



3 June 2009
[8-09]

PROPOSAL P1006

REMOVE COMMENCEMENT PROVISION FOR CERTAIN SPECIAL PURPOSE INFANT FORMULA RE-AFFIRMATION OF VARIATION

Executive Summary

The purpose of this Report is to consider the variation to Standard 2.9.1 – Infant Formula Products of the *Australia New Zealand Food Standards Code* (the Code) gazetted in June 2008 under the section 95 urgency provisions of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act), that removed a commencement provision relating to certain special purpose infant formula¹.

The amendment to the Code was made after a Declaration of Urgency and preparation of a draft variation which was gazetted on 26 June 2008. The variation took effect on the date of gazettal.

In May 2008, Food Standards Australia New Zealand (FSANZ) was alerted to the fact 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 could unintentionally jeopardise 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 the decision to amend clause 27 of Standard 2.9.1; or 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 proposal which may result in the amendments made to clause 27 of Standard 2.9.1 being varied or replaced.

In considering the Options, FSANZ foreshadows a future review of Standard 2.9.1, including consideration of the regulation of special purpose infant formula. As FSANZ is required to have regard to relevant policy guidance, work currently under way by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) on separate policy guidance on the intent of Part 2.9 – Special Purpose Foods and the regulation of infant formula products will assist with this future review.

These policy guidelines were not available within the 12 month statutory period for the reconsideration of Proposal P1006. Therefore, FSANZ has progressed this Proposal according to current statutory requirements under the FSANZ Act 1991.

Also, in re-considering the variation made, FSANZ must consider the costs and benefits of the variation made under urgency provisions and whether other measures would be more cost-effective. At this time, no other measures have been identified as being more cost-effective and that warrant preparation of a new (separate) proposal to address the specific objectives of Proposal P1006. FSANZ therefore considers Option 1 to be more cost effective to complete that process than the development of a new proposal under Option 2.

Decision

FSANZ re-affirms the urgent amendment made to clause 27 of Standard 2.9.1 – Infant Formula Products that removed the commencement provision (subclause 27(3) and consequentially removed subclause 27(2)).

Reasons for Decision

FSANZ is recommending that the variation to clause 27 of Standard 2.9.1 (see Attachment 1) is re-affirmed as it:

- 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;
- provides certainty for consumers, industry and enforcement agencies on the regulatory status of special purpose infant formula in the interim prior to the proposed future review of the infant formula standard; and
- provides net benefits to all affected parties and is more cost-effective than other measures at this time.

The preferred option would retain the variation to clause 27 of Standard 2.9.1 which was gazetted and came into effect on 26 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. 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 undertook an audit of the Code and found no other clauses requiring attention in a similar manner.

In reconsidering the variation made to Standard 2.9.1 in June 2008, a six week public consultation period was provided following the release of an Assessment Report in September 2008.

Of the seven submissions received to the Reconsideration Assessment Report, five submitters supported re-affirming the urgent amendments.

Two jurisdictional submitters considered the Code does not provide a detailed specific Standard for special purpose infant formulas, or for formulas for pre-term or low birth weight infants, and expressed concern at delaying development of such a standard until completion of Ministerial policy guidance, and completion of Proposal P242 – Foods for Special Medical Purposes.

The specific objective of this Proposal was to seek the removal of the commencement provision in clause 27 of Standard 2.9.1 so as to protect the health and safety of infants with specific medical conditions by not unduly hindering the formulation and supply of special purpose infant formula. Preparation of a new (separate) proposal which seeks to develop a new standard for special purpose infant formulas or for formula for pre-term or low birth weight infants is a broader issue beyond the original objectives and scope of this Proposal, and will be considered at a later date following the development of Ministerial policy guidance.

Use of the term 'claims' in the labelling requirements in Clause 28 of Standard 2.9.1 was also raised as a concern. The Code prohibits claims on infant formula products. However, to ensure the intent of Clause 28 is clear, changes to Clause 28 have been proposed for inclusion in an upcoming Code Maintenance Proposal².

A summary of submissions is at Attachment 2.

² FSANZ regularly seeks to amend the Code to maintain its currency and clarity. A Code Maintenance Proposal is developed to assess a range of proposed amendments to the Code. The proposed amendments are intended to correct minor errors, inconsistencies and ambiguities including issues raised in recent Applications and Proposals.

CONTENTS

1.	INTRODUCTION	2
2.	THE ISSUE / PROBLEM.....	2
2.1	<i>Requirements of the FSANZ Act</i>	3
3.	OBJECTIVES	4
4.	RELEVANT ISSUES	5
4.1	<i>Historical background to Clause 27</i>	5
4.2	<i>Special purpose infant formula</i>	5
4.3	<i>Division 3 – Infant Formula Products for Special Dietary Use</i>	6
4.4	<i>Future FSANZ work</i>	7
4.5	<i>Scope of Proposal P1006 – Remove commencement provision for certain special purpose infant formula</i>	9
4.6	<i>Other issues raised in submissions</i>	9
5.	OPTIONS	10
6.	IMPACT ANALYSIS	10
6.1	<i>Affected Parties</i>	10
6.2	<i>Benefit Cost Analysis</i>	10
7.	CONSULTATION.....	12
7.1	<i>Consultation at Initial Consideration</i>	12
7.2	<i>Consultation on Reconsideration of the urgent amendments</i>	12
7.1	<i>World Trade Organization (WTO)</i>	13
8.	CONCLUSION AND DECISION.....	14
8.1	<i>Reasons for Decision</i>	14
8.2	<i>Implementation and Review</i>	14
	ATTACHMENT 1 - VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE AS GAZETTED ON 26 JUNE 2008.....	<u>16</u>
	ATTACHMENT 2 - P1006 - SUMMARY OF SUBMISSIONS.....	16

1. Introduction

The purpose of this Report is to reconsider 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 formula³. 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 26 June 2008.

Under these urgency provisions, 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 gazettal, undertake a full assessment of the resulting variation to the Code, call for public comment and reconsider its decision.

This Report therefore reconsiders the decision made and the resulting urgent amendment as gazetted on 26 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)).

In May 2008 it was 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 applied, may adversely constrain manufacturers in formulating infant formula products for particular metabolic, immunological, renal, hepatic and malabsorptive conditions.

³ 'special purpose infant formula' in this Report means 'infant formula products specifically formulated to satisfy 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.

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 26 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 approved 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.

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

- (a) whether 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 other relevant matters.

Also, in assessing the standard or variation, FSANZ must call for public submissions.

Section 101 requires that after the submission period, and within 12 months after the standard or variation takes effect, the Authority 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.

Therefore, FSANZ must complete this assessment of the variation to Standard 2.9.1 gazetted on 26 June 2008, having regard to the matters above, by 26 June 2009.

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
- 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 subsidised through the respective Australian and New Zealand Government subsidy schemes (e.g. PBS⁴, PHARMAC⁵).

⁴ Pharmaceutical Benefits Scheme as administered by the Australia Government.

⁵ NZ Pharmaceutical Schedule, administered by PHARMAC (the Pharmaceutical Management Agency Ltd).

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 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 Infant formula products formulated for premature or low birthweight infants

In response to the P1006 Reconsideration Assessment Report provided in September 2008, some submitters recommended a review of the provisions for infant formula products for premature or low birth weight infants, as a priority. However, as Proposal P1006 relates to Subdivision 2 only, a review of these products is not within the scope of this Proposal. It is anticipated that regulation of products under *Subdivision 1 - Infant formula products formulated for premature or low birthweight infants* will be considered within the planned future review of Standard 2.9.1.

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

4.3.2.1 Composition

FSANZ is not aware of any evidence that the removal of the commencement provision in clause 27 (which in effect, continues the *status quo* and resolves the uncertainty created by the end of the five-year exemption period in June 2007) has increased any risk to public health and safety for infants who consume these special purpose infant formulas.

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

4.3.2.2 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.

Some submitters to the Reconsideration Assessment Report of September 2008 considered that the provisions in Clause 28 that require specific statements to appear in the label where 'a label contains a claim...' is defective in that it does not trigger these labelling requirements when the claim is made other than in a label, such as in an advertisement, or when the claim is of a more generic nature or when no claim is made at all.

Standard 2.9.1 prohibits claims on infant formula products. In addition, Transitional Standard 1.1A.2 specifically prohibits health claims from being made on these products.

The intent of clause 28 is to ensure that special purpose infant formula products are labelled with specific information as described above.

To ensure this intent is clear, changes to clause 28 were proposed under Proposal P293 – Nutrition, Health and Related Claims⁶. However, as Proposal P293 is currently under review, rewording of clause 28 to clarify labelling requirements will be addressed through an upcoming Code Maintenance Proposal⁷.

In addition, clause 13 in Standard 1.1.1 applies labelling provisions to advertising and prohibits advertisements for food from containing any statement, information, designs or representations which are prohibited from being included in a label for that food.

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 timing of this review is yet to be confirmed.

⁶ Proposed changes are included in a Consultation Paper for Proposal P293 available at <http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp293nutritionhealthandrelatedclaims/index.cfm>

⁷ A Code Maintenance Proposal is developed to assess a range of proposed amendments to the Code. The proposed amendments are intended to correct minor errors, inconsistencies and ambiguities including issues raised in recent Applications and Proposals.

4.4.1 Ministerial Council policy guidelines

When developing or varying food standards FSANZ must have regard to relevant Ministerial Council policy guidelines. 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.

A Working Group was established in March 2008 by the Food Regulation Standing Committee (FRSC) to develop a Policy Guideline on the intent of Part 2.9 of the Code. A Consultation Paper⁸ was released for public comment in January 2009.

In June 2008, FRSC established a separate Working Group to develop a Policy Guideline on Infant Formula Products covered under Standard 2.9.1 of the Code.

These policy guidelines have not been available within the 12 month statutory period for the reconsideration of Proposal P1006, Therefore, FSANZ has progressed this Proposal according to statutory requirements.

4.4.2 Proposal P242 – Foods for Special Medical Purposes

Some submitters to the Reconsideration Assessment considered there is a need to develop a specific standard for special purpose infant formula and expressed concern at the potential to delay this until completion of Proposal P242. Completion of Proposal P242 was recommended as a priority.

At Preliminary Final Assessment of Proposal P242 it was not proposed that special purpose infant formula would be included in the new draft standard for food for special medical purposes. Proposal P242 does however potentially provide a framework for future consideration on how best to regulate special purpose infant formula.

Submitters also noted that currently the special purpose infant formula products can be sold directly to the public, however as they are intended to be under medical supervision there may be grounds for restricted access e.g. only available through pharmacies / hospitals.

FSANZ has considered this issue with regard to foods for special medical purposes under Proposal P242⁹ and has proposed to restrict the retail sale of these products to certain specified providers only. The appropriateness of this approach to special purpose infant formula would be assessed in future consideration of the regulation of these types of products.

FSANZ considers there is a need to ensure regulatory consistency across standards for foods for special medical purposes including compositional and other provisions such as labelling, advertising and access to these products. Therefore, FSANZ will consider the applicability of the draft Standard 2.9.5 proposed under Proposal P242 to the regulation of special purpose infant formula.

⁸ Department of Health and Aging, Special Purpose Foods Consultation Paper on Food Regulation Policy Options.

<http://www.health.gov.au/internet/main/publishing.nsf/Content/foodsecretariat-pgdev>

⁹ FSANZ's consideration of this issue can be found in the Preliminary Final Assessment Report for Proposal P242 at

<http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp242foodsforspecialmedicalpurposes/index.cfm>

It is expected that completion of work on Proposal P242 and the review of the infant formula standard will await receipt of Ministerial policy guidance currently under development.

4.5 Scope of Proposal P1006 – Remove commencement provision for certain special purpose infant formula

The original specific objectives of Proposal P1006 were to protect the public health and safety of infants with specific medical conditions through not unduly hindering the formulation and supply of special purpose infant formula.

It is not within the scope of Proposal P1006 to prepare a proposal to develop a specific new standard for special purpose infant formula, including formula for pre-term and low birth-weight infants as suggested by some submitters. As outlined in Section 4.3, Proposal P1006 is confined to considering Subdivision 2 of Division 3 of Standard 2.9.1 only, so does not include infant formula products formulated for premature or low birthweight infants. Development of a new standard for these products would potentially go beyond the original objectives and scope of this Proposal and is considered better placed to occur through the proposed future review of Standard 2.9.1.

4.6 Other issues raised in submissions

4.6.1 Completion of Policy guidelines and development of proposals.

One submitter noted that FSANZ's recommendation to delay the development of a proposal until completion of policy guidance was not applied to Proposal P306 – Addition of inulin/FOS (fructo-oligosaccharide) and GOS (galacto-oligosaccharide) to foods.

Proposal P306 arose in response to an unintended consequence of enforcement action in 2007 which led to confusion among the broader food industry. Proposal P306 was an interim measure restricted in its consideration to a particular issue to resolve the regulatory uncertainty at that time.

4.6.2 Other statutory objectives

A submitter also considered that P1006 has not given sufficient consideration to FSANZ's other statutory objectives including having regard to promotion of consistency between domestic and international food standards such as Codex. The recently revised CODEX Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (Codex Stan 72-1981) includes two sections: one for infant formula (Section A); and another for formulas for special medical purposes intended for infants (Section B). As there is specific cross references between both sections, it is more appropriate to consider the Codex Standard on Infant Formula Products, in addition to other overseas regulations, as part of the foreshadowed future review of Standard 2.9.1.

4.6.3 Audit of the Code

A submitter also noted that the audit of the Code recently conducted by FSANZ may not have picked up recommendations such as where a temporary standard was developed but a commencement provision was not included e.g. the recommendation to review the provisions for pre-term and low birth weight infants.

FSANZ is aware of the recommendation to review the provisions for pre-term and low birth weight infants. As described in Section 4.3.1 this is outside the scope of Proposal P1006 and would be considered within the future review of the infant formula Standard.

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 26 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, including consumers, the food industry and governments in Australia and New Zealand.

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.

Further consultation in September 2008 following release of the Reconsideration Assessment Report did not identify any further impacts on stakeholders as a direct result of the removal of the commencement clause from Clause 27. However, some parties identified potential impacts resulting from the broader issue of the lack of a specific standard for specialised infant formula products. However, this is considered outside the scope of P1006.

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

Re-affirming 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 re-affirming 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 as gazetted on 26 June 2008 would remain in place, until the issue is fully re-considered by a new proposal. Consequently, in the interim, the impacts would be similar to Option 1.

Option 2 would enable the preparation of a new (separate) proposal which could result in a further variation to the standard. The impact of any proposed change to or replacement with a further or different amendment to clause 27 would be considered as part of a new separate proposal once prepared. However, a further variation to the standard at this time could potentially result in additional costs should there be a need for further consideration and amendments at a later date following completion of Ministerial policy guidance and the review of Standard 2.9.1.

In considering the options available the FSANZ Act requires that FSANZ consider whether '*other measures, would be more cost-effective than the standard or variation*' originally made under urgency provisions (see Section 2.1). Under Option 2, the preparation of a new Proposal would be undertaken in the absence of Ministerial policy guidance and would also pre-empt the planned review of Standard 2.9.1. This could result in a new variation that may be inconsistent with policy guidance or the review of Standard 2.9.1. This could potentially require further consideration and amendments at a later date with additional costs for identified affected parties.

6.2.3 *Comparison of Options*

Option 1 would ensure that certain special purpose infant formula remains available to infants with specific medical conditions in Australia and New Zealand and provide clarity for all parties at this time. The need for any further revision of clause 27 would be considered more broadly within the review of Standard 2.9.1.

Although Option 2 would also maintain the supply of these infant formula products, preparation of a new proposal which could result in the development of a new variation or standard that is inconsistent with policy guidance and the review of Standard 2.9.1 may therefore create additional costs for identified affected parties. Overall, Option 1 is the most cost effective option, and provides a net benefit at this time.

6.2.4 Office of Best Practice Regulation

FSANZ consulted the Office of Best Practice Regulation (OBPR) during the Reconsideration Assessment of this Proposal. The OBPR plays a central role in promoting the Council of Australian Government's objective of improving the effectiveness and efficiency of regulation. Their advice concurred with FSANZ's assessment noting that the *proposed change to remove the commencement provision for subclause 27(2) of Standard 2.9.1, which has the effect of returning to the status quo as it existed before 20 June 2007, appears to be of a minor or machinery of government nature and to not substantially alter existing arrangements.*

OBPR advised that no further regulatory impact assessment was required in this case.

7. Consultation

7.1 Consultation at Initial Consideration

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. 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 receipt of Ministerial policy guidance on the intent of Part 2.9 – Special Purpose Foods of the Code; 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 undertook an audit of the Code and no other clauses were identified as requiring attention in a similar manner.

7.2 Consultation on Reconsideration of the urgent amendments

In reconsidering the variation made to clause 27 of Standard 2.9.1, FSANZ sought further public comment following release of the Re-consideration Assessment Report in September 2008.

During the consultation period of 15 September to 27 October 2008, FSANZ received seven submissions. A summary of submissions is at Attachment 2. Five submitters supported re-affirming the amendment made to clause 27 of Standard 2.9.1. Two jurisdictional submitters supported Option 2.

Key issues arising from the submissions are as follows and have been addressed where appropriate throughout this Report:

- The Code does not provide a detailed standard for either certain special purpose infant formulas, or formulas for pre-term and low birth weight infants to protect their health and safety.

Concern was expressed at the potential to delay the review of Standard 2.9.1 and such standard development, and also completion of Proposal P242 until Ministerial policy guidance is completed. It was recommended that work on special purpose infant formulas progresses outside of the work on Proposal P242.

- Special purpose infant formula can currently be sold directly to the public. However as they are intended to be used under medical supervision there may be grounds for restricted access e.g. available through pharmacies / hospitals only.
- The labelling provisions in Clause 28 do not apply to claims such as in an advertisement; or when the claim is of a more generic nature, or if a claim is not made at all.

In addition submitters' also noted that:

- FSANZ's recommendation to delay the development of a proposal until completion of policy guidance was not applied to Proposal P306 – Addition of inulin/FOS and GOS to foods;
- P1006 has not given sufficient consideration to FSANZ's other statutory objectives including having regard to promotion of consistency between domestic and international food standards such as Codex; and
- The audit of the Code recently conducted by FSANZ may not have picked up recommendations such as where a temporary standard was developed but a commencement provision was not included e.g. the recommendation to review the provisions for pre-term and low birth weight infants.

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 Decision

Decision

FSANZ re-affirms the urgent 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 re-affirming the amendment made to clause 27 of Standard 2.9.1 (see Attachment 1) as it:

- 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;
- provides certainty for consumers, industry and enforcement agencies on the regulatory status of special purpose infant formula; and
- provides net benefits to all affected parties and is more cost-effective than other measures at this time.

The preferred option would retain the variation to clause 27 of Standard 2.9.1 which came into effect at gazettal on 26 June 2008.

8.2 Implementation and Review

Following re-affirmation of the variation to the Code by the FSANZ Board, notification of the Board's decision will be made to the Ministerial Council. Subject to any request from the Ministerial Council for a review, the amendments to the Code with respect to Standard 2.9.1 would be retained as gazetted on 26 June 2008.

ATTACHMENTS

1. Variation to the *Australia New Zealand Food Standards Code* as gazetted on 26 June 2008.
2. Summary of Submissions received following the Reconsideration Assessment Report

Variation to the *Australia New Zealand Food Standards Code* as gazetted on 26 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 sunseting

[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.

P1006 - Summary of Submissions

The following two regulatory options were presented in the Assessment Report for the Reconsideration of 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 proposal which may result in the amendments made to clause 27 of Standard 2.9.1 being varied or replaced.

FSANZ received seven submissions in response to the Assessment Report, during the public consultation period of 15 September to 27 October 2008. Five submitters supported Option 1 with the remaining two submitters preferring Option 2. A summary of submitter comments is provided in the table below.

Summary of submitter comments

No.	Submitter	Submission Comments
Industry		
1.	<i>New Zealand Food Safety Authority</i> <i>Carol Inkster</i>	<p>Supports Option 2 – to prepare a new proposal.</p> <p>Timeframe Notes the 5-year temporary exemption sought by industry in 2002 was to enable FSANZ to develop regulation for these special purpose products within the exception period of 5 years.</p> <p>Notes the 2002 report includes ‘health professionals have stated that it might even be more important for the base formula of the product to comply with the new standard, as these consumers are the more vulnerable infants’ and ‘this period will allow ANZFA to develop a special standard for ‘foods for ‘special medical purposes’ that could include these highly specialized infant formula products’.</p> <p>Preferred option At Initial Consideration of P1006, NZFSA supported the draft variation as it was vital to maintain the supply of these products to infants. However, it was also signaled that a new proposal was NZFSA's preferred option.</p> <p>Does not accept FSANZ's reasoning for preferring Option 1 because:</p> <ul style="list-style-type: none"> • The original standard followed an extensive decade long review of IF. • It was ANZFA's clear intention to set compositional requirements for these products. • It is contrary to ANZFA's original intent to prolong the ‘temporary’ exemption for years beyond that envisaged. • The standard as varied carries over the lack of regulatory clarity as to the addition of substances like additives, nutritive substances such as prebiotics, ingredients, vitamins and minerals or other optional ingredients being used overseas or in the domestic market for healthy infants.

No.	Submitter	Submission Comments
		<ul style="list-style-type: none"> • The compositional standard does not go into sufficient depth for regulators to take enforcement action. ANZFA clearly intended for the standard for these products to be developed in more depth. • FSANZ must have regard for other statutory objectives e.g. the recently adopted CODEX standard on infant formula now provides extensive guidance for the regulation of infant formula for special medical purposes. P1006 does not refer to this in detail. Notes CODEX requires compliance with many of the base requirements for formula for healthy infants, except where modification is needed to meet the particular condition. Considers that was the intent of the clause that P1006 has removed. • Does not believe the Cost Benefit Analysis sufficiently addresses issues. While infants suffering from the specified conditions are guaranteed a supply of these products the Code does still not provide a detailed standard for either pre-term formulas or certain special purpose infant formulas to protect their health and safety. • Notes FSANZ 'proposes to undertake a review of the infant formula standard in relation to ...the regulation of special purpose infant formula'. However scope and timeframe yet to be determined. Envisages waiting on the completion of policy guidance on the intent of Part 2.9 before this review takes place and P242 is completed. Considers this work should not be held off any longer. Supports work on Special Purpose Infant Formula progressing outside P242. • Notes the FRSC Working Group on infant formula products is developing policy guidelines. However does not expect that these will cover detailed elements of any particular formula. Recommends standards development through a proposal could be initiated and progressed concurrently with the work of FRSC. The proposal is unlikely to be completed in advance of the FRSC guidelines. • A proposal should be developed as a priority. This was the intention of the 5-year temporary exemption for the requirements of these special purpose formula. • Considers formula for pre-term and low birth-weight infants should be included in a proposal. • Currently these products can be sold direct to the public, however they are intended to be under medical supervision so there may be grounds for restricted access e.g. only through pharmacies / hospitals. • Availability and access to these products could be addressed by FRSC and incorporated into the proposal at that time. • Not clear why FSANZ recommends delaying development of proposals until completion of policy guidance, when this was not applied to P306. Does not consider the different approach has been adequately explained particularly given the absence of real progress with this proposal over the last 6 years despite the clear intent of ANZFA and the Standard.

No.	Submitter	Submission Comments
		<p><i>Infant formula products formulated for premature or low birth weight infants.</i></p> <p>Refers to Supplementary Final Assessment Report for P93 with respect to infants with special nutritional requirements including pre-term and low birth weight infants, some of whom may require formula under P1006.</p> <p>After a 10-year review ANZFA proposed a temporary regulation for such formulas as insufficient resources were available to do the assessment within the Inquiry into Standard 2.9.1. It was recommended a new proposal be prepared to assess the safety and efficacy of formula prepared for pre-term babies and that the current specific regulation be replaced by a temporary general provision.</p> <p>A summary recommendation for Section 7.1 also included a provision to the effect that infant formula product may be specifically formulated to satisfy the needs of preterm or low birth-weight infants but in all other respect must comply with the standard infant formula products. The report noted this provision would provide temporary regulatory status for these foods and require manufacturers to be able to justify their variations from the general standard.</p> <p>Section 7.1 also recommended that ANZFA prepare a proposal to review provisions for safe formulas for preterm and low birth-weight infants within 5 years of draft Standard 2.9.1 being adopted.</p> <p>As this has not occurred since 2002, NZFSA makes 2 points:</p> <ul style="list-style-type: none"> • the review ANZFA recommended on pre-term and low birth-weight formulas is well overdue; and • the audit of the Code recently conducted by FSANZ may not have picked up recommendations such as this where a temporary standard was developed but a commencement provision was not included. <p>Suggests FSANZ might consider a process to ensure reviews noted in assessment reports occur within the timeframe so that 'temporary' standards do not acquire a permanency that was never intended.</p>
2.	<p><i>NSW Food Authority</i></p> <p><i>Bill Porter</i></p>	<p>Supports Option 2 – to prepare a new proposal</p> <p>However, support is contingent on amendments to Clause 28 to address a significant labelling anomaly.</p> <p>Urges FSANZ to expedite development of an appropriate standard.</p> <p>Clarity</p> <p>Considers the existing and proposed clauses are extremely vague. It is not clear whether Clause 27 allows the indiscriminate addition of ingredients, additive and nutrients not otherwise permitted by the standard. In requiring that 'in all other respects the products comply with the Division' creates substantial uncertainty as to which provisions in that Division still apply.</p> <p>Labelling</p> <p>Has major concerns with the present drafting of clause 28, in relation to labelling. Clause 28 requires specific statements to appear in the label where 'a label contains a claim...'. </p>

No.	Submitter	Submission Comments
		<p>This provision is defective in that it does not trigger these labelling requirements when the claim is made other than in a label, such as in an advertisement.</p> <p>Also noted the labelling requirements are not triggered when no claim is made at all, or when the claim is of a more generic nature.</p> <p>Suggests that Standard 2.9.1 be amended to prescribe the name required in the label for such infant formula. Alternatively, clause 28 should be amended to require the three statements on such infant formula irrespective of whether a claim is made.</p> <p>Medical supervision The report states that special purpose infant formula is 'designed to be used under medical supervision'.</p> <p>Notes there is nothing in the standard to prevent the sale of these products in the open market, or the use of such products in the home under no supervision whatsoever.</p> <p>Available on prescription Whilst availability on 'prescription only' may also provide a safeguard against inappropriate use, previous enquiries with the Therapeutic Goods Administration have indicated that the prescription process is not available for foods.</p> <p>Proposal P242 The Final Assessment Report of P242 specifically excludes special purpose infant formula from its considerations, and indicates that amendments to accommodate such formula will follow on from the finalisation of Food for Special Medical Purposes.</p> <p>Suggests that consideration of special purpose infant foods not be deferred until P242 is finalised.</p>
3.	<p><i>Dietitians Association of Australia</i></p> <p><i>Annette Byron</i></p>	<p>Supports Option 1 – to re-affirm the amendment made</p> <p>Agrees special purpose formula should conform to the base standard for healthy infants except where necessary to meet the particular needs of the infant with a special condition.</p> <p>Agrees it is vital for health and safety reasons that the ongoing availability and supply of these products is certain.</p>
4.	<p><i>Food technology Association of Australia</i></p> <p><i>Rob Richards</i></p>	<p>Supports Option 1 – to re-affirm the amendment made</p> <p>No further comment provided.</p>
5.	<p><i>Infant Formula manufacturers Association of Australia</i></p> <p><i>Janet Carey</i></p>	<p>Supports Option 1 – to re-affirm the amendment made</p> <p>Agrees there is a significant risk to the public health and safety of infants with special medical conditions should infant formula manufacturers be hindered in the supply of these special purpose products.</p>

No.	Submitter	Submission Comments
		Also agrees that the removal of a commencement provision in clause 27 of Standard 2.9.1 will provide certainty for consumers, industry and enforcement agencies on the regulatory status of special purpose infant formula.
6.	<p data-bbox="284 409 376 439"><i>Nutricia</i></p> <p data-bbox="284 472 421 533"><i>Melanie McPherson</i></p>	<p data-bbox="531 398 1193 427">Supports Option 1 – to re-affirm the amendment made</p> <p data-bbox="531 461 1366 551">Urges FSANZ to re-affirm this amendment to give confidence and security of product supply to those individuals requiring modified infant formula products.</p> <p data-bbox="531 584 1378 730">Considers it is imperative to consumers that manufacturers of these products, NOT be found to be in breach of the Code. As the additional regulatory work has not been completed at this time, it is essential that the amendment be confirmed and that the supply of the products not be impeded.</p> <p data-bbox="531 763 1358 837">Notes that FSANZ initially granted urgency, that MINCO approved the initial amendment as of 26 June 2008 and FSANZ received no objections to this amendment.</p>
7.	<p data-bbox="284 848 432 909"><i>Queensland Health</i></p> <p data-bbox="284 943 424 972"><i>Gary Bielby</i></p>	<p data-bbox="531 860 1193 889">Supports Option 1 – to re-affirm the amendment made</p> <p data-bbox="531 922 1378 1046">Considers this approach is necessary as it will provide regulatory clarity and maintain the supply and availability of special purpose infant formula. This will protect the public health and safety of infants with particular nutritional requirements.</p> <p data-bbox="531 1079 1378 1169">Does not consider it appropriate to prepare a new proposal while policy guidance is being developed on the intent of Part 2.9 - Special Purpose Foods and Standard 2.9.1 - Infant Formula Products.</p> <p data-bbox="531 1202 1366 1254">Also notes that other relevant work such as Proposal P242 - Foods for Special Medical Purposes is still not complete.</p>