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

15 September 2008
[16-08]

PROPOSAL P1006
RECONSIDERATION OF THE URGENT REMOVAL OF A COMMENCEMENT PROVISION FOR CERTAIN SPECIAL PURPOSE INFANT FORMULA
ASSESSMENT REPORT

Executive Summary

The purpose of this Assessment Report is to re-consider a variation to Standard 2.9.1 – Infant Formula Products of the *Australia New Zealand Food Standards Code* (the Code) made in June 2008 under the section 95 urgency provisions of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), that removed a commencement provision relating to certain special purpose infant formula[1].

The amendment to the Code was made after a Declaration of Urgency and preparation of a draft variation which was gazetted on 30 June 2008.

In May 2008 it was brought to Food Standards Australia New Zealand's (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 applied, may have adversely constrained manufacturers in formulating infant formula products for particular metabolic, immunological, renal, hepatic and malabsorptive conditions. Manufacturers who are formulating these types of special purpose infant formula may technically have been in breach of the Code and open to enforcement action.

This situation created 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.

[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 the commencement provision may have unintentionally jeopardised the availability and supply of certain special purpose infant formula to infants with particular medical conditions, FSANZ, for public health and safety reasons, decided pursuant to section 95 of the FSANZ Act, to declare Proposal P1006 as urgent and to seek an emergency amendment to the Code.

Following Initial Consideration of Proposal P1006 the commencement provision in clause 27 of Standard 2.9.1 was removed 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 accordance with section 101 of the FSANZ Act, the Authority must now either re-affirm its decision to approve the urgent variation; or prepare a proposal within 12 months of the standard taking effect.

Therefore, the specific objective of this assessment is to either: re-affirm the decision to amend clause 27 of Standard 2.9.1; or to consider the need to prepare a new (separate) proposal for a further variation or replacement variation to clause 27 of Standard 2.9.1.

The following two regulatory options are now available for Proposal P1006:

Option 1 re-affirm the amendment made to clause 27 of Standard 2.9.1 which removed the commencement provision (subclause 27(3) and consequentially removed subclause 27(2)): or

Option 2 prepare a new (separate) proposal which may result in the amendments made to clause 27 of Standard 2.9.1 being varied or replaced.

Preferred option:

FSANZ's preferred approach is to re-affirm the amendment made to clause 27 of Standard 2.9.1 – Infants Formula Products that removed the commencement provision (subclause 27(3) and consequentially removed subclause 27(2)).

Reasons for Preferred Approach

FSANZ is recommending that the variation to clause 27 of Standard 2.9.1 (see Attachment 1) be reaffirmed as it provides net benefits to all affected parties.

The amendment:

- retains the *status quo* approach to permitting infant formulas to be specifically formulated to satisfy particular metabolic, immunological, renal, hepatic and malabsorptive conditions;

- 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; and

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

The preferred option would retain the variation to clause 27 of Standard 2.9.1 which was gazetted and came into effect on 30 June 2008.

Consultation

Under the urgency provisions of section 95 of the FSANZ Act, FSANZ conducted six business days (seven business days in Western Australia and New Zealand) of public consultation during the Initial Consideration of Proposal P1006. During the consultation period of 6-17 June 2008, FSANZ received 10 submissions. A summary of submissions is at Attachment 2. All submitters supported making the proposed urgent amendment to the Code.

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

Concern was also expressed that action to amend clause 27 of Standard 2.9.1 was not initiated until after the commencement clause came into effect and that other similar clauses may exist in the Code. In response, FSANZ has undertaken an audit of the Code and no other clauses require attention in a manner which gave rise to this urgent Proposal.

Invitation for Submissions

FSANZ invites public comment on this Report and the variations to the Code based on regulation impact principles for the purpose of re-considering the urgent amendment to the Code as 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) 27 October 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
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1. Introduction

The purpose of this Assessment Report is to re-consider a variation made in June 2008 to Standard 2.9.1 – Infant Formula Products of the *Australia New Zealand Food Standards Code* (the Code) that removed a commencement provision relating to certain special purpose infant formula[2]. This amendment was made following Initial Consideration of Proposal P1006 using urgency provisions under section 95 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act), and was gazetted on 30 June 2008.

Under the urgency provisions (section 95) 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. Once approved, FSANZ must within 12 months of the date of effect of the gazetted amendment, undertake an assessment of the resulting variation to the Code, call for public comment and reconsider its decision.

This Report therefore re-visits the decision made following Initial Consideration of Proposal P1006 and allows further opportunity for public consultation on the resulting urgent amendment as gazetted on 30 June 2008.

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. Prior to Proposal P1006 and the resultant variation to the Code, Subdivision 2, Division 3 of Standard 2.9.1 included 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.

As Standard 2.9.1 was gazetted on 20 June 2002, subclause 27(3) commenced operation on 20 June 2007, being five years after the commencement of Standard 2.9.1. The commencement effect of subclause 27(3) related to subclause 27(2) which applied 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.

In May 2008, the commencement of the operation of subclause 27(2) of Standard 2.9.1 on 20 June 2007, and the conditions that it applied might adversely constrain manufacturers in formulating infant formula products for particular metabolic, immunological, renal, hepatic and malabsorptive conditions, was brought to FSANZ's attention. Manufacturers who are formulating these types of special purpose infant formula may technically have been in breach of the Code and open to enforcement action.

This situation created 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.

Also, there was 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 the commencement provision may have unintentionally jeopardised the availability and supply of certain special purpose infant formula to infants with particular medical conditions, FSANZ, for public health and safety reasons, decided, pursuant to section 95 of the FSANZ Act, to declare Proposal P1006 as urgent and to seek an emergency amendment to the Code.

Following Initial Consideration of Proposal P1006, an amendment to the Code was gazetted on 30 June 2008 which removed the commencement provision in clause 27 of Standard 2.9.1. Attachment 1 provides the variation to clause 27 of Standard 2.9.1 as gazetted following Initial Consideration.

2.1 Requirements of the FSANZ Act

The FSANZ Act, Division 4 – Urgent applications and proposals, requires that if FSANZ approves a draft standard or a draft variation of a standard under the urgency provisions, FSANZ must also assess the resulting standard or variation within 12 months of the date of effect of the gazetted variation.

Division 4 Subsection 99(2) requires that in assessing the standard or variation, the Authority must have regard to the following matters:

(a) whet*her costs that have arisen, or will arise, from the standard or variation outweigh the direct and indirect benefits to the community, Government or industry that have arisen, or will arise, from the standard or variation;*
(b) whether other measures (available to the Authority or not) would be more cost-effective than the standard or variation;
(c) all relevant New Zealand standards;
*(d) any o*ther relevant matters.

Also, in assessing the standard or variation, FSANZ must call for public submissions. Division 4 Section 101 requires that after the submission period, and within 12 months after the standard or variation takes effect, FSANZ must:

(a) re-affirm its decision to approve the standard or variation; or
(b) prepare a proposal under section 55 for the development of:
(i) the variation, or further variation, of the relevant standard; or
(ii) a replacement standard.

3. Objectives

In accordance with the requirements of the FSANZ Act, the specific objective of this assessment is to re-consider the urgent variation made to clause 27 of Standard 2.9.1 and to either: re-affirm the original decision made in June 2008 which removed the previous commencement provision; or to consider the need to prepare a new separate proposal to consider a further variation or replacement variation to clause 27.

The original specific objectives of this Proposal were 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; and

- any written policy guidelines formulated by the Ministerial Council.

4. Relevant Issues

4.1 Historical background to Clause 27

During the review of infant formula (Proposal P93), FSANZ (then the Australia New Zealand Food Authority (ANZFA)) proposed to allow infant formula products to be specifically formulated to satisfy particular medical conditions provided that in all respects such formula 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 the 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 was not 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.

4.2 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.

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

Most products are formulated and manufactured overseas for global supply, and imported into Australia and New Zealand. It is therefore vital for health and safety reasons that the on-going availability and supply of these products for infants with particular nutritional needs can continue unhindered.

4.3 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 amendments made to clause 27 under Proposal P1006 urgency provisions 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) are not affected by the amendments and continue to operate.

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

4.3.1.1 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.

In preparing Proposal P1006, FSANZ considered that there was in fact a greater risk to public health and safety if these products were not allowed to continue under the regulatory arrangement put in place in June 2002. Therefore FSANZ removed 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.

Following Initial Consideration of Proposal P1006 the Code was amended to remove subclauses 27(2) and 27(3). However, it was expected that manufacturers would be able to formulate special purpose infant formula within the requirements of Division 3, so the amendment was drafted to reflect this (see Attachment 1).

4.3.1.2 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. The amendments to clause 27 do not affect these labelling requirements.

4.4 Future FSANZ work

FSANZ proposes to undertake a review of the infant formula standard in relation to the broader consideration of the regulation of special purpose infant formula: the scope and timing of this review is yet to be determined.

The Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) is currently developing separate policy guidelines on the intent of Part 2.9 – Special Purpose Foods, and on infant formula products. It is anticipated that work on these guidelines will not be completed until late 2009.

As FSANZ must have regard to any Ministerial Council policy guidelines when developing or varying food standards, it is therefore expected that a review of the infant formula standard and completion of work on Proposal P242 – Foods for Special Medical Purposes will await completion of these policy guidelines.

5. Options

In reconsidering the variation made to the Code under the urgency provisions, the following two regulatory options are available:

Option 1 re-affirm the resulting amendment made to clause 27 of Standard 2.9.1 which removed the commencement provision (subclause 27(3) and consequentially removed subclause 27(2)); or.

Option 2 prepare a new (separate) proposal which may result in the amendments made to clause 27 of Standard 2.9.1 being varied or replaced.

Under Option 2 a new proposal would re-consider the operation of clause 27 of Standard 2.9.1 including consideration of any unintended consequences or unresolved issues resulting from the urgent amendments made to clause 27. During consideration of this new proposal the amendments to clause 27 as gazetted on 30 June 2008 would remain in place.

6. 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.

Following stakeholder consultation on the Initial Consideration of this Proposal, no immediate costs from the proposed variation to clause 27 on affected parties were identified.

However, it was considered likely that there would be potential benefits for all affected parties through providing regulatory clarity, and in turn maintaining the supply and availability of special purpose infant formula. Re-consideration of the issue through this Assessment Report allows the impact of the urgent amendment to be given further consideration prior to final approval.

6.1 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.

6.2 Benefit Cost Analysis

This Benefit Cost Analysis assesses the immediate and potential impacts of each regulatory option on the affected parties.

6.2.1 Option 1 – re-affirm the amendment made to clause 27 of Standard 2.9.1

6.2.1.1 Consumers

Reaffirming the variation made to clause 27 of Standard 2.9.1 would maintain the availability of certain special purpose infant formula to infants with specific medical conditions in Australia and New Zealand, thus protecting their health and safety.

6.2.1.2 Industry

Maintaining the *status quo* through reaffirming the amendment made to clause 27 would provide clarity for industry, and enable manufacturers to continue to produce special purpose infant formula without the potential for enforcement action.

6.2.1.3 Government

Option 1 would maintain clarity regarding the regulatory status of these special purpose products and avoid the need for unnecessary enforcement action.

6.2.2 Option 2 – prepare a new (separate) proposal which may result in the amendments made to clause 27 of Standard 2.9.1 being varied or replaced.

Under Option 2 the amendments made to clause 27 of Standard 2.9.1 would remain in place as gazetted on 30 June 2008, until the issue is fully considered by a new proposal. Consequently, in the interim, the impacts would be similar to Option 1. The impact of any proposed change or replacement of the amendment to clause 27 would be considered as part of a new separate proposal once prepared.

Questions for submitters:

Have the amendments to clause 7 of Standard 2.9.1 made using the urgency provisions of the FSANZ Act and gazetted on 30 June 2008 resolved the issue/problem (as described in section 2) for all affected parties?
Are there any unforeseen unintended consequences or unresolved issues resulting from the amendments made to clause 7 of Standard 2.9.1 which would require further consideration through preparation of a new (separate) proposal?

Is there any evidence to suggest that the amendments made to clause 7 of Standard 2.9.1 need to be varied or replaced?

7. Consultation

At Initial Consideration FSANZ, having declared this Proposal urgent under section 95 of the FSANZ Act conducted six business days (seven business days in Western Australia and New Zealand) of public consultation.

During that consultation period of 6-17 June 2008, FSANZ received 10 submissions (see Attachment 2). All submitters supported making the proposed urgent amendment to the Code.

Key issues arising from submissions included:

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

- the need to progress Proposal P242 – Food for Special Medical Purposes, including definitions of the purpose of the products, the level of evidence required for claims on these products, access to these products, uncertainty over compositional specifications and indiscriminate addition of ingredients. These issues will be considered under Proposal P242 following completion of the Ministerial policy guidelines on the intent of Part 2.9 – Special Purpose Foods; and

- concern that action to amend clause 27 of Standard 2.9.1 was not initiated until after the commencement clause came into effect and that other similar clauses may exist in the Code. In response, FSANZ has undertaken an audit of the Code and no other clauses require attention in a manner which gave rise to this urgent Proposal.

FSANZ is now seeking public comment in order to assist the reconsideration of the resulting variation made following Initial Consideration of Proposal P1006.

7.1 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 retaining the amendment to the Code to provide permissions for special purpose infant formulas as proposed, would 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.

As it is not expected that this approach will result in a potential barrier to trade, WTO member nations have not been notified of the amendment to Standard 2.9.1 under either the Technical Barriers to Trade or Sanitary and Phytosanitary Agreements.

8. Conclusion and Preferred Option

Preferred Option:

FSANZ's preferred approach is to re-affirm the amendment made to clause 27 of Standard 2.9.1 – Infants Formula Products that removed the commencement provision (subclause 27(3) and consequentially removed subclause 27(2)).

8.1 Reasons for Decision

FSANZ is recommending the amendment made to clause 27 of Standard 2.9.1 (see Attachment 1) be re-affirmed as it provides net benefits to all affected parties. This is because the amendment:

- retains the *status quo* approach to permitting infant formulas to be specifically formulated to satisfy particular metabolic, immunological, renal, hepatic and malabsorptive conditions;

- 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; and

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

The preferred option would retain the variation to clause 27 of Standard 2.9.1 which came into effect at gazettal on 30 June 2008.

ATTACHMENTS

1. Variation to the *Australia New Zealand Food Standards Code* as gazetted on 30 June 2008
2. Summary of Submissions received following Initial Consideration

Attachment 1

Variation to the *Australia New Zealand Food Standards Code* as gazetted on 30 June 2008

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

[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

At Initial Consideration FSANZ, having declared Proposal P1006 urgent under section 95 of the FSANZ Act conducted six business days (seven business days in Western Australia and New Zealand) of public consultation.

Two regulatory options for Proposal P1006 were presented at Initial Consideration, namely:

- *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.

During the consultation period of 6-17 June 2008, FSANZ received 10 submissions. A summary of submitter comments is provided in the following table.

No.	Submitter	Comment
Industry		
1.	Australian Food and Grocery Council	Supports Option 2 – amend clause 27. Suggests that as FSANZ did not initiate 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.
2.	Food Technology Association of Australia	Supports Option 2 – amend clause 27. Raises concern that the "grey area" between foods and medicine is being ignored given these products maybe available on prescription and subsided under Australian or NZ pharmaceutical benefit/schedule schemes. Expresses concern over the delay in finalising Proposal P242 – Foods for Special Medical Purposes and suggests this also attracts urgent attention.
3.	Nutricia Australia	Supports Option 2 – amend clause 27.
4.	Wyeth Australia	Supports Option 2 – amend clause 27. 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.

No.	Submitter	Comment
		The current Proposal may allow for direct promotion to a consumer which is inconsistent with use under medical supervision.
Government		
5.	Department of Health, Western Australia	Supports Option 2 – amend clause 27 (on condition that a full review of the decision is conducted within 12 months). 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.
6.	Department of Health, South Australia	Supports Option 2 – amend clause 27. 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.
7.	Department of Human Services, Victoria	Supports Option 2 – amend clause 27. 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.
8.	NSW Food Authority	Supports Option 2 – amend clause 27. 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.
9.	New Zealand Food Safety Authority (NZFSA)	Supports Option 2 – amend clause 27. 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.
10.	Queensland Health	Supports Option 2 – amend clause 27. 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.