FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

6 June 2008
[10-08]

PROPOSAL P1006

REMOVE COMMENCEMENT PROVISION FOR CERTAIN SPECIAL PURPOSE INFANT FORMULA INITIAL CONSIDERATION REPORT

Executive Summary

The purpose of this Proposal is to seek a variation to Standard 2.9.1 – Infant Formula Products of the *Australia New Zealand Food Standards Code* (the Code) to remove a commencement provision relating to certain special purpose infant formula[1].

It has recently been brought to FSANZ's attention that the commencement of the operation of subclause 27(2) of Standard 2.9.1 on 20 June 2007, and the conditions that it applies may adversely constrain manufacturers in formulating infant formula products for particular metabolic, immunological, renal, hepatic and malabsorptive conditions. Manufacturers who are currently formulating these types of special purpose infant formula may technically be in breach of the Code and open to enforcement action.

This situation creates uncertainty for:

- the infant formula industry in continuing to formulate and supply these special purpose infant formula products within Australia and New Zealand;
- infants with medical conditions who may be solely reliant on these infant formula products to meet their particular nutritional requirements; and
- State/Territory and New Zealand Government agencies responsible for enforcing the Code.

There is a significant risk to the public health and safety of a very vulnerable population group i.e. infants with medical conditions, should infant formula manufacturers be hindered in the supply of these special purpose infant formula products.

[1] 'special purpose infant formula' in this Report means 'infant formula products specifically formulated to satisfy particular metabolic, immunological, renal, hepatic and malabsorptive conditions.

Given the concern that this commencement provision may unintentionally jeopardise the availability and supply of certain special purpose infant formula to infants with particular medical conditions, Food Standards Australia New Zealand (FSANZ) has for public health and safety reasons decided, pursuant to section 95 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), to declare this Proposal urgent (see Attachment 1) and to seek an emergency amendment to the Code (see Attachment 2).

The specific objectives of this Proposal are to seek the removal of a commencement provision in clause 27 of Standard 2.9.1 so as to:

- protect the public health and safety of infants with specific medical conditions who rely on special purpose infant formula products to meet their particular nutritional requirements; and

- ensure infant formula manufacturers are not unduly hindered in the formulation and supply of special purpose infant formula.

The following two regulatory options are available for this Proposal:

Option 1 do nothing; or

Option 2 amend Clause 27 of Standard 2.9.1 to remove the commencement provision (subclause 27(3) and a consequent removal of subclause 27(2)) thereby restoring the previous *status quo* approach to permitting infant formulas to be specifically formulated to satisfy particular metabolic, immunological, renal, hepatic and malabsorptive conditions.

So as to not jeopardise the availability and supply of special purpose infant formula in Australia and New Zealand, FSANZ is of the view that Option 1 i.e. do nothing is not acceptable. Therefore in the interest of protecting the public health and safety of infants with particular medical conditions, FSANZ's preferred approach is Option 2.

Preferred Approach

To amend Clause 27 of Standard 2.9.1 – Infants Formula Products to remove the commencement provision (subclause 27(3) and a consequent removal of subclause 27(2) thereby restoring the previous *status quo* approach to permitting infant formulas to be specifically formulated to satisfy particular metabolic, immunological, renal, hepatic and malabsorptive conditions.

Reasons for Preferred Approach

FSANZ is proposing to amend clause 27 of Standard 2.9.1 (see Attachment 2) as initial consideration indicates it will provide net benefits to all affected parties. This is because the proposed amendments:

- provide certainty for consumers, industry and enforcement agencies on the regulatory status of special purpose infant formula; and

- protects the public health and safety of infants with particular nutritional requirements by ensuring that the availability and supply of special purpose infant formulas in Australia and New Zealand is not unduly hindered.

The proposed variation will come into effect upon gazettal.

Consultation

FSANZ is seeking public comment in order to assist in assessing this Proposal. Such comments could cover:

- any information relevant to the Proposal;
- parties that might be affected having this Proposal approved or rejected; and
- potential costs and benefits to the identified affected parties.

Under section 95 of the FSANZ Act, FSANZ has declared this Proposal as urgent (see Attachment 1) and will now conduct six business days of consultation with stakeholders. As June 9 2008 is a public holiday (and therefore not a business day under the FSANZ Act) in all States except Western Australia and New Zealand, FSANZ will conduct seven business days of consultation in Western Australia and New Zealand.

Invitation for Submissions

FSANZ invites public comment on this Report and the draft variation to the Code based on regulation impact principles for the purpose of preparing an **urgent** amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in further considering this Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the 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, separate it from your submission and provide justification for treating it as confidential commercial material. Section 114 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. 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. Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 17 June 2008

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, hard copy 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

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

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1. Introduction

The purpose of this Proposal is to seek a variation to Standard 2.9.1 – Infant Formula Products of the *Australia New Zealand Food Standards Code* (the Code) to remove a commencement provision relating to certain special purpose infant formula[2].

There is concern that this commencement provision may unintentionally jeopardise the availability and supply of certain special purpose infant formula to infants with particular medical conditions in Australia and New Zealand. Consequently, Food Standards Australia New Zealand (FSANZ) has for public health and safety reasons decided, pursuant to section 95 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), to declare this Proposal urgent and to seek an emergency amendment to the Code (see Attachment 1).

2. The Issue / Problem

Standard 2.9.1 provides the compositional and labelling requirements for infant formula products, including those intended for infants with special nutritional requirements. Subdivision 2, Division 3 of Standard 2.9.1 includes the following clause:

> ***27 Composition***
>
> *(1) Subject to subclause (2), infant formula products may be specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions.*
>
> *(2) The permission in subclause (1) only applies where the infant formula products comply with –*
>
> *(a) this Division; and*
> *(b) all the other requirements of this Standard that are not inconsistent with this Division.*
>
> *(3) Other than for the operation of clause 28, subclause (2) takes effect 5 years after the commencement of this Standard.*

Standard 2.9.1 was gazetted on 20 June 2002. Subclause 27(3) therefore commenced operation on 20 June 2007, being 5 years after the commencement of Standard 2.9.1. The commencement effect of subclause 27(3) relates to subclause 27(2) which applies conditions to the permission allowing infant formula products to be specifically formulated for particular metabolic, immunological, renal, hepatic or malabsorptive conditions (as provided in subclause 27(1)).

[2] 'special purpose infant formula' in this Report means 'infant formula products specifically formulated to satisfy particular metabolic, immunological, renal, hepatic and malabsorptive conditions.

It has recently been brought to FSANZ's attention that the commencement of the operation of subclause 27(2) and the conditions that it applies may adversely constrain manufacturers in formulating infant formula products for particular metabolic, immunological, renal, hepatic and malabsorptive conditions. Manufacturers who are currently formulating these types of special purpose infant formula may technically be in breach of the Code and open to enforcement action.

This situation creates uncertainty for:

- the infant formula industry in continuing to formulate and supply these special purpose infant formula products within Australia and New Zealand;
- infants with medical conditions who may be solely reliant on these infant formula products to meet their particular nutritional requirements; and
- State/Territory and New Zealand Government agencies responsible for enforcing the Code.

There is a significant risk to the public health and safety of a very vulnerable population group i.e. infants with medical conditions, should infant formula manufacturers be hindered in the supply of these special purpose infant formula products.

FSANZ has therefore prepared this Proposal to seek the urgent removal of the commencement provision in Clause 27 so as to ensure the continuing and unhindered supply of infant formula products for particular metabolic, immunological, renal, hepatic and malabsorptive conditions within Australia and New Zealand.

3. Historical Background to Clause 27

During the review of infant formula (Proposal P93), it was proposed to allow infant formula products to be specifically formulated to satisfy particular medical conditions provided that in all respects they complied with the requirements of the proposed draft Standard 2.9.1.

At Supplementary Final Assessment (March 2002) of Proposal P93, the infant formula industry raised concerns that infant formula for specific clinical purposes should be allowed to adhere with accepted international norms for those purposes. It was noted that special purpose infant formula did not comply with the standard base formulation as proposed in draft Standard 2.9.1. Manufacturers also indicated that given the small volume of the market in Australia and New Zealand and the global nature of manufacturing, they would be unable to modify formulations to comply with the proposed draft Standard, and may need to withdraw supply of these formulations to sick babies.

At the time FSANZ (then ANZFA) noted that the supply of these infant formula products needed to be guaranteed for obvious health and safety reasons and concluded:

Therefore, although it is proposed that special purpose products are expected to conform to the base standard for healthy infants except where necessary to meet the particular needs of the infant with the special condition, ANZFA is proposing to include a temporary exemption for the compositional requirements of the standard to permit the supply of these products. The exemption is recommended for a period of five years from the adoption of the standard. This period will allow ANZFA to develop a special standard for 'foods for special medical purposes' that could include these highly specialised infant formula products. This will ensure that the particular needs of these infants are protected.

However for a variety of reasons, FSANZ has not been able to complete work on a standard for foods for special medical purposes within the predetermined five year exemption period. Work on a standard for foods for special medical purposes (Proposal P242) commenced in 2001, but has been at Final Assessment since 2004.

4. Objectives

The specific objectives of this Proposal are to seek the removal of the commencement provision in clause 27 of Standard 2.9.1 so as to:

- protect the public health and safety of infants with specific medical conditions who rely on special purpose infant formula products to meet their particular nutritional requirements; and

- ensure infant formula manufacturers are not unduly hindered in the formulation and supply of special purpose infant formula.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. 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 developing and varying standards, FSANZ must also have regard to:

- 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.

5. Relevant Issues

5.1 Special purpose infant formula

Special purpose infant formulas are designed to be used under medical supervision to meet the particular nutritional needs of infants with medical conditions. These medical conditions can be quite rare and in some circumstances breastfeeding and standard milk-based infant formula may be unsuitable. Many special purpose infant formulas are available only through prescription and are subsided through the respective Australian and New Zealand Government subsidy schemes (e.g. PBS[3], PHARMAC[4]).

There are only a small number of manufacturers who supply the domestic market with special purpose infant formulas. Most products are formulated and manufactured overseas for global supply, and imported into Australia and New Zealand. It is therefore vital for obvious health and safety reasons that the on-going availability and supply of these products for infants with particular nutritional needs can continue unhindered.

5.2 Division 3 – Infant Formula Products for Special Dietary Use

Division 3 of Standard 2.9.1 provides the compositional and labelling requirements for infant formula products for special dietary use in three subdivisions:

- Subdivision 1 – Infant formula products formulated for premature or low birthweight infants;

- Subdivision 2 – Infant formula products for metabolic, immunological, renal, hepatic and malabsorptive conditions; and

- Subdivision 3 – Infant formula products for specific dietary use based upon protein substitutes.

The proposed amendments to Clause 27 are only intended to affect those products regulated by Subdivision 2 and should not impact on the infant formula products covered by the other two subdivisions. Additionally, provisions relating to the composition and labelling of lactose free and low lactose infant formulas (Clauses 29 and 30) should also not be affected by the proposed amendments and will continue to operate.

[3] Pharmaceutical Benefits Scheme as administered by the Australia Government.
[4] NZ Pharmaceutical Schedule, administered by PHARMAC (the Pharmaceutical Management Agency Ltd).

5.2.1 Subdivision 2 – Infant formula products for metabolic, immunological, renal, hepatic and malabsorptive conditions

5.2.1.1 Composition

FSANZ has not been made aware of any evidence that the regulatory approach taken, including the permission to specifically formulate special purpose infant formulas, has not provided adequate protection of public health and safety during the relevant five-year exemption period since June 2002. Additionally, any risks associated with these types of infant formulas are generally minimised by their use under medical supervision.

FSANZ considers that there is in fact a greater risk to public health and safety if these products are not allowed to continue under the regulatory arrangement put in place in June 2002. Therefore FSANZ is seeking to remove the commencement provision in clause 27 to, in effect, continue the *status quo* and to resolve the uncertainty created by the end of the five-year exemption period in June 2007.

The proposed variation has been drafted to remove subclauses 27(2) and 27(3). However it is expected that manufacturers will be able to formulate special purpose infant formula within the requirements of Division 3, so the proposed amendment has been drafted to reflect this (see Attachment 2).

5.2.1.1 Labelling

Infant formula products specifically formulated for particular metabolic, immunological, renal, hepatic and malabsorptive conditions have specific labelling requirements. Clause 28 of Standard 2.9.1 requires these products to be labelled with:

- advice that the product is not suitable for general use and should be used under medical supervision;
- the condition, disease or disorder for which the food has been formulated; and
- the nutritional modifications made to the product.

This labelling is considered important to ensure the safe and appropriate use of these special purpose infant formulas. Therefore the proposed amendments to Clause 27 will not affect these labelling requirements.

5.3 FSANZ's proposed future action

Under the urgency provisions of the FSANZ Act, the key basis for exercising these powers is to resolve an immediate problem with the operation of the Code; in this case clause 27 of Standard 2.9.1. If approved, FSANZ must within 12 months of gazettal, undertake a full review of this decision and any variation to the Code.

In relation to broader consideration of the regulation of special purpose infant formula, FSANZ proposes to undertake a review of the infant formula standard; the scope and timing of this review is yet to be determined. In addition, FSANZ will consider how best to re-commence work on Proposal P242 – Foods for Special Medical Purposes, and the applicability of this draft Standard to the regulation of special purpose infant formula.

The Australia and New Zealand Food Regulation Ministerial Council has recently agreed to the development of separate policy guidance on the intent of Part 2.9 – Special Purpose Foods[5], and on infant formula. When developing or varying a food standard FSANZ must have regard to any Ministerial policy guidance (see section 4 above), and it is therefore expected that a review of the infant formula standard and completion of work on Proposal P242 will await this policy guidance. The timelines for completion of this policy work is unclear at this stage.

6. Options

The following two regulatory options are available for this Proposal:

Option 1 do nothing; or

Option 2 amend clause 27 of Standard 2.9.1 to remove the commencement provision (subclause 27(3) and a consequent removal of subclause 27(2)) thereby restoring the previous *status quo* approach to permitting infant formulas to be specifically formulated to satisfy particular metabolic, immunological, renal, hepatic and malabsorptive conditions.

7. Impact Analysis

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sectors of the community, which includes consumers, food industry and governments in Australia and New Zealand. The benefits and costs associated with proposed amendments to the Code will be analysed using regulatory impact principles.

7.1 Affected Parties

Those potentially affected by the above options include:

1. infants with certain medical conditions and their carers, as well as the health professionals supervising their medical care;
2. manufacturers and importers of special purpose infant formulas; and
3. State/Territory, Australian and New Zealand Governments.

[5] Part 2.9 of the Code includes Standard 2.9.1 – Infant Formula Products, Standard 2.9.2 – Foods for Infants, Standard 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods, Formulated Supplementary Sports Foods and (currently reserved) a standard for a foods for special medical purposes (as proposed by Proposal P242 currently at Final Assessment).

The impact of the proposed change to clause 27, Standard 2.9.1 on the affected parties will be determined prior to FSANZ conducting a final assessment of this Proposal. FSANZ's preferred approach at this stage is Option 2.

8. Consultation

FSANZ is seeking public comment in order to assist in assessing this Proposal. Such comments could cover:

- any information relevant to the Proposal;
- parties that might be affected having this Proposal approved or rejected; and
- potential costs and benefits to the identified affected parties.

Under section 95 of the FSANZ Act, FSANZ has declared this Proposal as urgent and will now conduct six business days of consultation with stakeholders.
As 9 June 2008 is a public holiday (and therefore not a business day under the FSANZ Act) in all States except Western Australia and New Zealand, FSANZ will conduct seven business days of consultation in Western Australia and New Zealand.

8.1 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 Code to provide permissions for special purpose infant formulas will ensure continued international trade and imports to the Australian and New Zealand market, thereby protecting the public health and safety of infants who rely on these products for their particular nutritional requirements. This issue will be fully considered prior to approval and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade (TBT) or Sanitary and Phytosanitary Measures (SPS) Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

9. Conclusion and Preferred Option

So as to not jeopardise the availability and supply of special purpose infant formula in Australia and New Zealand, FSANZ is of the view that Option 1 i.e. do nothing is not acceptable. Therefore in the interest of protecting the public health and safety of infants with particular medical conditions, FSANZ's preferred approach is Option 2.

Preferred Approach

To amend clause 27 of Standard 2.9.1 – Infants Formula Products to remove the commencement provision (subclause 27(3) and a consequent removal of subclause 27(2) thereby restoring the previous *status quo* approach to permitting infant formulas to be specifically formulated to satisfy particular metabolic, immunological, renal, hepatic and malabsorptive conditions.

9.1 Reasons for Preferred Approach

FSANZ is proposing to amend clause 27 of Standard 2.9.1 (see Attachment 1) as initial consideration indicates it will provide net benefits to all affected parties. This is because the proposed amendments:

- provide certainty for consumers, industry and enforcement agencies on the regulatory status of special purpose infant formula; and

- protects the public health and safety of infants with particular nutritional requirements by ensuring that the availability and supply of special purpose infant formulas in Australia and New Zealand is not unduly hindered.

The proposed variation will come into effect upon gazettal

ATTACHMENT

1. Draft variation to the *Australia New Zealand Food Standards Code*

Attachment 1

Draft variation to the *Australia New Zealand Food Standards Code*

Subsection 87(8) of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunsetting

To commence: on gazettal

[1] ***Standard 2.9.1*** *of the Australia New Zealand Food Standards Code is varied by omitting clause 27*, *substituting –*

27 Composition

Infant formula products may be specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions provided that in all other respects the products comply with this Division.