

26 June 2008
[11-08]

PROPOSAL P1006

REMOVE COMMENCEMENT PROVISION FOR CERTAIN SPECIAL PURPOSE INFANT FORMULA APPROVAL 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 formula¹.

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.

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 and to seek an emergency amendment to the Code.

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

The specific objective 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 interests of protecting the public health and safety of infants with particular medical conditions, FSANZ's recommended approach is Option 2.

Decision

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 recommending amending clause 27 of Standard 2.9.1 (see Attachment 1) as it will provide net benefits to all affected parties. This is because the proposed amendments:

- provide certainty at this time 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, having declared this Proposal urgent under section 95 of the FSANZ Act, has conducted six business days (seven business days in Western Australia and New Zealand) of public consultation. During the consultation period of 6-17 June 2008, FSANZ received 10 submissions. All submitters supported making the proposed urgent amendment to the Code (Option 2). A summary of submissions is at Attachment 2.

A number of submitters commented on FSANZ's proposed future plan for considering the regulation of special purpose infant formula in the longer term. Whilst noting that development of ministerial policy guidance is underway, most submitters supported progression of this future work as a priority once Ministerial policy guidance is received by FSANZ.

Additionally a number of submitters expressed concern over the current lack of certainty in the regulation of special purpose infant formula and that the proposed amendment does not resolve this uncertainty. As indicated above, FSANZ has proposed a future review of the infant formula standard and expects to consider these issues at this time.

CONTENTS

1.	INTRODUCTION	2
2.	THE ISSUE / PROBLEM.....	2
3.	HISTORICAL BACKGROUND TO CLAUSE 27	3
4.	OBJECTIVES	3
5.	RELEVANT ISSUES	4
5.1	<i>Special purpose infant formula</i>	4
5.2	<i>Division 3 – Infant Formula Products for Special Dietary Use</i>	4
5.3	<i>FSANZ’s proposed future action</i>	6
6.	OPTIONS	6
7.	IMPACT ANALYSIS	6
7.1	<i>Affected Parties</i>	6
8.	CONSULTATION.....	7
8.2	<i>World Trade Organization (WTO)</i>	7
9.	CONCLUSION AND DECISION.....	7
9.1	<i>Reasons for Decision</i>	8
	ATTACHMENT 1 - DRAFT VARIATION TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS</i> <i>CODE</i>	9
	ATTACHMENT 2 - P1006 - SUMMARY OF SUBMISSIONS AT INITIAL CONSIDERATION	10

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 formula².

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 make 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)).

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:

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

- 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 objective 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; and
- 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;
- 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 subsidised through the respective Australian and New Zealand Government subsidy schemes (e.g. PBS³, PHARMAC⁴).

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:

³ Pharmaceutical Benefits Scheme as administered by the Australia Government.

⁴ NZ Pharmaceutical Schedule, administered by PHARMAC (the Pharmaceutical Management Agency Ltd).

- 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 do 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.

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 1).

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 assessment of this variation to the Code, call for public comment and reconsider its decision.

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 Foods⁵, 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 <i>status quo</i> 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).

Following stakeholder consultation, no immediate costs on affected parties have been identified. There are however potential benefits for all affected parties through providing regulatory certainty at this time, which in turn avoids hindering the supply and availability of special purpose infant formula. FSANZ must within the next 12 months give further consideration, including public and stakeholder consultation, to the regulatory impact on affected parties of this Proposal. FSANZ's recommended approach at this stage remains Option 2.

8. Consultation

FSANZ, having declared this Proposal urgent under section 95 of the FSANZ Act, has conducted six business days (seven business days in Western Australia and New Zealand) of public consultation. During the consultation period of 6-17 June 2008, FSANZ received 10 submissions. All submitters supported making the proposed urgent amendment to the Code (Option 2). A summary of submissions is at Attachment 2.

A number of submitters commented on FSANZ's proposed future plan for considering the regulation of special purpose infant formula in the longer term. Whilst noting that development of ministerial policy guidance is underway, most submitters supported progression of this future work as a priority once ministerial policy guidance is received by FSANZ.

Additionally a number of submitters expressed concern over the current lack of certainty in the regulation of special purpose infant formula and that the proposed amendment does not resolve this uncertainty. As indicated above, FSANZ has proposed a future review of the infant formula standard and expects to consider these issues at this time.

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 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 within 12 months of the date of effect of the variation to the Code 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 Decision

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 interests of protecting the public health and safety of infants with particular medical conditions, FSANZ's recommended approach is Option 2.

Decision

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 Decision

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

- provide certainty at this time 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.

ATTACHMENTS

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. Summary of Submissions

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 sunseting

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.

Attachment 2

P1006 – Summary of Submissions at Initial Consideration

No.	Submitter	Comment
Industry		
1.	Australian Food and Grocery Council	<p>Supports Option 2 – amend clause 27.</p> <p>Suggests that as FSANZ did not initiated action until after the ‘sunset clause’ came into effect there is need for review of internal procedures by FSANZ. Agrees with urgency as allowing circumstances that risk continuation of supply, and the unnecessary technical breach in supplying such products should not be permitted.</p>
2.	Food Technology Association of Australia	<p>Supports Option 2 – amend clause 27.</p> <p>Raises concern that the “grey area” between foods and medicine is being ignored given these products maybe available on prescription and subsidised under Australian or NZ pharmaceutical benefit/schedule schemes.</p> <p>Expresses concern over the delay in finalising Proposal P242 – Foods for Special Medical Purposes and suggests this also attracts urgent attention.</p>
3.	Nutricia Australia	Supports Option 2 – amend clause 27.
4.	Wyeth Australia	<p>Supports Option 2 – amend clause 27.</p> <p>Comments that the intended purpose of infant formula for special dietary use provides no clear definition so that there is a risk of misinterpretation of suitability. The level of evidence required for claims on these products is not stipulated leading to a significant risk to public health and safety. The current proposal may allow for direct promotion to a consumer which is inconsistent with use under medical supervision.</p>
Government		
5.	Department of Health, Western Australia	<p>Supports Option 2 – amend clause 27 (on condition that a full review of the decision is conducted within 12 months).</p> <p>Considers that there should be improved controls in accessing these products as it is aware that these products, although for use under medical supervision, are freely available in the marketplace. Assumes this will be considered as part of ministerial policy guidance development. The policy guidelines for infant formula should be progressed as a matter of priority.</p>
6.	Department of Health, South Australia	<p>Supports Option 2 – amend clause 27.</p> <p>Agrees that the regulation, particularly the compositional specifications should be re-considered as part of the proposed infant formula standard review. Agrees that the review should await Ministerial Council policy guidance but supports expediting the review as soon as possible.</p>

No.	Submitter	Comment
7.	Department of Human Services, Victoria	<p>Supports Option 2 – amend clause 27.</p> <p>Recognises that the review of infant formula standard and progress on related work (Proposal P242 – Foods for Special Medical Purposes) is dependent on the policy development work under-way.</p>
8.	NSW Food Authority	<p>Supports Option 2 – amend clause 27.</p> <p>Urges FSANZ to expedite development of an appropriate standard, noting that progress is contingent on ministerial policy guidance. Considers that both the proposed and existing standard are vague, particularly in regards to the possible indiscriminate addition of ingredients, additives and nutrients not otherwise permitted in the infant formula standard which creates substantial uncertainty. Is concerned that the standard does not prevent sale of these products without medical supervision and that availability on prescription does not provide a safeguard against inappropriate use.</p>
9.	New Zealand Food Safety Authority (NZFSA)	<p>Supports Option 2 – amend clause 27.</p> <p>In regards to future work, NZFSA strongly supports progression of work on the regulation of special purpose infant formula outside work on Proposal P242 – Foods for Special Medical Purposes.</p>
10.	Queensland Health	<p>Supports Option 2 – amend clause 27.</p> <p>Considers that the proposed future action (review of infant formula standard and re-commencement of work on Proposal P242 – Foods for Special Medical Purposes) needs to be progressed as a matter of priority.</p>