

Regulatory Impact Statement: Policy Guideline for the Regulation of Infant Formula Products

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INTRODUCTION

Food Standards Australia New Zealand (FSANZ) develops standards for food sold in Australia and New Zealand. The Australia and New Zealand Food Regulation Ministerial Council (the Ministerial Council) oversees this work and provides the policy framework for FSANZ in the form of policy guidelines. FSANZ must ‘have regard’ to a range of considerations, including any relevant policy guidelines, when developing or reviewing food standards.¹

In light of recent developments in infant formula products, FSANZ has indicated an intention to review the relevant regulatory provisions.

To provide a policy setting for this work, a draft Policy Guideline has been prepared by the Food Regulation Standing Committee (FRSC) Working Group on Infant Formula Products to indicate the Ministerial Council’s high level expectations for the regulation of infant formula products. This is the first policy guideline covering these products.

It is difficult to fully assess the final regulatory impact of a Ministerial Council policy guideline, as the responsibility for developing the specific details of food standards lies with FSANZ. Therefore, this regulatory impact statement (RIS) provides a high level assessment of the potential impacts of changes to the regulation of infant formula products arising from the draft policy guideline, on the assumption that standards set by FSANZ will reflect the policy principles contained in the guideline.

BACKGROUND

Infants are one of the most vulnerable population groups. As a result of this vulnerability, there is a greater level of risk to be managed for infants compared to other population groups. In both Australia and New Zealand breastfeeding is recognised as the normal way to feed infants.² There is a significant body of evidence to show that breastfeeding has benefits to the infant and mother beyond simple nutrition, and is also associated with improved population health outcomes.³

The Australian National Health and Medical Research Council (NHMRC) *Dietary Guidelines for Children and Adolescents in Australia* describes the benefits of breastfeeding to infants and mothers and notes that ‘Australia has a long history of promoting and supporting breastfeeding in its public health policy.’ In November 2009, the Australian Health Ministers’ Conference endorsed the *Australian National Breastfeeding Strategy 2010-2015*. The objective of the strategy is to ‘increase the percentage of babies who are fully breastfed from birth to six months of age, with continued breastfeeding and complementary foods to twelve months and beyond.’⁴

Similarly, the New Zealand Government has funded the development of the National Breastfeeding Promotion Campaign ‘to improve breastfeeding rates and duration, especially

¹ Under section 18(2)(e) of the FSANZ Act 1991

² New Zealand Ministry of Health, *Guidelines on Health Infants and Toddlers*, May 2008, and NHMRC *Dietary Guidelines*

³ The Australian House of Representatives Standing Committee on Health and Ageing, *Best Start Report*, 2007, Section 3, p. 37..

⁴ Australian Health Ministers’ Conference 2009, *The Australian National Breastfeeding Strategy 2010-2015*. Australian Government Department of Health and Ageing, Canberra, p. 1.

for high-need groups, and Māori and Pacific peoples who have lower rates of breastfeeding than the non-Māori and non-Pacific population'.⁵

Given the health benefits of breastfeeding, policies are in place in Australia and New Zealand to reduce the barriers to breastfeeding. These include restrictions on the ways that breastmilk substitutes, such as infant formula, can be promoted to consumers.

However, for some infants, an infant formula product is necessary and may be the sole source of nutrition. Infant formula products must provide essential nutrients for normal growth and development. In addition, the potential impact for infants from the ingestion of unsafe or unsuitable food products is extremely high. Consequently, consumers have high expectations for the safety and suitability of infant formula products.

The less developed immune and gastrointestinal systems⁶ in infants require care to be taken in balancing the bio-availability of nutrients with the ability of the infant to digest them. For example, it is possible that a substance that is quite acceptable in the general food supply may be unsuitable for infants at certain levels. The inability of an infant to properly digest a food component may lead to stresses on other organs and associated negative health outcomes.

For the above reasons, infant formula products are some of the most closely regulated food products generally available to consumers.

The current regulation of infant formula products

Infant formula products sold and/or produced in Australia and New Zealand are regulated under Standard 2.9.1 'Infant Formula Products', of the Australia New Zealand Food Standards Code (the Food Standards Code).⁷ Standard 2.9.1 defines an infant formula product as 'a product based on milk or other edible food constituents of animal or plant origin which is nutritional adequate to serve as the principal liquid source of nourishment for infants.' An infant is defined as: 'a person under the age of 12 months'. Infant formula products include infant formula, follow-on formula, and other formulas for infants with special dietary needs.

Infant formula is a 'product represented as a breast milk substitute for infants and which satisfies the nutritional requirements of infants aged up to four to six months.' Follow-on formula is 'an infant formula product represented as either a breast-milk substitute or replacement for infant formula and which constitutes the principal liquid source of nourishment in a progressively diversified diet for infants aged from six months.'⁸

Standard 2.9.1 establishes the mandatory composition of infant formula products and requires that specific categories of substances proposed to be used in infant formula products are subject to pre-market approval by FSANZ. This takes the form of a general prohibition on the addition of vitamins, minerals, food additives or nutritive substances to infant formula unless specifically permitted in the Food Standards Code.⁹ Elsewhere in the Food Standards Code, there are prohibitions against using processing aids (Standard 1.3.3) and adding novel foods (Standard 1.5.1), foods derived from gene technology (Standard 1.5.2), and irradiated foods (Standard 1.5.3) unless specifically permitted.

⁵ See Ministry of Health: <http://www.moh.govt.nz/moh.nsf/indexmh/heha-national-breastfeeding-campaign#publications>

⁶ Mahan LK and Escott-Stump S. *Krause's Food, Nutrition, and Diet Therapy*. 11th edition. Saunders: Philadelphia.

⁷ In New Zealand, products solely for export can be exempted from the requirements of Standard 2.9.1 in order to meet importing country requirements. In Australia, the Food Standards Code does not apply to exports.

⁸ Australia New Zealand Food Standards Code, Standard 2.9.1 'Infant Formula Products', clause 1, p. 3.

⁹ See clause 6 of Standard 2.9.1

Labelling and advertising of infant formula products

In addition to standards for composition, Standard 2.9.1 also requires specific instructions for the use of infant formula products on the label, and prohibits specific representations on the label of infant formula products including:

- pictures of infants;
- pictures that idealise the use of infant formula products;
- the words ‘humanised’ or ‘maternalised’ or words of similar effect;
- words claiming the formula is suitable for all infants;
- information relating to the nutritional content of human milk;
- that an infant formula product is suitable for a particular condition, disease or disorder (except where specifically required by the standard); and
- references to the presence of any nutrient or nutritive substance (except in relation to the declaration of ingredients, provision of nutrition information, and for certain special purpose infant formula).

In addition to the prohibition of specific representations in respect to infant formula products, the Food Standards Code (in Standard 1.1A.2 – Transitional standard – health claims) prohibits ‘any claim for therapeutic or prophylactic action’ (Clause (3)(a)). Standard 1.1A.2 also prohibits:

- the word ‘health’ from being used in conjunction with the name of a food (Clause (3)(b));
- any representation or claim which could be interpreted as medical advice (Clause 3(c)); and
- reference to any disease or physiological condition (Clause 3(d)).

Furthermore, Standard 2.9.1 requires infant formula product to carry the following warning statement: ‘Breast milk is best for babies. Before you decide to use this product, consult your doctor or health care worker for advice.’ Many of the additional labelling restrictions for infant formula products were adopted to support the promotion of breastfeeding, and to protect consumers from being misled as to the relative merits of breastfeeding and formula feeding.

Australia and New Zealand are signatories to the World Health Organization’s Code of Marketing of Breast Milk Substitutes (1981) (the WHO Code). The WHO Code is primarily concerned with the marketing practices of infant formula product companies. The WHO Code’s provisions concerning mandatory labelling are given effect in Australia and New Zealand by Standard 2.9.1.

There are general legal provisions which affect the types of representations which may be made about food, including infant formula products. Section 52 of the *Trade Practices Act 1974* prohibits a corporation from engaging in misleading or deceptive conduct. Section 53 contains particular prohibitions on false or misleading representations. The enforcement of these provisions is the responsibility of the Australian Competition and Consumer Commission (ACCC). There are similar provisions in:

- the New Zealand *Fair Trading Act 1986*¹⁰ (which is administered by the New Zealand Commerce Commission);
- fair trading legislation in the States and Territories (administered by the relevant authorities in those States and Territories)¹¹; and
- food legislation in each of the States and Territories,¹² and in New Zealand.¹³

There are also provisions in the Australian *National Trade Measurement Regulations 2009* (‘the NTM Regulations’) which prohibit certain expressions. Regulation 4.29 of the NTM Regulations prohibits a representation about any ingredient or component of a product unless the representation can be tested for its truth by testing the product.

International standards

Australia and New Zealand have undertaken to seek consistency between domestic food standards and the international food standards developed by the Codex Alimentarius Commission (Codex). Codex has two standards that apply to infant formula products: Codex Standard 72-1981 (Infant formula and formula for special dietary uses) and Codex Standard 156-1987 (Follow-up formula). Codex Standard 72-1981 was revised in 2007. The Codex standards are the basis for international trade in infant formula products, and include provisions establishing the essential composition of infant formula products, and providing for the addition of ‘optional ingredients’. Standard 2.9.1 is largely consistent with the Codex standards.

Regulation in comparable markets

The largest global producers of infant formula products are the European Union (EU) and the United States (US). The International Association of Infant Formula Manufacturers notes that North America and Western Europe are the principal consumers of infant and baby food, because of their purchasing power and demand for product convenience.¹⁴ Regulatory requirements in these areas are therefore likely to provide the framework for product development and have the greatest influence on incentives for innovation.

US regulations

Infant formula products are regulated in the US by specific legislation and regulations that set out the essential nutrient composition of infant formula. Other substances added to infant formula need to be approved as either a food additive or regarded by US Food and Drug Administration (USFDA) as Generally Recognised as Safe (GRAS). For a substance to be recognised as GRAS, there must be a consensus among qualified experts that the scientific data and information support the safety of the substance under the conditions of intended use. Manufacturers apply for GRAS status by providing comprehensive supporting documentation of safety to the USFDA for their evaluation and decision of no objection.

For a new or modified infant formula, the USFDA should be notified at least 90 days before marketing. The notification includes evidence that the formula will provide adequate nutrition for infants to thrive. Depending on the modification, the notification may contain

¹⁰ See particularly ss 9 and 13.

¹¹ For example, the *Fair Trading Act 1992* (ACT), s 13.

¹² See s 14 of the Model Food Provisions (Annex A to the *Food Regulation Agreement*)

¹³ See s 10 of the New Zealand *Food Act 1981*.

¹⁴ “About the Infant Food Industry” International Association of Infant Food Manufacturers, 2002

clinical testing results that measure growth and development, acceptability and availability of certain nutrients.¹⁵

EU regulation

In EU Member States, infant formula products are regulated under national legislation giving effect to European Commission (EC) Directive 2006/141/EC. For ‘optional ingredients’, as well as an assessment of safety, Article 5 of the EC Directive requires that ‘suitability for the particular nutritional use by infants.... be established by generally accepted scientific data.’ Furthermore, the Directive provides that ‘such suitability shall be demonstrated through a systematic review of the available data relating to expected benefits and to safety considerations as well as, where necessary, appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.’¹⁶ While the text of the EC Directive refers specifically to the ‘suitability for the particular nutritional use by infants’ of a substance, supported by ‘a systematic review of the available data’, the practical effect of the provision (as seen in a recent assessment concerning the potential addition of the substance lutein to infant formula products) is that the consumption of a substance by infants must be demonstrated to have clear link to a specific health benefit for infants if it is to be approved for use in infant formula products in the EU.¹⁷

The EC Directive also establishes that ‘it is appropriate to set out specific conditions for the use of nutrition and health claims concerning infant formulae’ and notes that it is ‘necessary ... to define the conditions under which nutrition and health claims are authorised, and to establish a list of authorised claims.’¹⁸ A list of authorised nutrition and health claims is set out in Annex IV of the Directive.

The regulatory system for infant formula products in the EU presents two key differences to the US and the Australia/New Zealand systems: the requirement to demonstrate benefit, and the ability to make prescribed claims where those claims have been substantiated. To date, this difference has not had a significant impact on the trade in infant formula products between the EU and Australia/New Zealand. A significant proportion of infant formula products available in Australia and New Zealand originate from companies based in the EU.

Market Analysis

As noted above, the Australian and New Zealand Governments recognise breastfeeding as the normal way to feed infants. However, there are some situations where infants are not able to be breastfed. In such situations, infant formula should be used.

In 2008 the Longitudinal Study of Australian Children reported that 18 per cent of 1 month old infants were fed infant formula only, with 11 per cent receiving a combination of breastmilk and infant formula.^{19, 20} At three months of age, 53 per cent of infants were fed ‘non-breastmilk’, which may include both infant formula products and complementary foods.

¹⁵ Further information is provided at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/InfantFormula/ucm056524.htm>

¹⁶ EC Directive 2006/141/EC, Article 5. Available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:401:0001:0033:EN:PDF>

¹⁷ Scientific Opinion of the Panel on Dietetic Products Nutrition and Allergies on a request from the European Commission on the ‘suitability of lutein for the particular nutritional use by infants and young children’. *The EFSA Journal* (2008) 823, 1-24. Available at: <http://www.efsa.europa.eu/en/scdocs/scdoc/823.htm>

¹⁸ EC Directive 2006/141/EC, (26)

¹⁹ The Australian House of Representatives Standing Committee on Health and Ageing, Best Start Report, 2007, p. 7

A similar pattern is discernible in the New Zealand statistics, in 2007, 19 per cent of infants were fed infant formula only at six weeks, and 41% of infants fed infant formula products at six months of age.²¹

In 2008, the total live births for Australia and New Zealand were 296,600²² and 64,500²³ respectively. This means that approximately 56,240 Australian and 12,255 New Zealand are fed infant formula within the first month of life, with infant formula comprising a part of approximately half of all infants' diets by six months of age.

There are several companies marketing and, to varying degrees, manufacturing and/or importing infant formula products in Australia and New Zealand. Those companies include Bayer, Bellamys, Dairy Goat Co-operative (N.Z.) Ltd, Fonterra, Heinz Watties, Infant Formula Australia, Nestlé, Nutricia, Snowbrand, Tatura, and Wyeth.

Below are statistics describing the domestic and export market for infant formula products in Australia and New Zealand:

	Value	
Domestic consumption (2009)	Australia	A\$132.8 million
	New Zealand	NZ\$39.81 million ²⁴
Imports (2008)	Australia	Data not available
	New Zealand (value for duty)	NZ\$4.26 million ²⁵
Exports (2008)	Australia	Data not available
	New Zealand (FOB)	NZ\$192.20 million ²⁶

While data is not available for total imports and exports of infant formula products for Australia, indicative figures provided by Australian Customs to FSANZ show that a majority of infant formula products are imported to Australia from the EU or from New Zealand.

In addition, a retail survey conducted for Western Australia (WA) Health showed that of 62 products surveyed, 34 were imported from the EU, 16 from New Zealand, and two from other countries. The remaining seven products were produced in Australia.²⁷

²⁰ Australian Institute of Family Studies. Growing Up in Australia: The Longitudinal Study of Australian Children, Annual Report 2006-2007. 2008. Cited at: <http://www.aifs.gov.au/growingup/pubs/ar/ar200607/index.html>

²¹ National Breastfeeding Advisory Committee, National Strategic Plan of Action for Breastfeeding 2008-2012, New Zealand Ministry of Health, March 2009, p. 27.

²² Australian Bureau of Statistics, Births: Australia 2008, release 3301.0

²³ Statistics New Zealand

²⁴ Source: ACNielsen, 2009 figures

²⁵ Statistics New Zealand, import figures for tariff code 1901100900: Food preparations; of flour, meal, starch, malt extract or milk products, (not containing cocoa), for infant use, put up for retail sale, January-December 2008

²⁶ Statistics New Zealand, export figures for tariff code 1901100900: Food preparations; of flour, meal, starch, malt extract or milk products, (not containing cocoa), for infant use, put up for retail sale, January-December 2008.

²⁷ Western Australia Health, Impact of food labelling on Consumer food Choice Project -Infant Formula Case Study Topline Report, December 2008, p. 4

Product development

Infant formula product companies invest significant resources in product development and innovation. Information provided in confidence to the FRSC Working Group by a number of infant formula product companies indicates that two to four per cent of annualised sales are spent on research and product development.

‘Standard’ and ‘premium’ infant formula products

Infant formula products are generally positioned as either ‘standard’, or ‘premium’ (‘Gold’, ‘Plus’, etc.). Both ‘standard’ and ‘premium’ formulas meet the essential composition requirements as set out in the Standard 2.9.1, but ‘premium’ formulas contain additional or ‘value added’ ingredients. The price difference between ‘standard’ and ‘premium’ formulas can be significant. A survey conducted for Western Australia Health indicated that cost of infant formula products per 900g container range from A\$12.95-\$35.95.²⁸ An informal survey at a New Zealand supermarket indicated that the average price difference between products positioned as ‘standard’ and ‘premium’ may be estimated at NZ\$6.²⁹

STATEMENT OF THE PROBLEM

The existing regulatory regime for infant formula products is generally considered adequate in managing most known safety risks to infants associated with the use of these products.

However, recent developments in the composition and marketing of infant formula products have revealed a gap in the current regulations that was not anticipated at the time the regulations were developed.

As the essential nutritional composition of infant formula products is well established internationally and has not substantially changed for over a decade, the limitations with the current regime are most clearly seen in relation to the addition of new ‘optional’ substances to infant formula products.

The FRSC Working Group has identified two problems in relation to the current regulatory regime, and its treatment of new substances.

The problems are:³⁰

1. Incomplete regulatory oversight of the addition of substances to infant formula products. Some substances can currently be used in infant formula products without pre-market safety assessment. This is primarily an issue of regulatory design with implications for managing health and safety risks to infants.
2. Substances may be added to infant formula products with the intention of providing a nutritional or health benefit to the infant, but there is no process to substantiate whether those substances have a role in normal growth and development. A substance’s role in normal growth and development is substantiated where there is evidence to link appropriate physiological, biochemical and/or functional measures of the substance’s activity to specific health outcomes for infants, in infancy, childhood or later life. This

²⁸ Ibid., p. 4

²⁹ Informal survey conducted by NZFSA at New World, Willis Street, Wellington, 18 January 2010

³⁰ In the Policy Options Consultation Paper on the Regulation of Infant Formula Products, three problems were identified and described as: 1. a lack of regulatory clarity; 2. a lack of regulatory oversight on the addition of ingredients used in the general food supply; and 3. a need to address ‘health benefit’. Following consultation, it became clear that problems 1 and 2 were different aspects of the same problem, and so are now described as a single problem.

issue has implications for addressing the potential for risks to infants associated with the use of unnecessary substances in infant formula products.

Discussion of the problems is set out below.

1. Incomplete regulatory oversight of the addition of substances to infant formula products.

As noted above, Standard 2.9.1, and the Food Standards Code in general, require the pre-market approval by FSANZ of all nutritive substances, novel foods, food additives, and processing aids proposed to be used in infant formula products. In order to be used in infant formula products, such substances must be listed in the Food Standards Code for that specific use.

However, under the current provisions of Standard 2.9.1, food that falls outside these prohibitions may be added to infant formula. Clause 10(3) of Standard 1.1.1 provides that ‘in cases where no specific foods are authorised for addition in a standard, any other food or anything that may be lawfully added to that food may be added.’

Standard 2.9.1 includes a general expectation (in the form of the definition of infant formula product) that the constituents of infant formula will contribute to a product that is ‘nutritionally adequate to serve as the principal liquid source of nutrition for infants.’ This means that while most ‘general’ foods and substances (i.e. those outside the categories listed above) that do not have a history of safe use in infant formula products are unlikely to be used in these products, there is no explicit restriction on their use. There is therefore potential for substances to be used in infant formula products that have not been shown to be ‘nutritionally adequate’, either through having a history of safe use in infant formula products in Australia and New Zealand, or being subject to pre-market approval by FSANZ.

This appears to be an oversight in the design of the existing regulatory framework. It is inconsistent for there to be a pre-market assessment requirement for most types of substances used in infant formula products, while others, which may have a comparable degree of physiological, biochemical or functional effect, are not subject to similar assessments.

It is highly unlikely that an infant formula company would introduce a product to market that risked harming infants. There are clear provisions in food legislation against the use of substances that might be unsafe for the intended consumer. However, due to the vulnerability of infants, and the likely use of infant formula products as the sole source of nutrition, any failure in deterrent, whether commercial, or ethical, would result in an outcome that is unacceptable to the public.

For these reasons, the model adopted in the development of the current regulation is based on pre-market safety approval.

The use of a pre-market approval process is broadly consistent with the approaches taken in both the EU and US. The gap in the current regulatory arrangements in Australia/New Zealand identified above means that the level of regulation is potentially less than in these markets.

Although it is unlikely that an infant formula manufacturer in Australia/New Zealand would introduce a product to market that poses an unacceptable risk to infants, where a pre-market approval step is not taken, there remains uncertainty for regulators and public health practitioners, as to the true level of risk. The potential health and social costs of unintentionally exposing infants to a hazard in infant formula products is very high. Given this potential cost, uncertainty as to the true level of risk associated with a substance may be deemed unacceptable, and result in regulatory action. Interpretative contests with regulators arising from a lack of regulatory clarity over which substances should be subject to regulatory

approval can be costly for both industry and regulators. Such contests can be avoided by making the regulatory provisions clear.

- 2. Substances may be added to infant formula products with the intention of providing a nutritional or health benefit to the infant, but there is no process to substantiate whether those substances have a role in normal growth and development.*³¹

Advances in food technology have increased the possibility that applications will be made to add ‘optional’ substances to infant formula products with the intention of providing health benefits to infants, and to bring the composition of infant formula closer to that of breastmilk. Under the existing regulations, if such substances are subject to pre-market approval by FSANZ, they are assessed in line with FSANZ’s objectives, the first of which is the ‘protection of public health and safety’. Together with safety, FSANZ considers evidence for the physiological, biochemical and functional effects of the substance in infant physiology and bases any approvals on this assessment. However, the approval decision is based on available evidence and does not require the substantiation of a link between those effects and specific health outcomes for the infant in infancy, childhood or later life (defined for the purposes of this paper as the substance’s ‘role in normal growth and development’). An illustrative example of such a link may be found in the relationship between the presence of antibodies in blood (a biochemical marker or measure), and their established role in building immunity to disease (a positive health outcome). Where evidence for this link exists, the physiological, biochemical or functional measure can be used as an indicator of health outcome.

Most substances currently permitted for use in infant formula products are used to meet the mandatory compositional requirements and fulfil a clear role in the normal growth and development of infants, such as essential vitamins and minerals. It is on this basis that the essential composition of infant formula products is prescribed in Standard 2.9.1, and in the international Codex standard.

There are several ‘optional’ substances currently permitted for use in infant formula products, including long chain polyunsaturated fatty acids (e.g. omega 3 and 6), lutein, oligosaccharides, and nucleotides. While there is some evidence to suggest that these substances may have roles in normal growth and development, the evidence is by no means convincing.^{32, 33, 34}

Innovation in infant formula product development is primarily focused on replicating the normal composition of breastmilk. Comparability with breastmilk is also a consideration in the FSANZ pre-market assessment process. However, evidence for the precise role of many of the substances ordinarily found in breastmilk is either not available or is inconclusive.³⁵ While it is important that the use of infant formula products leads to health outcomes for

³¹ A substance’s role in normal growth and development is substantiated where there is evidence to link appropriate physiological, biochemical and/or functional measures of the substance’s activity to specific health outcomes for infants, in infancy, childhood or later life. This issue has implications for addressing the potential for risks to infants associated with the use of unnecessary substances in infant formula products.

³² The Cochrane Collaboration. Simmer K, Patole SK, Rao SC. Longchain polyunsaturated fatty acid supplementation in infants born at term (Review). 2008. Cited at <http://www.thecochranelibrary.com>

³³ Life Sciences Research Office Report: Assessment of Nutrient Requirements for Infant Formulas. The Journal of Nutrition: Supplement. 2008.

³⁴ European Food Safety Authority ‘Safety, bioavailability and suitability of lutein for the particular nutritional use by infants and young children[1] - Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies’, October 2008. Available at <http://www.efsa.europa.eu/en/scdocs/scdoc/823.htm>

³⁵ Riordan J. Breastfeeding and Human Lactation 3rd Edition. Jones and Bartlett Publishers. 2004

formula fed infants that are as close as possible to those of breastfed infants, this may not be achieved by simply replicating the composition of breastmilk. Complicating factors exist, such as the differences in breastmilk micronutrient composition between geographical regions.³⁶

In a 2003 report that informed the development of the revisions to the Codex Standard, an international expert group coordinated by the European Society of Pediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN)³⁷ stated that ‘data on the composition of human milk of healthy, well-nourished women can provide some guidance for the composition of infant formulae, but gross compositional similarity is not an adequate determinant or indicator of the safety and nutritional adequacy of infant formulae.’ The international expert group recommended that ‘the adequacy of infant formula composition should be determined by a comparison of its effects on physiological (e.g. growth patterns), bio-chemical (e.g. plasma markers) and functional (e.g. immune responses) outcomes in infants fed formulae with those found in populations of healthy, exclusively breast-fed infants.’

The international expert group concluded that ‘infant formulae should only contain components in such amounts that serve a nutritional purpose or provide another benefit. The inclusion of unnecessary components, or unnecessary amounts of components, may put a burden on metabolic and other physiologic functions of the infant.’³⁸ Unnecessary components in the infant’s diet that are not utilised by the body are generally excreted, often as solutes in urine but can have an impact. Such impacts are well known. For example, Mahan and Escott-Stump note that since water in the diet is limited and the infant’s ability to concentrate urine is also limited (up to around six weeks),³⁹ concentrations of solutes at excessive levels can place a burden on the infant’s renal function. While healthy infants are able to adequately process solutes,⁴⁰ the ESPGHAN international expert group points out that ‘the need to excrete any additional solutes will reduce the margin of safety, especially under conditions of stress, such as fever, diarrhoea or during weight loss.’⁴¹ The risks to the infant are therefore increased.

The potential for unanticipated negative health consequences associated with the inclusion of an increasing number of ‘optional substances’ in infant formula products that are not essential to infant nutrition was a concern cited in submissions by the majority of government, public health and consumer submitters..

There has only been one substance subject to pre-market approval in Australia/New Zealand to date that fits the problem definition discussed here. However, it is likely that advances in food technology will see new substances come forward as candidates for inclusion in infant formula products. Potential examples include immunoglobulins and cholesterol,⁴² both of which are found naturally in breastmilk.

³⁶ Jensen RG. Handbook of Milk Composition. Academic Press: San Diego, California. 1995

³⁷ ESPGHAN is an eminent paediatric research organisation in Europe and has conducted extensive reviews of the literature in respect to infant formula products and infant nutrition. The FRSC Working Group has been advised by Australian and New Zealand experts in the field that the advice of ESPGHAN is highly regarded.

³⁸ Koletzko et al. Global Standard for the Composition of Infant Formula: Recommendations of an ESPGHAN Coordinated International Expert Group. Journal of Pediatric Gastroenterology and Nutrition. 2005; 41: 586.

³⁹ Mahan LK and Escott-Stump. Krause’s Food, Nutrition and Diet Therapy 11th edition: Chapter 8, Nutrition During Infancy p.215. 2004. Saunders: USA.

⁴⁰ Derived from advice provided to the FRSC Working Group by FSANZ

⁴¹ Koletzko et al. op cit. p. 586.

⁴² It has been hypothesised that the presence of cholesterol in breastmilk is associated with long term benefits for infants’ cardiovascular health. See, Riordan J. *Breastfeeding and lactation*. 3rd edition. Jones and Bartlett Publishers: Massachusetts

The problem confronting regulators is to ascertain the appropriate level of caution to apply to consideration of new substances for use in infant formula products. The accumulation of optional substances in infant formula may have unanticipated health consequences for infants, but it is impossible to predict the degree of risk.

Given the particular vulnerability of infants it may be appropriate to consider whether the addition of optional substances should be limited to those that have a substantiated benefit in terms of normal growth and development.

Infant formula product companies invest significant resources in product development. Clarifying policy on the assessment of beneficial effects in regulatory approvals is important to ensure regulatory certainty for investments in product development.

OBJECTIVES

It should be noted that a Policy Guideline for the Regulation of Infant Formula Products will restate the existing assumptions underpinning Standard 2.9.1, as well as potentially proposing new policy in specific areas. If new policy is included, it will be to address the problems identified above.

The overall objectives for a Policy Guideline on the Regulation of Infant Formula Products are:

1. to protect the health and safety of infants;
2. to ensure the composition of infant formula products achieves a health outcome for formula-fed infants that is as close as possible to the health outcome of populations of exclusively breastfed infants;
3. to ensure the composition of breastmilk is used as a primary reference for the composition of infant formula products;
4. to ensure that infant formula products provide appropriate levels of substances that are essential for normal growth and development;
5. to ensure that infant formula products are not represented as equivalent or better foods than breastmilk;
6. to ensure that the representation of infant formula products does not mislead consumers;
7. to ensure that the representation of infant formula products enables appropriate and safe use; and
8. to provide a regulatory environment that enables innovation that benefits those infants who need infant formula products.

STATEMENT OF POLICY OPTIONS

It is assumed that the existing regulatory arrangements will be maintained with respect to all areas where problems have not been identified. Given the vulnerability of infants, and the role of infant formula products in their diets, a reduction in the level of regulation is not considered a viable option and is not discussed further.

The proposed options have evolved since the development of the Policy Options Consultation Paper. That paper proposed five possible options, which are summarised below:

Option 1: All ingredients that are proposed to be used in infant formula products require a pre-market assessment, and demonstrate a health benefit through effectiveness studies.

Option 2: All ingredients that are proposed to be used in infant formula products require a pre-market assessment, and demonstrate a health benefit through efficacy studies.

Option 3: All ingredients that are proposed to be used in infant formula require a pre-market assessment by FSANZ.

Option 4: Specified categories of ingredients proposed to be used in infant formula products require a pre-market assessment by FSANZ for the use in infant formula products. Specified categories of ingredients may include food additives, processing aids, novel foods and nutritive substances. This option most closely resembled the status quo.

Option 5: Any ingredients that can be used in the general food supply may be used in infant formula products without the requirement for a pre-market assessment by FSANZ specific to the use of that ingredient in infant formula products.

The consultation process revealed that requiring a determination of the ‘health benefit’ of a substance to the infant with evidence of ‘effectiveness’ or ‘efficacy’ was impractical. It would severely constrain innovation, as ethical considerations would make the generation of sufficient evidence to demonstrate effectiveness or efficacy almost impossible. In addition, it would establish the pre-market assessment barrier at a much higher level than is contemplated by the relevant Codex standards. Option 5 was also viewed as untenable by nearly all submitters, as the risks to infants as a vulnerable population are too high to permit a form of self-regulation.

Elements of the options proposed in the Policy Options Consultation Paper are carried through into the policy options explored below. They include the application of a pre-market approval requirement to all substances that do not have a history of safe use in infant formula products in Australia and New Zealand, and the substantiation of a substance’s role in the normal growth and development of infants as a key consideration in pre-market approval.

The proposed options are:

Option 1 (base case)

- The Ministerial Council would not issue a Policy Guideline on the Regulation of Infant Formula Products. This option maintains the status quo.

Option 2

- The Ministerial Council would issue a Policy Guideline requiring the pre-market assessment of all substances without a history of safe use in infant formula products in Australia and New Zealand. Those substances currently used or specifically permitted in infant formula products in Australia and New Zealand would be considered to have a ‘history of safe use’ at the levels currently used, and so would not be subject to further regulatory assessment.

- Pre-market assessment would include consideration of the physiological, biochemical and functional effects of a substance in infants, but would not extend to substantiating a link between those effects and a specific health outcome for infants in infancy or childhood (i.e. the role of the substance in normal growth and development).

Option 3

- The Ministerial Council would issue a Policy Guideline (as in Attachment 1) requiring the pre-market assessment of all substances without a history of safe use in infant formula products in Australia and New Zealand (as in option 2 above).
- The Policy Guideline would also clarify that the substantiation of a substance's role in normal growth and development should be a key consideration in the pre-market approval process. A substance's role in normal growth and development would be substantiated where there is appropriate evidence to link the physiological, biochemical and/or functional effects of the substance in the infant to specific health outcomes for infants, in infancy or childhood. This link would be limited to infancy and childhood as it is considered that there are too many variables in life course between infancy and later life that confound such links. It would be FSANZ's responsibility to determine the level of evidence necessary to substantiate a substance's role in normal growth and development.

IMPACT ANALYSIS

The policy options outlined above primarily concern the process for introducing new substances into infant formula products produced or sold in Australia and New Zealand. It is therefore important to set out the existing regulatory costs for introducing such substances.

Introducing a new substance to infant formula products in Australia and New Zealand

Persons (including businesses and organisations) can apply for the development of permissions in the Food Standards Code to add vitamins, minerals, or nutritive substances (as well as food additives, processing aids, foods derived from gene technology, novel foods, and irradiated foods) to infant formula products. Applications can be 'paid' or 'unpaid'.

Both paid and unpaid applications are associated with a statutory timeline of 9-12 months. Assessment of a paid application commences immediately, while an unpaid application is placed in a queue. The statutory timeline for an unpaid application only comes into effect once work on the application commences.

The costs to an applicant are:

- costs for the preparation of the application (compiling necessary documents, research findings, and information), estimated at A\$100,000;⁴³
- fee for a paid application (in the upper band of FSANZ's general procedure): A\$112,000;
- the cost of conducting research to demonstrate the safety of the substance for use in infant formula products: A\$400,000.⁴⁴

⁴³ This figure was provided by an infant formula product company in-confidence to the FRSC Working Group

⁴⁴ This figure was provided to the FRSC Working Group in confidence by an infant formula product manufacturer, and is based on the estimated cost of a clinical trial with a sample of 20 infants. The appropriateness of this estimate was confirmed by academic experts in infant nutrition consulted by the Working Group.

- the opportunity cost in waiting for a pre-market assessment to be undertaken. This cost is likely to be larger for unpaid applications.

The total cost to an applicant for a paid application is therefore estimated to be A\$612,000.⁴⁵

There have been relatively few applications to use new substances in infant formula products since the current regulations were put in place in 2002: five in total, less than one per year. In addition, over the last seven years, there has only been one example of a combination of substances used in infant formula products where it was unclear as to whether that particular combination of substances, either individually or as a combination, should be subject to pre-market assessment.⁴⁶

Analysis of options

The regulation of infant formula products affects:

- Consumers (primarily infants and their carers);
- Industry (product manufacturers, wholesalers, exporters, importers, and retailers);
- Governments (the States, Territories and Commonwealth of Australia, and New Zealand); and
- Public health professionals and organisations (doctors, dietitians, public health organisations).

The potential impacts of the policy options outlined above are analysed relative to how well they address the problems identified and support the policy objectives.

Option 1 (base case)

This option maintains the status quo. Therefore it will not give rise to any additional costs or benefits. The costs and risks associated with the existing regulatory arrangements have been identified in the statement of the problem above.

Option 2

Benefits

Consumers	<ul style="list-style-type: none"> • Addresses the gap in the current regulatory arrangements identified in problem 1,⁴⁷ and in doing so, supports policy objective 1.⁴⁸ • Reduces risks to infants associated with consumption of infant formula products that contain substances that have not been subject to an adequate safety assessment. The FRSC Working Group has been unable to quantify the avoided social cost of infant injury or mortality arising from a
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⁴⁵ The figure provided is indicative. There is likely to be great variability in the actual cost of applications. Most of the cost is associated with research. The costs for research may either not be borne by the applicant (e.g. may be publicly available in the literature), or may be borne by the applicant but also used for regulatory approval in other markets, in which case the total research cost should not be attributed to regulatory requirements in Australia/New Zealand. There is also the possibility that FSANZ will require further research to be conducted, which will add to the cost of the application.

⁴⁶ See FSANZ Proposal P306 – Addition of inulin / FOS & GOS to food.

⁴⁷ Problem 1 is: Incomplete regulatory oversight of the addition of substances to infant formula products. This is primarily an issue of regulatory design with implications for managing health and safety risks to infants.

⁴⁸ To protect the health and safety of infants

	compositional hazard in infant formula products. However, the ‘value of statistical life’ (VOSL) ⁴⁹ figure developed by the New Zealand Transport Agency (NZTA) is illustrative: The VOSL for 2008 (fatality or permanent disability) was NZ\$3.35 million, while the average social cost of a serious injury was estimated at NZ\$591,000. ⁵⁰
Industry	<ul style="list-style-type: none"> • Reduces financial and legal risks associated with conflicting interpretations about which substances are subject to a pre-market assessment requirement. A recent case of conflicting interpretations is likely to have cost the company involved hundreds of thousands of dollars.
Government	<ul style="list-style-type: none"> • Reduces financial and legal risks associated with conflicting interpretations about which substances are subject to a pre-market assessment requirement. In a recent case, a regulator spent more than A\$1 million on enforcement action based on an interpretation of the existing regulatory provisions. • Reduces the potential for ad-hoc proposals to be raised to address conflicting interpretations and thus ensures a pre-market assessment approach consistent with international and counterpart market standards and expectations. • It would reduce the potential that ad-hoc proposals are raised to address conflicting interpretations thus ensuring a pre-market assessment approach consistent with international and counterpart market standards and expectations. The costs of proposals are borne by FSANZ, and, depending on the number of staff hours invested may be comparable to the cost of a paid application: up to A\$112,000. • Reduces political risks by ensuring there are no ‘loopholes’ in regulation.
Public health professionals	<ul style="list-style-type: none"> • Provides confidence to public health professionals that all of the substances used infant formula products in Australia and New Zealand either have a history of safe use, or have been subject to a pre-market approval.

Costs

Consumers	<ul style="list-style-type: none"> • Cost of pre-market assessment likely to be reflected in increased prices for products containing new substances (however, such products are usually positioned as ‘premium’, and so would normally attract a higher price anyway).
Industry	<ul style="list-style-type: none"> • Increases the cost of innovation by extending the pre-market approval

⁴⁹ ‘The cost of pain and suffering due to a loss of an unidentified life from a road crash is estimated by the amount of money the New Zealand population would be willing to pay for a safety improvement that results in the expected avoidance of one premature death.’ From, New Zealand Ministry of Transport, The Social Cost of Road Crashes and Injuries, June 2006 Update.

⁵⁰ New Zealand Ministry of Transport, The Social Cost of Road Crashes and Injuries, June 2008 Update, p. i. Available at [http://www.transport.govt.nz/research/Documents/Social%20Cost%20June%202008%20update%20\(final\).pdf](http://www.transport.govt.nz/research/Documents/Social%20Cost%20June%202008%20update%20(final).pdf)

	<p>requirements. The estimated total cost of pre-market assessment is between A\$100,000⁵¹ for an unpaid application for a substance with safety approval in a comparable market (the EU or US) where similar evidence for safety is required to support pre-market approval, and A\$612,000⁵² for a paid application from Australian or New Zealand company producing solely for the domestic/trans-Tasman market. There are relatively few infant formula product traded solely on the domestic/trans-Tasman market. In addition more than half of all infant formula products sold in Australia are sourced from Europe. Therefore, it may be possible to identify an indicative figure for the cost increase at the mid-point of A\$300,000 per application (assuming a paid application).</p> <ul style="list-style-type: none"> • There have been five applications since 2002, and one instance where there was confusion about whether a substance should be subject to pre-market assessment. If a similar frequency prevails over the next eight years, the additional total cost to the industry of this option will be the cost of one pre-market assessment: an indicative A\$300,000 (as above). • If the extension of the pre-market approval requirement leads to an increase in unpaid applications, the queue for assessment of those applications would become longer. This has the potential to increase the opportunity costs (foregone revenue, etc.) for any applicants who have lodged unpaid applications with FSANZ.
Government	<ul style="list-style-type: none"> • Reduce potential economic gains to Australia and New Zealand because of reduced product innovation on the domestic market (NB. exports must meet importing country requirements, and so domestic policy does not necessarily affect export trade).
Public health professionals	<ul style="list-style-type: none"> • Does not address concerns of experts in the field of infant nutrition that only substances with substantiated roles in normal growth and development should be permitted in infant formula products.

Consistency with international and overseas market standards

- This option would result in regulations that are consistent with international standards and overseas market standards. The level of regulation would be slightly higher than the US (in so far as the addition of all substances without a history of safe use would be subject to a regulatory assessment, rather than a combination of GRAS approval and pre-market notifications for new formulations), but would be less than the EU in respect to determining the role in normal growth and development of substances proposed to be used in infant formula products.

Option 3

Benefits

⁵¹ This cost is the cost of preparing the application, and is based on estimates provided by one infant formula product company.

⁵² This cost is comprised of the cost of preparing the application (A\$100,000), the FSANZ application fee (A\$112,000), and research costs to demonstrate safety (estimated by one infant formula product company at A\$400,000).

Option 3 incorporates, and would have the same, benefits as option 2 in terms of closing the existing regulatory gap identified in problem 1,⁵³ and would also address the associated risks to consumers, industry and regulators. The additional benefits of option 3 over option 2 are outlined below.

Consumers	<ul style="list-style-type: none"> • Reduces potential risks to infants associated with the accumulation of ‘optional’ substances in infant formula products by limiting these to substances with substantiated roles in normal growth and development. • Provides confidence to caregivers that the ‘optional’ substances used in infant formula products have substantiated roles in normal growth and development.
Industry	<ul style="list-style-type: none"> • It would provide clarity to industry on governments’ expectations that substances used in infant formula products should have a role in normal growth and development. There have been delays in the regulatory approval process as result of policy debate on this issue. • Regulations developed under this option could be used by exporters as a trading advantage where the Australian/New Zealand standard is the platform for market access. Australian and New Zealand producers would retain the ability to export infant formula products that meet importing country requirements. This claimed benefit is largely speculative, and would depend on the particular trading situations, for example, if a country required importers of infant formula products to be listed, and a pre-condition of the listing is that the substances used in the importers products are associated with evidence that they have a role in normal growth and development.
Government	<ul style="list-style-type: none"> • A highly cautious approach provides confidence that a vulnerable population group is protected to the greatest extent possible while providing for innovation. • Creates a regulatory environment that directs research toward understanding the role of substances in normal growth and development to a greater extent. This may have long term benefits to formula-fed infants. Under the status quo there is little to encourage research on the role of those substances in normal growth and development.
Public health professionals	<ul style="list-style-type: none"> • It would provide confidence to health professionals that a high level of caution has been applied to the assessment of substances used in infant formula products, as the role of those substances in normal infant growth and development would be more likely to be substantiated.

Costs

As option 3 incorporates option 2, the costs identified below are costs in addition to those associated with option 2.

⁵³ Problem 1 is: ‘Incomplete regulatory oversight of the addition of substances to infant formula products. This is primarily an issue of regulatory design with implications for managing health and safety risks to infants’.

Consumers	<ul style="list-style-type: none"> • Additional research costs to support a pre-market assessment under this option may be passed on to consumers as part of the premium that is generally applied to products containing innovative new substances. Assuming (conservatively) distribution of two million units over eight years, and total cost of research component it passed to consumers, the additional cost to consumers would be less than A\$2 per unit. • There is a possibility that infants may lose the opportunity of benefiting from innovative infant formula products where there is not sufficient evidence at pre-market approval stage to demonstrate that the substances have a role in normal growth and development.
Industry	<ul style="list-style-type: none"> • Limit the scope for innovation, as only some substances will have roles in normal growth and development, and those that don't may be excluded from use in these products. • The inclusion of the substantiation of a substance's role in normal growth and development will require the generation of more supporting evidence than is currently required for pre-market approval. The additional cost is estimated at A\$600,000 per application.⁵⁴ • Extending the range of substances subject to pre-market assessment would extend the application of these costs. There have been five applications since 2002 (and one situation in which there was a lack of clarity as to whether the pre-market approval requirement applied). In one of those applications there was little evidence to substantiate that the substance had a role in normal growth and development. Therefore, if a similar frequency prevails over the next eight years, the additional total cost to the industry of this option would be the cost of research to support one pre-market assessment, up to A\$600,000. However, the full cost would only apply where the product was not imported from or intended for export to the EU.
Government	<ul style="list-style-type: none"> • Nil
Public health professionals	<ul style="list-style-type: none"> • Nil

Consistency with international and overseas market standards

- This option would result in regulations that are consistent with international standards.
- This option would result in regulatory arrangements that apply the same level of regulation as the EU, but greater than that applied in the US.

⁵⁴ These estimate figures for research costs were provided by an infant formula product company in-confidence to the FRSC Working Group, based on the anticipated cost of a randomised controlled trial with a sample of 100 infants. The research costs are indicative, and are subject to a high degree of variability depending on the extent of research available in the public domain (i.e. that does not need to be generated by the applicant), and the total global market for the product and the relative size of the Australia/New Zealand market to the global market. Costs are only applied where an applicant seeks permission to introduce a new substance to infant formula products.

CONSULTATION

In order to inform the development of a Policy Guideline for the Regulation of Infant Formula Products, the FRSC Working Group prepared a public consultation paper to seek the views of interested parties.

In developing the Consultation Paper, the Working Group sought expert advice from four Australian/New Zealand infant nutrition and health specialists, and one paediatrician. The consultation paper proposed five policy options (as outlined above on page 15).

The consultation process was advertised in national newspapers in both Australia and New Zealand, and the Consultation Paper was distributed to all stakeholders on the Food Regulation Secretariat's stakeholder database, and to other stakeholders known to individual jurisdictions to have an interest in the area. It was also available to the general public via the FSANZ website.

The Consultation Paper was released on 30 June 2009, with submissions accepted for a period of nine weeks up to 1 September 2009. Forty-nine submissions were received with 15 from industry stakeholders, 13 from consumers and consumer advocacy organisations, 10 from public health organisations and specialists, and 11 from government departments.

Three stakeholder consultation meetings were also held in August 2009, in Wellington, Melbourne and Sydney. The Wellington and Melbourne stakeholder meetings were attended by the experts in infant health and nutrition who contributed to the Policy Options Consultation Paper. The views of the experts as expressed in discussions at the earlier consultation meetings were relayed to participants at the Sydney meeting.

Industry submissions

- The principal concerns identified by industry submitters included the need to harmonise domestic standards with those applying internationally.
- Industry submitters stressed the need for clear pre-market approval criteria, so that companies can anticipate and respond appropriately to requirements.
- In relation to the demonstration of a substance's role normal growth and development⁵⁵ as a determining factor in pre-market approval, most industry submitters offered tentative support if provision was made to make claims about the substance's role. In the absence of an ability to make claims, industry submitters considered that such a provision would be excessive.
- Industry submitters pointed out that it can be difficult to generate evidence of efficacy or effectiveness to substantiate a substance's role in normal growth and development, as research on infants is associated with strict ethical considerations. Industry submitters urged caution in being too prescriptive about the levels required to support pre-market approvals.

Consumer submissions

- Consumer submitters stressed that the main priority of infant formula product regulation should be the health and safety of infants, and protecting the primacy of breastfeeding.

⁵⁵ This was referred to as 'health benefit' in the consultation paper. Most submitters took issue with the words 'health benefit', so 'role in normal growth and development' is used to capture the idea that substance should 'do something for' or 'be useful' for infants.

- Consumer submitters supported widening the pre-market approval requirements and requiring the demonstration of a substance's role normal growth and development as a determining factor in pre-market approval.
- Consumer submitters raised concerns about the labelling of infant formula products, and in particular the use of claims in marketing.

Public health submissions

- Most public health submitters raised similar issues to those raised by consumer submitters.
- Public health submitters in general supported a more prescriptive regulatory approach, including the widening of the pre-market approval requirements and requiring the demonstration of a substance's role normal growth and development as a determining factor in pre-market approval.
- A number of public health submitters raised technical issues in relation to the composition of infant formula products. However, these are more appropriately addressed by FSANZ in a standard setting context, rather than by FRSC in a policy context.

Government submissions

- Government submitters expressed support for the policy options that included widening the range of substances subject to pre-market approval, and requiring that, where relevant, pre-market assessment include demonstration of a substance's role normal growth and development as a determining factor.
- Government submitters also raised concerns about the marketing of infant formula products, and in particular the use of claims that may be in contravention of the existing regulatory provisions.
- Government submitters provided detailed comments on criteria for determining the essential composition of infant formula products. This information will be forwarded to FSANZ for consideration in any future review of the relevant regulatory standards.

EVALUATION AND CONCLUSION

Summary of each option

Option 1 (status quo)

While it is acknowledged that the current regulatory arrangements are largely sufficient to manage most risks to infants associated with the use of infant formula products, there is scope for addressing the gap in the regulations identified in Problem 1. There is also scope for determining government policy in relation to the substantiation of the role of substances used in infant formula products in normal infant growth and development (Problem 2).

Although the maintenance of the status quo is not associated with any additional direct costs to industry, the potential costs associated with inconsistencies in the interpretation of unclear regulatory provisions are significant. The costs to regulators and industry associated with the status quo are related to enforcement action based on unclear regulatory provisions. While there is always a cost to enforcement action, if it is taken on unclear regulatory provisions, it is likely the costs will be greater for both parties. In a recent case concerning the addition of a linked set of substances to infant formula products, the costs exceeded A\$1 million for the regulator, and potentially similar costs for the affected company.

Problem 1 notes that the potential health and social costs of unintentionally exposing infants to a hazard in infant formula products are high. While industry has considerable incentives and a legal responsibility to ensure products are safe and suitable for infants, due to the vulnerability of infants and the fact that infant formula products may be their sole source of nutrition, the existing approach is to apply pre-market safety approval. The gap identified in problem 1 is inconsistent with this approach and creates a potential risk.

Option 2

The benefits of option 2 are a reduction in the risk to infants associated with the gap in existing regulations identified in problem 1, and in the legal risk to industry and regulators in relation to compliance with unclear regulation.

Given the costs associated with the risks to infants, the risks associated with enforcement action based on unclear regulatory provisions, and the small practical extension of the requirement for pre-market approval, it is considered that a pre-market approval requirement for all substances without a history of safe use in infant formula products sold in Australia and New Zealand has a net benefit.

Option 2 does not address the concern that under the status quo, there is no clear policy on whether substances can be used in infant formula without a substantiated role in normal infant growth and development. Given the vulnerability and immaturity of infants, experts have advised the FRSC Working Group that only substances with substantiated roles in normal growth and development should be used in infant formula products.

Option 3

This option incorporates option 2. As noted above, it is considered that the extension of the pre-market approval requirement has a net benefit.

In addition, option 3 would clarify the Australian and New Zealand Governments' position in respect to the inclusion of the substantiation of a substance's role in normal growth and development in the pre-market approval process. This option would likely increase costs to industry of pre-market assessments by up to A\$600,000 per application. However, actual costs will depend on the level of evidence already available for the substance, and whether the evidence is generated solely for regulatory approval in Australia/New Zealand or for approval across a number of markets (e.g. the EU, which has a similar requirement in place).

It is difficult to determine whether option 3 would be associated with a net cost or net benefit. There is inherent uncertainty in the risks associated with the future accumulation of optional substances in infant formula products (uncertainty in terms of avoided health costs). In addition, the costs of this option would be dependent on the particular substance subject to pre-market assessment, and the level of evidence that FSANZ determines is necessary to substantiate the substance's role in normal growth and development, and whether the additional research is generated solely for regulatory approval in Australia/New Zealand (the full cost of research to support an application cannot be attributed to the Australia/New Zealand policy guideline if pre-market approval is sought for the substance in another market with similar regulatory requirements).

There is also the possibility that the higher bar of an option 3 approach would preclude the use of substances in infant formula products that may over time prove to be beneficial for infants, thereby denying infants a benefit. However, it should be noted that option 3 does not preclude the approval of substances that do not have substantiated roles in normal growth and development; instead it requires this to be a key consideration in FSANZ's processes. Nor

would it preclude introduction of substances to infant formula products later if evidence for a benefit became available.

Adoption of this policy approach would clearly signal governments' highly cautious approach to the safety and suitability of infant formula products, and would, to some extent, direct industry product development research into the role of substances in normal growth and development. Such investment may have long-term benefits for all infants. This option therefore supports policy objective 2.⁵⁶ Its role in relation to policy objective 8⁵⁷ is less certain, as it could reduce the number of new products introduced to the Australia/New Zealand market, but any products introduced would be more likely to provide genuine benefits. It would not affect industry innovation in export products (other than trans-Tasman trade), as these are produced to meet importing country requirements.

CONSISTENCY WITH INTERNATIONAL STANDARDS

A key consideration in determining policy in relation to the use of 'optional' substances in infant formula is consistency with the international Codex standards. The Codex approach allows the addition of 'optional ingredients' where the following two criteria are met:

- 'Other ingredients may be added in order to provide components ordinarily found in human milk and to ensure that the formulation is suitable as the sole source of nutrition for the infant or to provide other benefits that are similar to outcomes of populations of breastfed babies.'
- 'The suitability for the particular nutritional uses of infants and the safety of the optional ingredients must be scientifically demonstrated. The formula shall contain sufficient amounts of these ingredients to achieve the intended effect, taking into account levels in human milk.'

The Government Departments within the Commonwealth responsible for food regulation policy have been consulted in the development of the policy options set out in this regulatory impact statement.

In New Zealand, the New Zealand Food Safety Authority (NZFSA) is responsible for ensuring the consistency of New Zealand food standards with those applying internationally. NZFSA considers that the inclusion of the demonstration of a substance's role in normal growth and development as a determining factor in pre-market approval is not required by the Codex standard. However, NZFSA considers that such a policy would not be inconsistent with the Codex standard.

RECOMMENDED OPTION

Based on the information available, option 2 has the clearest net benefit. However, it has not been possible to determine which option is likely to have the greatest net benefit.

Option 3 would deliver additional benefits, but the extent to which the additional benefits exceed the additional costs cannot be quantified at this time.

⁵⁶ To ensure the composition of infant formula products achieves a health outcome for formula-fed infants that is as close as possible to the health outcome of populations of exclusively breastfed infants.

⁵⁷ To provide a regulatory environment that enables innovation that benefits those infants who need infant formula products.

Option 3 might be favoured if a high weighting is given to taking a highly precautionary approach to infant safety on the grounds that over time an increasing number of new substances in infant formula products may risk placing a physiological burden on infants that leads to adverse health outcomes. Limiting the optional substances in infant formula products to those with a substantiated role in normal growth and development would reduce the risk of placing an unnecessary burden on infants.

IMPLEMENTATION AND REVIEW

If a policy guideline is adopted, FSANZ would be required to have regard to it when developing, reviewing or varying any food standard relating to infant formula products.

FSANZ has indicated its intention to review Standard 2.9.1. The specific regulatory impacts which may arise from the FSANZ review will be quantified and explored in the regulatory impact assessments that FSANZ is required to undertake when proposing a change to existing regulatory provisions. FSANZ has advised that due to uncertainties in the value of the costs and benefits associated with the highly precautionary approach outlined in option 3, if this option is favoured there may be difficulties in demonstrating a clear net benefit at the standards setting phase.

The FSANZ standard review process also includes a consultation component, such that interested parties will be able to submit views on the appropriateness of different regulatory options.

**AUSTRALIA AND NEW ZEALAND FOOD REGULATION
MINISTERIAL COUNCIL**

Food Regulation Standing Committee

Regulation of Infant Formula Products

Policy Guideline – Option 3

SCOPE/AIM

Purpose

This Policy Guideline provides guidance on the expectations of the Australia and New Zealand Food Regulation Ministerial Council for the composition, labelling, advertising and promotion⁵⁸ of infant formula products.

It is recognised that breastfeeding is the normal and recommended way to feed an infant and that the regulation of breastmilk substitutes, such as infant formula, has implications for health outcomes for all infants, formula-fed and breastfed.

Infants are a vulnerable population group because they have immature immune systems and organs and are dependent on adults for feeding. For some infants, infant formula products may be the sole or principal source of nutrition. For these reasons there is a greater level of risk to be managed compared to other population groups. The regulatory framework for infant formula products should include requirements commensurate with this level of risk for the composition, labelling, advertising and promotion of infant formula products.

Scope

This Policy Guideline is intended to cover infant formula, follow-on formula and infant formula for special dietary uses for infants from 0 to 12 months of age.

The requirements for the composition, labelling, advertising and promotion of Special Purpose Foods, such as infant formula, are governed by specific standards in Part 2.9 of the Australia New Zealand Food Standards Code (the Food Standards Code). Some of the general provisions in the Food Standards Code also apply to standards in Part 2.9.

The Policy Guidelines on the Fortification of Food with Vitamins and Minerals and the Addition of Substances other than Vitamins and Minerals do not apply to infant formula products. The Policy Guideline on the Intent of Part 2.9 is relevant to the regulation of infant formula products. The Policy Guideline on Nutrition, Health and Related Claims covers potential exclusions from the ability to make claims for certain categories of foods, including infant formula products.

⁵⁸ Reference to ‘advertising and promotion’ in this Policy Guideline is made with reference to section 16(d) of the Food Standards Australia New Zealand Act 1991 (Cth), which provides that information about food used in labelling, promotion and advertising may be subject to regulation by standards and variations of standards made under the Act.

HIGH ORDER POLICY PRINCIPLES

The Food Standards Australia New Zealand Act 1991 establishes a number of objectives for FSANZ in developing or reviewing of food standards (section 18 of the FSANZ Act).

1. The objectives (in descending priority order) of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures are:
 - (a) the protection of public health and safety; and
 - (b) the provision of adequate information relating to food to enable consumers to make informed choices; and
 - (c) the prevention of misleading or deceptive conduct.
2. In developing or reviewing food regulatory measures and variations of food regulatory measures, the Authority must also have regard to the following:
 - (a) the need for standards to be based on risk analysis using the best available scientific evidence;
 - (b) the promotion of consistency between domestic and international food standards;
 - (c) the desirability of an efficient and internationally competitive food industry;
 - (d) the promotion of fair trading in food;
 - (e) any written policy guidelines formulated by the Australian and New Zealand Food Regulation Ministerial Council (that was established by the Food Regulations Agreement in 2000)

These objectives apply to the development of standards regulating Infant Formula Products.

A number of other policies are also relevant to the development of food standards including:

- the Council Of Australian Governments document ‘Principles and Guidelines for National Standard Setting and Regulatory Action by Australia and New Zealand Food Regulatory Ministerial Council and Standard Setting Bodies’ (1995, amended 1997) (Australia only);
- New Zealand Code of Good Regulatory Practice (November 1997);
- the Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System;

SPECIFIC POLICY PRINCIPLES – Overarching Principles

Specific Policy Principles are principles that support and are limited by the High Order Principles.

The specific policy principles applying to all infant formula products are:

- (a) The regulation of infant formula products should recognise that breastfeeding is the normal and recommended way to feed an infant.

- (b) The regulation of infant formula products should not be inconsistent with the national nutrition policies and guidelines of Australia and New Zealand that are relevant to infant feeding.
- (c) The regulation of infant formula products should be based on risk analysis, taking into account the vulnerability of the population for whom they are intended and the importance of these products in the diets of formula fed infants.

SPECIFIC POLICY PRINCIPLES - Composition

- (d) The composition of infant formula must be safe, suitable for the intended use and must strive to achieve as closely as possible the normal growth and development (as measured by appropriate physiological, biochemical and/or functional outcomes) of healthy full term exclusively breastfed infants when infant formula used as the sole source of nutrition up to six months of age.
- (e) The composition of follow-on formula must be safe, suitable for the intended use and must strive to achieve as closely as possible the normal growth and development (as measured by appropriate physiological, biochemical or functional outcomes) of healthy full term breastfed infants at the appropriate age when follow-on formula used as the principal source of liquid nourishment in a progressively diversified diet.⁵⁹
- (f) The essential composition of infant formula and follow on formula should be prescribed in regulation and must satisfy the nutritional requirements of infants.
- (g) Compositional requirements for infant formula and follow-on formula products should only be mandated in regulation where there is sufficient evidence to demonstrate that they are safe and essential for normal growth and development of infants.
- (h) The composition of breastmilk should be used as a primary reference for determining the composition of infant formula and follow-on formula.
- (i) Pre-market assessment, relative to principles (d) and (e), should be required for any substance proposed to be used in infant formula and follow-on formula that:
 - i. does not have a history of safe use at the proposed level in these products in Australia and New Zealand; or
 - ii. has a history of safe use in these products in Australia and New Zealand, but which, having regard to source,⁶⁰ has a different form/structure, or is produced using a substantially different technique or technology.
- (j) Substances subject to pre-market assessment for use in infant formula and follow-on formula should have a substantiated beneficial role in the normal growth and development of infants or children, or a technological role, taking into account, where relevant, the levels of comparable substances in breastmilk. A substance's role in normal growth and development is substantiated where there is appropriate evidence to link the physiological, biochemical and/or functional effects of the substance to specific health outcomes for

⁵⁹ This Policy Guideline recognises that if an infant is thriving on regular or standard infant formula and complementary foods, there is generally no advantage in changing to a follow-on formula.

⁶⁰ For the sake of clarity, this principle does not apply to substances with a history of safe use in infant formula products in Australia and New Zealand that are sourced from a different supplier.

infants, in infancy or childhood. Particular caution should be applied by the Authority where such links are less clear.

SPECIFIC POLICY PRINCIPLES – Labelling and Advertising

The specific policy principles applying to the labelling and advertising of all infant formula products are:

- (k) The labelling and advertising of infant formula products should be consistent with the World Health Organization International Code of Marketing of Breast Milk Substitutes⁶¹ as implemented in Australia and New Zealand.
- (l) The labelling and advertising of infant formula products should not represent those products as an equivalent to, or better food than, breastmilk.
- (m) The labelling and advertising of infant formula products should provide information on the appropriate and safe use of those products.
- (n) The Authority should:
 - i ensure that the prohibitions and restrictions on nutrient content, health, therapeutic, and prophylactic claims in the Food Standards Code are clear and effective for infant formula products; and
 - ii consider whether the current labelling regime is leading to consumers being misled about the quality or effectiveness of an infant formula product.

SPECIFIC POLICY PRINCIPLES – Infant Formula Products for Special Dietary Uses

Infant formula products for special dietary uses refers to products specifically formulated to meet the dietary needs of:

- premature or low birth weight infants; or
- infants with metabolic, immunological, renal, hepatic and malabsorptive conditions.

These infants have special dietary or medical needs and are an even more vulnerable population group than infants generally. The diet of these infants is usually managed under the supervision of a medical specialist or paediatric dietitian.

As infant formula products for special dietary uses are formulated for relatively small population groups with varying needs, the specific policy principles relating to the composition for infant formula and follow on formula (principles (d)-(h)) above) do not apply to these products. Policy principles relating to the pre-market assessment of substances without a history of safe use in infant formula (i)-(j) may apply to infant formula products for special dietary uses at the discretion of the Authority.

The specific policy principles for infant formula products for special dietary uses are:

- (o) Infant formula products for special dietary uses must be safe, suitable and meet the nutritional requirements to support the growth, development and dietary management of the infants for whom they are intended.

⁶¹ World Health Organization. *International Code of Marketing Breast-milk Substitutes*. Geneva. 1981.

- (p) The composition of infant formula products for special dietary uses should be based on appropriate scientific evidence.
- (q) The labelling and advertising of infant formula products for special dietary uses should clearly specify the special dietary or medical uses for which the product is intended.

ADDITIONAL POLICY GUIDANCE

Expert group

FSANZ should consider establishing an independent scientific expert group that may provide advice prior to pre-market assessment, based on scientific criteria established by the Authority, on whether:

- i. a substance proposed to be added to infant formula products has a history of safe use in infant formula or follow-on formula in Australia and New Zealand; and
- ii. there is evidence available that the substance has a substantiated beneficial role in the normal growth and development of infants or children.

Relevant international agreements

The regulation of infant formula products in Australia and New Zealand should be consistent to the greatest extent possible with:

- relevant World Health Organization agreements; and
- relevant World Trade Organization agreements, Codex standards and guidelines.

Definitions

For the purpose of this Policy guideline, the following definitions apply:

follow-on formula means an infant formula product represented as either a breastmilk substitute or replacement for infant formula and which can constitute the principal liquid source of nourishment in a progressively diversified diet for infants aged from six to 12 months of age

infant means a person under the age of 12 months

infant formula means an infant formula product represented as a breastmilk substitute for infants and which satisfies, as the sole source of nourishment, the nutritional requirements of infants up to six months of age

infant formula product means a manufactured product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve as the principal liquid source of nourishment for infants.