

**Submission by the Australian Breastfeeding Association**

**To**

**FSANZ**

**Consultation paper- proposal P1028**

**Regulation of infant formula- infant formula products for  
special dietary use**

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**Date:**

**28th September 2017**

The Australian Breastfeeding Association (ABA) welcomes the opportunity to make comment on the *FSANZ Consultation paper – Proposal P1028 Regulation of Infant formula – Infant formula products for special dietary use*.

This submission will focus on products for transient gastroenterological conditions and hydrolysed protein formula (extensive and partial), their potential to undermine breastfeeding and their lack of effectiveness.

The Australian Breastfeeding Association is particularly concerned by the statement from FSANZ that:

*Stakeholders have noted that the ease of access to some of the less specialised infant formula products may lead to caregivers selecting to use an IFPSDU product over breastfeeding, based on self-diagnosis. **FSANZ is not aware of evidence of a problem with the current distribution channels for IFPSDU.*** p59

This statement is dismissive of both:

- the detrimental impact of premature weaning (due to formula use) on the health and wellbeing of Australian babies and mothers and
- the need for evidence to inform decision making.

Despite being made aware by stakeholders in previous consultations that:

*These readily available products could potentially lead to the unnecessary replacement of breastfeeding with formulas that are promoted to manage perceived diarrhoea, hunger and unsettled behaviour (FSANZ, p57)*

FSANZ still presents no evidence, and appears to have made no attempt to find evidence, of the impact of products for transient gastroenterological conditions on breastfeeding.

This is unacceptable.

How can FSANZ make well-informed, evidence-based decisions when it doesn't have the evidence?

What duty of care does FSANZ have in this situation to be aware of the evidence in order to protect the health and wellbeing of Australian babies and mothers by protecting breastfeeding?

ABA has done the research and will present the evidence, the readily-available, high-level evidence which confirms that:

1. Premature weaning is detrimental to the health and wellbeing of Australian babies and increases health costs considerably.
2. The ready availability of formula (in supermarkets and pharmacies) and formula marketing undermines breastfeeding and leads to premature weaning.
3. Formulas which claim to have therapeutic benefit for transient gastroenterological conditions and allergies have not been proven to be effective for such conditions.

## The evidence

### 1. Premature weaning is detrimental to the health and wellbeing of Australian babies and increases health costs considerably

The *Lancet Breastfeeding Series Paper 1*, published in 2016 (Victora et al., 2016), collated the best available evidence that showed that premature weaning has major health consequences for all babies, even in high-income countries like Australia. A large number of systematic reviews with meta-analyses were presented and the researchers concluded that it is undeniable that:

Breastfeeding significantly reduces:

- Mortality due to infectious diseases
- Diarrhoea incidence
- Admission to hospital for diarrhoea
- Lower respiratory infections (incidence or prevalence)
- Admissions to hospitals for respiratory infections
- Acute otitis media
- Dental malocclusions

Breastfeeding also significantly increases IQ.

In premature babies, breastmilk helps protect from necrotising enterocolitis (a serious illness in which tissues in the intestine (gut) become inflamed and start to die) and sepsis (a life-threatening, overwhelming response to an infection) (Schanler, Shulman, & Lau, 1999).

In all babies, breastfeeding reduces the risk of Sudden Infant Death Syndrome (SIDS) and is included in the practices known to reduce risk in the Red Nose (formerly SIDS and Kids) safe sleep literature (Red Nose, 2016). Any duration of breastfeeding is protective against SIDS, however, the protective effect is stronger for exclusive breastfeeding, reducing the risk by 73%.

The *Lancet Breastfeeding Series Paper 2* (Rollins et al., 2016) then went on to calculate, in economic terms, the financial losses countries incur when breastfeeding is not supported. Economic losses associated with cognitive deficits due to the use of formula in the first six months of life were determined. It was calculated that, in 2012, **Australia incurred an economic loss of US\$ 6.3 billion**, equivalent to 0.42% of Gross National Income (GNI).

Table 1. **Economic losses (as % of GNI) associated with cognitive deficits** based on current infant feeding practices, as compared to all children receiving at least some breastmilk up to age six months, by country.

Country	Economic loss, 2012	Economic loss as % of GNI
Australia	US\$ 6.3 billion	0.42
India	US\$ 0.63 billion	0.03
USA	US\$ 84.24	0.53

Source: Rollins, N. C., Bhandari, N., Hajeebhoy, N., Horton, S., Lutter, C. K., Martines, J. C., ... & Group, T. L. B. S. (2016). Why invest, and what it will take to improve breastfeeding practices? *The Lancet*, 387(10017), 491-504. Appendix p115

*The fact that the reproductive cycle includes breastfeeding and pregnancy has been largely neglected by medical practice, leading to the assumption that breastmilk can be replaced with artificial products without detrimental consequences. This neglect is particularly important in high-income countries, where fewer than one in every five children are breastfed by the age of 12 months. For each doubling in national gross domestic product per person, breastfeeding prevalence at 12 months decreases by 10 percentage points. (Victora et al., 2016, p. 485)*

*In terms of inequalities, our findings show that **breastfeeding is one of the few positive health behaviours that is more prevalent in poor than in rich countries.** (Victora et al., 2016, p. 487).*

It is undeniable that premature weaning is detrimental to the health and wellbeing of Australian babies.

Breastmilk and formula are not equivalent, and never will be, despite claims by formula manufacturers.

In high-income countries like Australia, accessibility to and ignorance of the fact that breastmilk cannot be replaced by formula without detrimental consequences is having a measurable effect on the health and wellbeing of all babies (during infancy and as they grow) and a subsequent long-term financial cost on health systems with increased rates of obesity, diabetes and cardiovascular disease. Around 8-24% of current chronic disease cases in Australia are estimated to be attributable to high rates of formula feeding of babies in previous generations (Smith & Harvey, 2010).

## **2. The ready availability of formula (in supermarkets and pharmacies) and formula marketing undermines breastfeeding and leads to premature weaning**

*The breastmilk substitute industry is large and growing, and its **marketing undermines efforts to improve breastfeeding.** (Rollins et al., 2016, p491)*

*Although the advertising of infant and follow-on formula products in Australia is prohibited by the Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement (1992), toddler milk is advertised without restriction. Recent research suggests that Australian mothers perceive advertisements for toddler milk to also be advertisements for infant formula. Furthermore, **they tend to accept the messages they encounter in these advertisements uncritically.** (Berry, Jones & Iverson, 2011, p9)*

The International Code of Marketing of Breastmilk Substitutes, the WHO Code, exists because the marketing of formula can, and does, undermine breastfeeding and leads to premature weaning of infants. The WHO Code implicitly recognised that health workers, women, and families are susceptible to direct and indirect marketing strategies (World Health Organization, 1981).

***Marketing by the infant feeding industry and the availability of formula, including the distribution of free samples, increase rates of bottle-feeding.*** Formula advertisements portray formula milk to be as good as or better than breastmilk, or present it as a lifestyle choice rather than a decision with health and economic consequences. Mothers report that media is an important source of information, and findings from studies in several countries associate recollection of formula advertisements with decreased breastfeeding. ***Marketing messages can also convey that breastfeeding is difficult and that breastmilk substitutes help to settle fussy babies.*** (Rollins et al., 2016, p495)

In a 2013 US study, a range of women (preconceptional, pregnant, exclusive breastfeeders, and formula feeders) were asked to state what they believed formula advertisements said about how the products related to human milk (superior, inferior, similar) and how they reported reacting to these interpretations (Parry, Taylor, Hall-Dardess, Walker, & Lobbok, 2013). The researchers found that:

*Participants reported that the advertisements conveyed an expectation of failure with breastfeeding, and that formula is a solution to fussiness, spitting up, and other normal infant behaviors. Participants reported that the advertisements were confusing in terms of how formula-feeding is superior, inferior or the same as breastfeeding.* (Parry et al., 2013, p115)

When specifically asked about formulas for *feeding-related problems*, the women stated that:

***... the advertisements gave them the impression that their own milk could not solve common infant problems as well as formula would.***

The women frequently reported that the advertisements **offer solutions for breastfeeding women that encourage formula use, that is, if your breastfed baby has this issue then purchase this formula product to fix it.** Participants also reported that the advertisements made them think that infant formula was being presented as a medical solution to these problems, many of which could well have been normal baby behaviours such as fussiness and spitting up.

***You can't change your milk, but I can change my formula and maybe that will solve my problem... That I probably can go [on] trying until I find one that fits right. Or it's sort of, you know, when you're going down the cold medicine aisle. You're like, "OK. I've got fussiness and spit-up, so which one can I use?" so to speak.*** (Formula Group)

***I think it's sort of providing you these options of "This is something that formula can do that your breastmilk necessarily can't do."*** (Pregnant Group)

***I feel like it does imply that these can be solutions to problems caused by breastfeeding.*** (Pregnant Group) (Parry et al., 2013, p120)

**Marketing by the infant feeding industry and the availability of formula leads to premature weaning.**

Women's confidence in their bodies to produce breastmilk that is perfect for their own baby's needs is undermined by a plethora of formulas that make claims that they can solve feeding-related problems.

It is clear from the women's voices above, that their confidence in their ability to provide breastmilk for their baby is being undermined.

Despite claims that they are only providing an alternative to breastmilk, **given their obligation to their shareholders is to make profits, formula manufacturers succeed and make profit when breastfeeding is undermined and fails.**

**3. Formulas which claim to have therapeutic benefit for transient gastroenterological conditions and allergies have not been proven to be effective for such conditions.**

*Infant formula sales in the US are a competitive and profitable marketplace environment. As such, **there is a tendency for companies to release a variety of new products to seek a competitive advantage and to market them to consumers who are unaware of the scientific framework for their use. FDA restrictions on such releases are designed to ensure that there is minimal evidence of risk, but often the evidence for benefit is not established. Some of these products may confuse families relative to the value of breast-feeding or to the value of spending money on more expensive formulas than are medically needed.*** (Abrams, 2015, p760).

In 2015, Steven Abrams wrote a commentary expressing his concern that the manufacture and sale of specialised infant formulas with small compositional changes, such as reduced lactose, is not evidence based and has little if any benefit to infants, parents and paediatricians. He proposed a moratorium on the development of new products until an evidence base exists, but recognising that this would be unlikely to occur, he proposed that *regulatory and marketplace changes should rapidly be developed by nonbiased information sources.*

*A highly competitive infant formula market has resulted in **direct-to-consumer marketing** intended to promote the sale of modified formulas that **claim to ameliorate common infant feeding problems.*** (Belamarich, Bochner, & Racine, 2016, p437)

### **Formulas for transient gastroenterological conditions**

In late 2016, a paper entitled: *A critical review of the marketing claims of infant formula products in the United States* was published in the *Clinical Pediatrics* journal by researchers who were able to declare no conflicts of interest in regard to the research. The researchers compared the health benefit claims made on the infant formula product labels around infantile colic, crying and perceived gastrointestinal distress, with the evidence in systematic reviews. See Table 2 below for list of health benefit claims.

So what did the systematic reviews reveal about the legitimacy of the claims?

Table 2. Health benefit claims of 13 formulas in the US.

	<b>Formula Brand Name</b>	<b>Formula modification</b>	<b>Claims</b>
1	Nutramigen with Enflora LGG	Amino acids, reduced lactose, probiotic	Fast management of colic
2	Nutramigen	Amino acids, reduced lactose	Fast management of colic
3	Enfamil Gentlease USA	Whey hydrolysate, reduced lactose	For fussiness, gas and crying. Helps reduce fussiness, gas, and crying within 24 hours. Easy to digest protein
4	Enfamil Reguline	Whey hydrolysate, prebiotic	Easy to digest gentle protein
5	Enfamil ProSobee	Soy protein, reduced lactose	Soy for fussiness and gas reduces fussiness and gas
6	Similac Sensitive	Reduced lactose	For fussiness and gas due to lactose sensitivity. Complete nutrition for sensitive tummies
7	Similac Total Comfort	Whey hydrolysate, reduced lactose	For discomfort due to persistent feeding issues. Partially broken down protein for easy digestion
8	Similac Soy Isomil	Whey hydrolysate, reduced lactose	For fussiness and gas
9	Similac Expert Care Alimentum	Casein hydrolysate, reduced lactose	For food allergies and colic due to protein sensitivity
10	GERBER GOOD START Gentle	Whey hydrolysate	Comfort proteins advantage. Easy to digest
11	GERBER GOOD START Soothe	Whey hydrolysate, reduced lactose, probiotic	Comfort proteins advantage. Easy to digest For excessive crying, colic, and fussiness
12	GERBER GOOD START Soy	Soy protein, reduced lactose	Easy to digest. For sensitive tummy
13	GERBER GOOD START Gentle for supplementing	Whey hydrolysate, probiotic	Gentle nutrition for when breastfeeding moms supplement comfort proteins advantage

Source: Belamarich, P. F., Bochner, R. E., & Racine, A. D. (2016). A critical review of the marketing claims of infant formula products in the United States. *Clinical Pediatrics*, 55(5), 437-442.



**Casein hydrolysates** – a study of 122 infants enrolled in a trial of casein hydrolysate milk (or hypoallergenic diet for breastfeeding mothers) versus standard cow's milk formula or control diets for breastfeeding mothers. Based on the results of this study the review concluded that there was **insufficient evidence of an effect**.

**Whey hydrolysate formulas** – a double blind randomised controlled trial of 43 infants fed a whey hydrolysate formula versus standard formula. Infants fed whey hydrolysate cried less and this result was statistically significant. However, unblinding of four parents who fed hydrolysate and a wide confidence interval around the effect led the reviewer to conclude that the **available evidence was of low quality**.

**Soy-based formula for colic** – two studies of which one was too small, and the other suffered from methodological weaknesses. Regarding soy formula, the review concluded that there was **no direct information**.

**Low-lactose milks for colic** – a randomised controlled trial of 53 infants that found a **non-significant difference in crying time**.

**Oral probiotics to prevent or treat excessive infant crying** – 12 randomised controlled trials of 1825 infants that compared oral probiotics to placebo or no treatment found there is still **insufficient evidence for probiotic use in formula fed infants to manage colic and crying**.

### **Hydrolysed formulas for allergies**

In 2016, Boyle et al., published a systematic review with meta-analysis, as part of a series of systematic reviews commissioned by the UK Food Standards Agency to inform guidelines on infant feeding. The review found that there was no evidence to support the claims made by manufacturers of partially and extensively hydrolysed formula that these formulas reduced allergies in babies.

*37 eligible intervention trials of hydrolysed formula were identified, including over 19000 participants. There was evidence of conflict of interest and high or unclear risk of bias in most studies of allergic outcomes and evidence of publication bias for studies of eczema and wheeze. Overall there was **no consistent evidence that partially or extensively hydrolysed formulas reduce risk of allergic or autoimmune outcomes in infants at high pre-existing risk of these outcomes**.*

*There was no evidence to support the health claim approved by the US Food and Drug Administration that a partially hydrolysed formula could reduce the risk of eczema...*  
(Boyle et al., 2016, p1)

These findings had an immediate impact.

In Melbourne, May 2016, there was an Infant Feeding Summit, hosted by the Centre for Food & Allergy Research, part of Murdoch Children's Research Institute at the Royal Children's Hospital. The purpose of the summit was to refine the infant feeding recommendations that Australian



allergists and immunologists were giving to both health professionals and parents. The recommendation regarding hydrolysed formulas changed to:

***Hydrolysed (partially and extensively) infant formula are not recommended for prevention of allergic disease.*** (ASCIA, 2016)

The change in recommendation was made because high-quality evidence showed that these formulas did not prevent allergic disease.

Clearly, the body of evidence, reveals that there is little evidence for the effectiveness of these products.

Since there is little evidence of the effectiveness of formulas for transient gastroenterological conditions and hydrolysed formulas, and formula manufacturers are not likely to voluntarily cease developing new products based on small compositional changes (which increases the number of products and increases their potential profits), then stronger regulation is required.

FSANZ may claim its role is just to ensure the product is safe and has no role in determining the efficacy of such products. However, as an agent of the Australian Government, **FSANZ has a duty of care to protect Australian babies and mothers from the inappropriate introduction of unnecessary products which may be detrimental to their health and wellbeing, especially breastfed babies.**

Infant formulas are a unique group of foods. They are often the sole food a baby receives for many months. **The history of formula development is littered with mistakes and infants have died** (Minchin, 1998; Minchin, 2015).

It is essential that governments provide a degree of regulation for the protection of a vulnerable group. There is a clear opportunity for FSANZ to provide such regulation.

To ensure that formulas, which claimed to be helpful for transient gastroenterological conditions and allergies, are not used inappropriately and there is not a proliferation of these products to 'manage' infant behaviours (many of which are likely to be normal baby behaviours), ABA submits that:

- Only those formulas which are evidence based and effective for the intended condition are introduced into the Australian market.
- Clear labelling states that these formulas are only for babies who are already formula fed with medically diagnosed conditions.
- There be no exemption from the statement: *Breastmilk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice.*
- These formulas are not made available in supermarkets. As a minimum they should be pharmacy-only products and on the advice of the pharmacist
- Best practice safeguards would be in place to ensure that specialised formulas, that are found to be effective, should only be available on prescription and under medical supervision to ensure women aren't 'diagnosing' their babies' conditions.

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## References

ABA is happy to provide full copies of references, if requested.

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