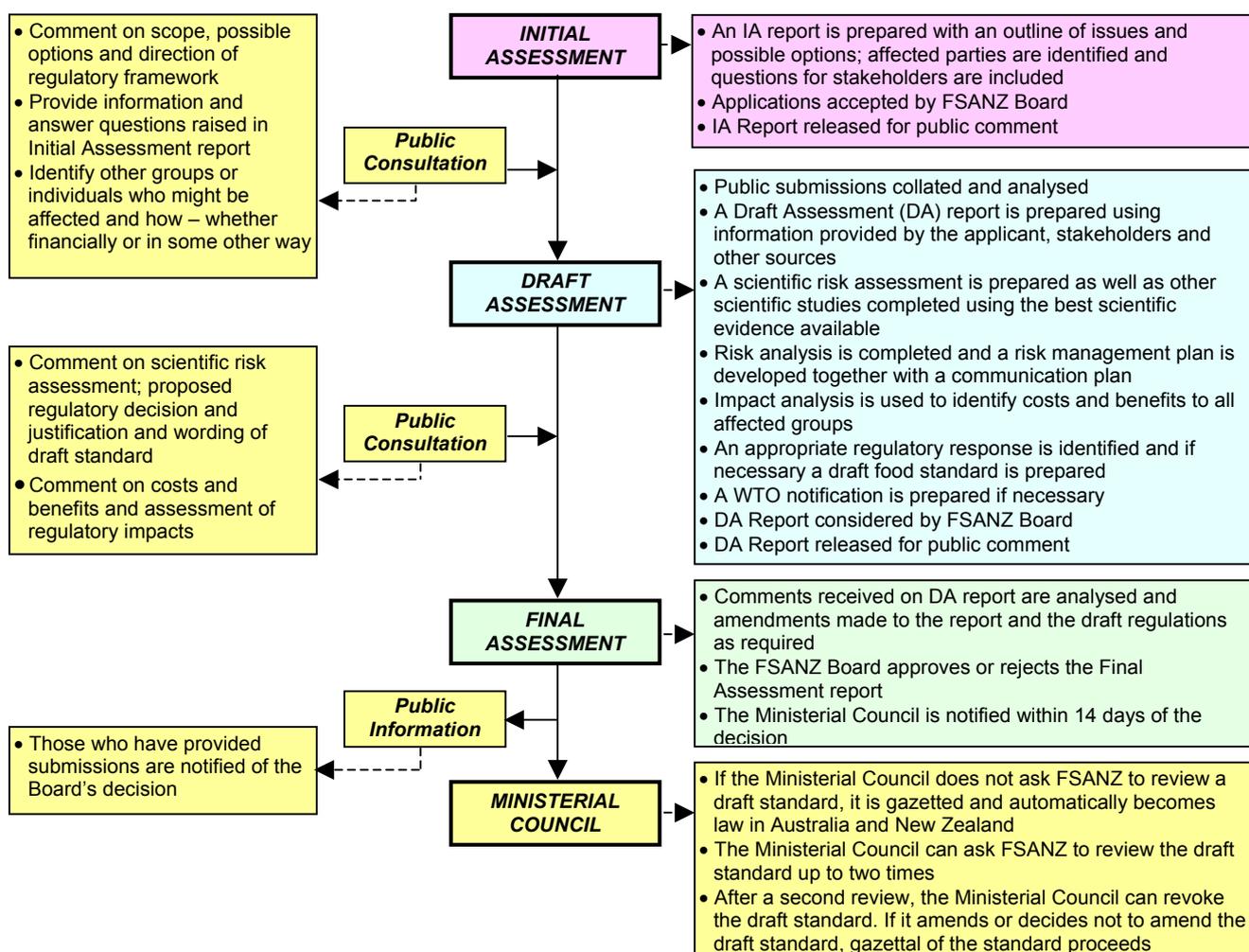
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Commonwealth; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Commonwealth, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Commonwealth, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared an Initial Assessment Report of Proposal P274 – Review of Minimum Age Labelling of Foods for Infants, which includes the identification and discussion of the key issues.

FSANZ invites public comment on this Initial Assessment Report for the purpose of preparing an amendment to the *Australia New Zealand Food Standards Code* for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist the FSANZ in preparing the Draft Assessment for this proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). Information providing details of potential costs and benefits of the proposed change to the *Australia New Zealand Food Standards Code* from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word ‘Submission’ and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions should be received by FSANZ **by 27 August 2003**. Submissions received after this date may not be considered, unless the Project Manager has given prior agreement for an extension. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the [Standards Development](#) tab and then through [Documents for Public Comment](#). Questions relating to making submissions or the application process can be directed to the Standards Liaison Officer at the above address or by emailing slo@foodstandards.gov.au.

Further Information

Further information on this Application / Proposal and the assessment process should be addressed to the FSANZ Standards Liaison Officer at one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
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Assessment reports are available for viewing and downloading from the FSANZ website www.foodstandards.gov.au or alternatively paper copies of reports can be requested from FSANZ's Information Officer at info@foodstandards.gov.au including other general enquiries and requests for information.

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Executive Summary

The purpose of this Proposal is to review the minimum age labelling of infant foods as required by Standard 2.9.2 – Foods for Infants of the *Australia New Zealand Food Standards Code* (the Code). This Initial Assessment therefore raises issues on the minimum age labelling of infant foods and discusses possible regulatory options.

FSANZ seeks comments on this Initial Assessment, particularly in relation to the expected impact(s) of the proposed regulatory options, from all interested parties. Comments received will assist in the preparation of a Draft Assessment, including a preferred regulatory approach to the minimum age labelling of infant foods.

Regulatory Problem

While the minimum age labelling required by Standard 2.9.2, ‘from 4 months’, is consistent with current New Zealand infant feeding guidelines, it is however, no longer considered consistent with revised guidelines in Australia. The revised Australian guidelines recommend the introduction of solid foods at around six months of age. This situation has the potential to create confusion for consumers (i.e. parents/carers), particularly in Australia, as the labelling of infant foods will conflict with the recommended timing of the introduction of solids to infants.

Objectives

The specific objectives of this Proposal are that the regulatory requirements for minimum age labelling of foods for infants:

- protect the health and safety of infants;
- provide adequate information for parents/carers to make appropriate choices for infant feeding;
- are consistent with infant feeding guidelines in Australia and New Zealand; and
- are based on the best available scientific evidence.

Regulatory Options

At Initial Assessment, two regulatory options have been identified:

- maintaining the current minimum age labelling requirements (Option 1);
- amending Standard 2.9.2 to better reflect Australian and New Zealand infant feeding guidelines, and provide sufficient guidance for parent/carers to make appropriate choices in infant feeding by either: raising the minimum reference age above four months (Option 2A); or replacing the reference to ‘age’ with an alternate scheme (Option 2B) that recognises developmental milestones in relation to infant feeding.

Impact Analysis

FSANZ is required to assess the relative impact of each of the proposed options on the identified parties. This Initial Assessment discusses potential costs and benefits of the proposed options and invites comments, particularly in response, but not restricted to, the series of boxed questions in Sections 5 and 7 of this report.

1. Introduction

The purpose of this Proposal is to review the minimum age labelling of infant foods as required by Standard 2.9.2 – Foods for Infants of the *Australia New Zealand Food Standards Code* (the Code).

In April 2003, the Australia and New Zealand Food Regulation Ministerial Council (the Ministerial Council) requested Food Standards Australia New Zealand (FSANZ) to review the minimum age labelling requirements for infant foods, to resolve an apparent inconsistency with the revised Australian National Health and Medical Research Council (NHMRC) *Dietary Guidelines for Children and Adolescents* (incorporating *Infant Feeding Guidelines for Health Workers*), released in June 2003. In addition Ministers asked that a review of minimum age labelling also consider and accommodate New Zealand infant feeding guidelines.

This Initial Assessment raises issues on the minimum age labelling of infant foods and discusses proposed regulatory options. FSANZ seeks comments on this Initial Assessment, particularly in relation to the expected impact(s) of the proposed regulatory options from all interested parties. Comments received will assist in the preparation of a Draft Assessment, including a preferred regulatory approach, on the minimum age labelling of infant foods.

2. Background

2.1 Infant Feeding Recommendations

2.1.1 International

In March 2001, the World Health Organization (WHO) conducted an expert consultation on the optimal duration of exclusive breastfeeding¹. The outcome of this consultation was a recommendation, applying to populations, of *exclusive breastfeeding for 6 months, with introduction of complementary foods and continued breastfeeding thereafter*. This revised WHO's previous recommendation of exclusive breastfeeding for the first four to six months of life². Subsequently, the Fifty-fourth World Health Assembly (WHA) in May 2001 adopted a comprehensive resolution³ on infant and young child feeding, which called on WHO Member States (including Australia and New Zealand):

to strengthen activities and develop new approaches to protect, promote and support exclusive breastfeeding for six months as a global public health recommendation, taking into account the findings of the WHO expert consultation on the optimal duration of exclusive breastfeeding, and to provide safe and appropriate complementary foods, with continued breastfeeding, for up to two years of age or beyond, emphasizing channels of social dissemination of these concepts in order to lead communities to adhere to these practices.

¹ World Health Organization (2002) The Optimal Duration of Exclusive Breastfeeding - Report of an Expert Consultation, Geneva, Switzerland, 28-30 March 2001

² WHO Infant Feeding Recommendation. Wkly Epidemiol Rec. 1995; 70:119-120

³ WHA 54.2 Infant and Young Child Nutrition

2.1.2 Australia

The recently revised NHMRC *Dietary Guidelines for Children and Adolescents* (incorporating *Infant Feeding Guidelines for Health Workers*)⁴ reflect the WHO recommendations. The Guidelines recommend exclusive breastfeeding for the first six months of life and introduction of solid foods at around six months, to meet the infant's increasing nutritional and developmental needs. In recognising the requirements of individual infants, the revised guidelines also state *infants' needs differ, and a small number may benefit from the introduction of solids before the age of six months, but not before four months*. Previously, NHMRC recommendations⁵ encouraged breastfeeding for the first four to six months of life and introduction of solids thereafter.

2.1.3 New Zealand

Currently the New Zealand *Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2 years)*⁶ recognise that breast milk is the ideal food for infants. The guidelines recommend infants be fed exclusively on breast milk from birth to four-six months of age and preferably until at least 12 months, with appropriate complementary solid foods being introduced at around four-six months. The guidelines state that weaning⁷ should occur when an infant is at the appropriate stage of development and nutritional need, which will vary between individuals, although it is also noted that infants should not have solid food before four months. FSANZ has been advised that there are no plans to review New Zealand's infant feeding guidelines in the foreseeable future.

2.1.4 Other International Recommendations

Current recommendations in the United Kingdom⁸, Canada⁹ and the United States of America¹⁰ are, in general, similar to New Zealand and Australia's previous recommendations, i.e. that women be encouraged to exclusively breast feed, preferably for four to six months, and are discouraged from introducing solid foods before four months of age.

2.2 Current Regulation of Minimum Age Labelling

2.2.1 Australia and New Zealand

Standard 2.9.2 – Foods for Infants of the Code provides the compositional and labelling requirements of foods intended and/or represented for use as foods for infants, excluding infant formula products which are regulated by Standard 2.9.1 – Infant Formula Products.

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

⁵ NHMRC Dietary Guidelines for Children and Adolescents (1995)

⁶ New Zealand Ministry of Health, Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2): A Background Paper. (1999)

⁷ In this case 'weaning' means the phase during which the infant changes from a purely liquid diet of breast milk or infant formula (or both) to one which contains all the varied foods typical of that family.

⁸ Weaning and weaning diets; Committee on Medical Aspects of Food and Nutrition Policy (1994)

⁹ Canadian Paediatric Society, Dietitians of Canada and Health Canada. Nutrition for Healthy Term Infants. Minister of Public Works and Government Service. Ottawa, 1998

¹⁰ Good Nutrition for the Highchair Set; www.cfsan.fda.gov/~dms/wh-hichr

An infant is defined as a person up to the age of 12 months. In relation to minimum age labelling, Clause 5(3) of Standard 2.9.2 requires the label of an infant food to contain:

- a statement indicating the consistency of the food and the minimum age, expressed in numbers, of the infants for whom the food is recommended, and
- where the food is recommended for infants between the age of 4-6 months, in association with the statement required above the words – *‘Not recommended for infants under the age of 4 months’*.

In addition the label of an infant food must not include a recommendation, express or implied, that the food is suitable for infants less than four months old (Clause 5(2)).

2.2.2 International Regulations

2.2.2.1 Codex Alimentarius

Codex standards exist for Processed Cereal-Based Foods for Infants and Children (CODEX STAN 74-1981) and Canned Baby Foods (CODEX STAN 73-1981). Neither standard provides guidance on the minimum age labelling of infant foods, although the Codex standard for cereal-based foods is currently under revision (at step 3) and the proposed scope of this draft revised standard is yet to be agreed upon. However, in recognition of the aforementioned WHO recommendation, current drafting¹¹ does refer to foods being intended for infants *generally from the age of 6 months onwards*.

2.2.2.2 European Commission (EC)

The EC Directive on processed cereal-based foods and baby foods for infants and young children (96/5/EC) requires the mandatory labelling of infant food with:

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 four months for any product.

2.2.2.3 United States of America (US)

The *Code Of Federal Regulations* 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).

2.2.2.4 Canada

Division 25 of the Canadian *Food and Drug Regulations* 1954 sets out the requirements for infant foods and allows the naming of foods to reflect their consistency using the following terms:

¹¹ Report of the 24th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (ALINORM 03/26A APPENDIX III)

- “strained” meaning the named food where it is of a generally uniform particle size that does not require and does not encourage chewing by infants before being swallowed; and
- “junior” meaning the named food where it contains particles of a size to encourage chewing by infants, but may be readily swallowed by infants without chewing.

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 six months of age (B25.061 (1)).

2.3 Current Infant Food Market

There are three major manufacturers of infant foods in Australia and New Zealand. Currently manufacturers label their products with the minimum age for whom the food is recommended in accordance with Standard 2.9.2 of the Code. The ages chosen by manufacturers are four months, six months and either eight or nine months depending on the manufacturer. In addition, all these manufacturers uniformly use a colour code of blue, red and green respectively, to differentiate products corresponding to these reference ages. Historically, parents have relied on this colour-coding in addition to the minimum age reference in making appropriate infant food choices.

2.4 Previous Consideration of Minimum Age Labelling

The age suitability of infant foods was considered in Proposal P215 – Foods for Infants and Young Children as part of the development of joint Australian and New Zealand food standards. The Draft Assessment Report (October 1999) notes the current Australian and New Zealand recommendations to introduce solids from four to six months of age and states that this ‘age’ will be used as a reference age for label statements about the suitability of the food. In addition to assist carers with low literacy skills, the reference age was proposed to be in a numerical form.

This approach was maintained at Final Assessment (April 2000) on the basis that:

- it reflected WHO recommendations and current infant feeding policy in both Australia and New Zealand; and
- was consistent with the then current food labelling provisions in both Australia and New Zealand, and with Codex standards.

In addition, to address concerns raised on the health risks associated with early feeding of solids i.e. before four months of age, it was proposed to include, in association with the age suitability reference, the labelling statement, ‘not recommended for infants under four months of age’ for those infant foods targeted at four, five and six month old infants.

3. Regulatory Problem

While the minimum age labelling required by Standard 2.9.2 is consistent with current New Zealand infant feeding guidelines, it is however, no longer considered consistent with revised recommendations in Australia. Similarly, the labelling may be inconsistent with WHO recommendations on exclusive breast-feeding. This situation has the potential to create confusion for consumers (i.e. parents/carers), particularly in Australia, as the labelling of infant foods will conflict with the recommended timing of the introduction of solids to infants.

4. Objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives that are set out in section 10 of the *Food Standards Australia New Zealand Act 1991*. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In addition, FSANZ must also have regard to the following:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

The specific objectives of this Proposal are that the regulatory requirements for minimum age labelling of foods for infants:

- protect the health and safety of infants;
- provide adequate information for parents/carers to make appropriate choices for infant feeding;
- are consistent with infant feeding guidelines in Australia and New Zealand; and
- are based on the best available scientific evidence.

5. Relevant Issues

5.1 The Transition to Solid Foods

The timing of transition from a purely liquid (breast milk or infant formula) diet to one that includes a range of other (solid) foods varies between infants and is dependent on achievement of developmental milestones which indicate that an infant is 'ready' for solid foods. At around six months of age there are increased nutritional needs when breast milk or infant formula alone can no longer meet the nutritional requirements of infants.

There are also risks associated with both the early and late introduction of solid foods to an infant's diet. Therefore the appropriate timing of the introduction of solids is an important factor affecting the health and development of an infant.

A recent Australian study¹² found that the majority of mothers did follow the then recommended timing of introduction of solids (i.e. four – six months) as the mean age for introduction of solids was 4.3 months. In this study, the groups most likely to introduce solids before four months were very young mothers, first-time mothers and mothers speaking languages other than English. Another earlier study showed that forty percent of infants under four months of age were having solid foods and the majority of these were not being breastfed¹³. A more recent paper¹⁴ reports that the majority of infants (61.5%) have solid foods by the age of 26 weeks.

In New Zealand it is estimated that up to half of infants start solid foods before six months of age, and that Pacific Island and Maori peoples are more likely than other New Zealanders to introduce solids before 26 weeks.¹⁵

5.2 Inconsistency Of Infant Food Labelling with WHO, Australian and New Zealand Infant Feeding Guidelines

The revised NHMRC *Dietary Guidelines for Children and Adolescents* (incorporating *Infant Feeding Guidelines for Health Workers*) have updated previous recommendations on the introduction of solids and now recommend exclusive breast-feeding to six months of age, which reflects the WHO recommendation, and introduction of solids at around six months. However the Guidelines also state that:

Although exclusive breast-feeding 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 recommendation¹⁶.

Currently the New Zealand *Food and Nutrition Guidelines for Healthy Infants and Toddlers (0-2 years)* recommend that, depending on the stage of physiological development of individuals, it is appropriate that infants are given solid foods from between four and six months of age. The change in Australian guidelines means that there is a potential inconsistency between the recommendations of the two countries.

The New Zealand Government has indicated that it is not intending to review its recommendations in the near future. They also note that while exclusively breast fed infants may not require solids until six months of age there is not the data to support this as being the appropriate recommendation for partially breast-fed or formula fed infants.

¹² Graham VA, Gibbons K, Marraffa C, Henry L, Myers J. Filling the gap: weaning practices of children aged 0–2 years in western metropolitan Melbourne. *J Paediatr Ch Hlth* 1998; 34(6): 513–17.

¹³ Retallack SJ, Simmer K, Gibson RA. Infant weaning practices in Adelaide: the results of a shopping complex survey. *J Paediatr Ch Hlth* 1994; 30(1): 28–32.

¹⁴ Donath SM, Amir LH. The introduction of breast milk substitutes and solid foods: evidence from the 1995 National Health Survey. *Aust NZ J Public Health* 2002; 26(5): 481-484

¹⁵ New Zealand Ministry of Health, Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2): A Background Paper. (1999).

¹⁶ NHMRC Dietary Guidelines for Children and Adolescents (incorporating Infant Feeding Guidelines for Health Workers) (2002), page 48

5.3 Consistency and Texture of Infant Foods

Manufacturers produce foods of different textures in order to meet the changing requirements of infants as they grow. The co-ordination of swallowing movements that are required to deal with semi-solid foods are not achieved until between four and six months of age. Infant foods labelled as suitable ‘from 4 months’ are a smooth pureed texture with no lumps. At around five-six months of age infants begin to develop teeth and their feeding behaviour changes from sucking to biting and chewing. The texture of infant food changes when labelled ‘from 6 months’ to being a smooth puree with soft pieces included encouraging the acts of biting and chewing. From about nine months molar teeth have started to erupt and infants are able to grind their teeth and can chew soft lumpy textures. As they are also able to sit unsupported and their fine motor co-ordination is developing, self-feeding is encouraged. Infant foods labelled suitable for over nine month olds are of a soft texture but include chunks to meet changing developmental requirements.

Currently in Australia and New Zealand an ‘age’ reference is used to distinguish these different textures of infant foods. Internationally there are other approaches used to label for the consistency of infant foods, namely ‘stage’ and ‘phase’. A leading infant food company in the US use a ‘stages’ approach to labelling according to developmental signs of eating readiness with no mention of age¹⁷ e.g. 1st Foods, 2nd Foods etc. The use of ‘phases’ or ‘steps’ appears to combine developmental timing (beginner/starter) with age references (from six months, from 8-9 months). This approach appears to be used predominantly where legislation does not permit labelling of infant food as suitable for use in infants under the age of six months eg. Canada.

5.4 Role of Labelling in Consumer Education

Traditionally infant food manufacturers have labelled infant foods to indicate the suitability of their products for different infant ages including colour coding. Parents/carers rely on this information to choose products suitable for their infant. In addition parents/carers also receive information and advice on infant feeding from health professionals e.g. doctors, maternal and child health nurses, dietitians and nutritionists.

Current regulations do not allow the label on an infant food to include a recommendation, express or implied, that it is suitable for infants less than four months. Infant foods that are recommended for infants between four and six months require the statement *not recommended for infants under the age of four months* to be included on the label. The purpose of these labelling requirements is to discourage the early introduction of solid foods to infants.

It could be argued that, on the basis of revised guidelines, having infant foods labelled ‘from 4 months’ encourages consumers to perhaps inappropriately start their child on solid foods at four months, when they may not be ready developmentally. Conversely, a change to labelling could provide less information and thereby not indicate to parents that four to six months may be an appropriate time for some infants to be given solid foods.

¹⁷ The Gerber Feeding Plan, www.gerber.com

In considering the issues presented in this Initial Assessment, submitters are particularly encouraged to comment on the following questions:

Do you consider that there is inconsistency between the infant feeding guidelines of Australia and New Zealand, particularly in the context of the WHO recommendations?

Is 'age' an appropriate benchmark for indicating the suitability of foods for the differing developmental milestones of infants?

Should minimum age labelling of infant foods accommodate the individual variation of infants i.e. between 4 – 6 months?

Do you consider that another classification scheme, such as phases or stages, could provide sufficient guidance for consumers to make informed choices about the appropriateness of a food for their infant?

If there were a change in the current approach to minimum age labelling, is it likely that the risks to infants associated with either the early or late introduction of solid foods would change?

What should be the role of infant food labelling in educating parents/carers about the appropriate timing of introduction of solid foods?

6. Regulatory Options

At Initial Assessment, two possible regulatory options have been identified, namely:

Option 1 – Maintain Status Quo

This option would mean that the current minimum age labelling requirements would be maintained. Consequently, infant foods would continue to require labelling using an 'age' reference such as 'from 4 months'.

Option 2 – Amend the minimum age labelling requirements in Standard 2.9.2 by either: raising the minimum reference age (Option 2A); or replacing the reference to 'age' with an alternate scheme e.g. phases or stages (Option 2B).

Under this option, the current minimum age labelling requirements in Standard 2.9.2 would be amended, in addition to other consequential amendments, to better reflect Australian and New Zealand infant feeding guidelines, and provide sufficient information to parent/carers on the timing and consistency of infant foods to allow them to make appropriate choices.

Submitters are particularly encouraged to comment on the following question:

Are there other possible options that should be considered at Draft Assessment?
If so – please provide details and information on the costs and benefits associated with the option/s.

7. Impact Analysis

7.1 Affected Parties

The parties affected by the options outlined above can be broadly divided into three groups, namely:

- consumers/community particularly the parents/ carers of infants who rely on food labels to provide sufficient information to make informed choices in feeding their infants;
- the governments of New Zealand, the States and Territories and the Commonwealth of Australia including enforcement agencies and the health sector; and
- the manufacturers and/or importers of infant food who supply the Australian and New Zealand market.

7.2 Impact Analysis

FSANZ is required to assess the relative impact of each of the proposed options on the identified parties as discussed above. The regulatory impact assessment is conducted to identify and evaluate the advantages of regulation, particularly in meeting the objectives of this Proposal. In conducting this Initial Assessment, FSANZ invites submitters to provide details of potential costs and benefits of the proposed options and invites comments of those costs and benefits as identified below:

7.2.1 Consumers/Community

By maintaining the current approach to labelling consumers will continue to receive information on the suitability of infant food products. However, current labelling could genuinely confuse parents/carers who receive advice from health professionals based on infant feeding recommendations of introduction of solids ‘around six 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, parents/carers who are most influenced by the labelling on infant foods (e.g. ‘from 4 months’) when making a decision to introduce foods to their infants may prematurely commence their infant on solids at four months. Again in this situation infant health may be compromised.

If labelling was changed as proposed in Option 2, parents/carers will continue to be provided with information on the suitability of infant food products but in a manner that is likely to be more consistent with, and will therefore reinforce, infant feeding recommendations in both Australia and New Zealand.

However, if labelling is changed as per Option 2A, where the permitted minimum age is increased consistent with infant feeding recommendations, infant foods that previously were presented as suitable for two different ‘stages’ (‘from 4 months’ and ‘from 6 months’) may be less easily differentiated which may mean that it is harder for consumers to make appropriate choices.

Additionally, with any new labelling there may need to be education provided on what the new labels mean. For example, if a ‘stage’ or ‘phase’ approach was implemented (Option 2B), parents/carers may be required to gain a higher level of knowledge of the physiological and developmental changes of their child, and the corresponding changes in food requirements than what historically was expected with an ‘age’ based label. This may be difficult for some parents/carers, for example those with poor literacy skills, and consequently this lack of understanding may mean that infants are fed inappropriately.

7.2.2 Industry

Under Option 2, industry is likely to incur significant costs in implementing a new approach to minimum age labelling, perhaps more so for Option 2B. There may also be costs for industry associated with the education of consumers on any new labelling. However, as industry is already receiving feedback from consumers and health professionals that current labelling is inconsistent with WHO recommendations, there are risks to industry in maintaining the status quo (Option 1). Consumers may perceive no change to labelling as industry acting irresponsibly and undermining infant feeding recommendations. This may lead consumers to lack confidence in manufacturers and distrust their products, and consequently choose not to purchase them.

7.2.3 Government

There are possible risks associated with Option 1 for government, particularly in Australia, as maintaining current labelling may contradict the government’s education efforts on infant feeding recommendations and thereby reduce the desired public health gain resulting from the implementation of the infant feeding guidelines. A change to the labelling of infant foods, particularly Option 2B, will require an education strategy to ensure parents/carers understand the meaning of the new labelling, particularly in the context of infant feeding guidelines. The prime responsibility for and cost of this education is likely to fall to government.

Submitters are particularly encouraged to comment on the following questions:

Do you agree with the identified costs and benefits as outlined above?

Which is your preferred regulatory option and why?

How would the costs and/or benefits change under the other proposed regulatory option/s?

Please provide quantitative/qualitative data, where possible, to support your response.

8. Consultation

8.1 Public Consultation

This Initial Assessment Report has been released for public consultation. The views of submitters will assist in the development of the Draft Assessment and a preferred regulatory approach on the minimum age labelling of infant foods. Further public comment will be sought on the Draft Assessment, including any proposed draft variation/s to the Code.

8.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are relevant international standards and amending the minimum age labelling requirements for infant foods is unlikely to have a significant effect on international trade as currently the vast majority of infant foods are locally manufactured. However, this issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia and New Zealand's obligations under the WTO Technical Barrier to Trade (TBT) Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.