

17 August 2015

Adjudication Branch
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Submission by the Australian Breastfeeding Association on Infant Nutrition Council Limited applications for authorisation A91506 and A91507

The Australian Breastfeeding Association (ABA) welcomes the opportunity to comment on the applications made by the Infant Nutrition Council Limited (INC). We appreciate the extension to close of business today, 17 August 2015.

ABA's submits that the reauthorisation of the MAIF Agreement as proposed by the Infant Nutrition Council Limited should not be granted for the following reasons:

1. Australia should not be committed to the MAIF Agreement for a period of a further 10 years.
2. The scope of the MAIF Agreement as described by the Infant Nutrition Council (INC) for this reauthorisation does not protect optimal breastfeeding effectively in Australia.
3. The MAIF Agreement and MAIF Complaints Tribunal are inadequate as Australia's official application of the World Health Organization's (WHO) International Code of Marketing of Breast Milk Substitutes and subsequent World Health Assembly (WHA) resolutions.

We have expanded on these concerns in the attached submission, In additiona we also include at Appendix 1 a summary of evidence that supports the importance of infant breastfeeding in relation to associated health outcomes.

We are happy for our submission to be made public on the public register on the ACCC's website.

Please contact me if you would like further information about the Australian Breastfeeding Association or this submission.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Rebecca Naylor', is positioned above the printed name.

Rebecca Naylor
Chief Executive Officer

Response to the Infant Nutrition Council Limited application for authorisation A91506 and A91507, *Marketing in Australia of Infant Formula: Manufacturers and Importers Agreement (MAIF Agreement)*



17 August 2015

Breastfeeding is important to the health, nutrition and well being of infants and young children and the the health and well being of mothers. The Australian government's recognition of the importance of infant feeding practices is reflected in the Australian National Breastfeeding Strategy and the National Health and Medical Research Council's Infant Feeding Guidelines^{1,2}. International and Australian public health bodies recommend that all infants be exclusively breastfed for the first six months of life and continue to be breastfed at least into their second year of life^{1,3}. For a variety of reasons, it is not always possible to follow these recommendations. Where breastfeeding is unavailable, it is recommended that infants be fed a commercial infant formula (breastmilk substitute) that meets Codex Alimentarius standards^{1,3}. Nonetheless, feeding with infant formula carries a variety of risks.

There is a significant and increasing amount of research showing that there are health risks associated with both not breastfeeding and early weaning. There are considerable health and financial costs associated with premature weaning in developed countries. In 2002 premature weaning in Australia was estimated to cost \$60-120 million annually for just 5 childhood diseases.⁴ Recent estimates in the United Kingdom assessed the cost of premature weaning as £40-60 million if maternal breast cancer was included.⁵

In Australia we continue to see a rapid increase in childhood obesity and subsequent lifetime risks of non-communicable diseases in Australia. Evidence has emerged that children who are not breastfed have increased risk of overweight/obesity and type-2 diabetes.^{6,7}

These figures highlight the costs to Australian community's health and the economy of an inadequate system for regulating the marketing of breastmilk substitutes. While initiation of breastfeeding in Australia exceeds 96%, in 2010 rates of exclusive breastfeeding at 5 months are low (15%)⁸, only 28% of children were still being breastfed at all, at 12 months, 9% at 18 months and 5% at 24 months.⁹ These figures are well below the Australian Governments own health recommendations¹.

¹ NHMRC. *Infant Feeding Guidelines for Health Workers*. Canberra: Commonwealth of Australia; 2013

² Australian Health Ministers' Conference. *Australian National Breastfeeding Strategy 2010-2015*. Canberra: Department of Health and Ageing 2009

³ WHO, UNICEF. *Global Strategy for Infant and Young Child Feeding*. Geneva: WHO; 2003

⁴ Smith, Thompson and Ellwood. Hospital system costs of artificial infant feeding: estimates for the Australian Capital Territory. *Aust NZ J Public Health* 2002 26, 6

⁵ Renfrew M. et al. Preventing disease and saving resources: the potential contribution of increasing breastfeeding rates in the UK. UNICEF UK 2012

⁶ Horta, B. L., Bahl, R., Martinez, J. C. and Victora, C. G. (2007) Evidence on the long term effects of breastfeeding: systematic review and meta analyses, World Health Organisation, Geneva.

⁷ Horta BL, Victora CG. Long-term effects of breastfeeding: a systematic review. World Health Organization, Geneva 2013

⁸ Australian Institute of Health and Welfare 2011, 2010 Australian National Infant Feeding Survey: Indicator Results. Canberra: AIHW.

⁹ Australian Institute of Family Studies (AIFS) 2008, *Growing Up In Australia: The Longitudinal Study of Australian Children, Annual Report 2006-07*; www.aifs.gov.au/growingup/pubs/ar/ar200607/breastfeeding Accessed 9 August 2015.

In contrast to these low breastfeeding rates, Australia has seen high growth of sales volume of infant formula (28%), follow on formula (44%) and toddler milk (237%) from 2009 to 2014. The total value of milk formula sales more than doubled over this period from AUD \$240 million to AUD \$546 million.¹⁰

Infant formula is a breast milk substitute and as such, a whole food for infants. Improper preparation and consumption can be harmful and as such, we request proper and robust consultation with government health agencies prior to a ruling by the ACCC.

The Australian Breastfeeding Association objects to the reauthorisation of the MAIF Agreement as proposed by the Infant Nutrition Council Limited for the following reasons:

1. Australia should not be committed to the MAIF Agreement for a period of a further 10 years.

The original MAIF agreement dates from September 1992. There is now a greater body of evidence on the importance of breastfeeding and risks of formula feeding. Our population is faced with new challenges that were not evident or as prevalent in 1992, such as the growing epidemic of childhood obesity and invention of follow on formulas, toddler milks and growing up milks. It would be naive to think that the original MAIF agreement would be suitable in its current state for a further 10 years.

The World Health Organisation (WHO) has recently released new recommendations on the marketing of foods to infants and children that will be considered by the WHA in 2016.¹¹ In order to improve breastfeeding rates and lower childhood obesity in Australia, the Australian Breastfeeding Association urges the Commonwealth government to ensure policies and regulations are consistent and up-to-date with World Health Organization recommendations on infant and young child feeding and marketing of foods for children. Therefore, any authorisation of the MAIF Agreement should be only interim, until the Australian Parliament has considered its response to the revised WHO recommendations.

In particular, we ask that the ACCC give consideration to the following reviews in determining the period of authorisation of the MAIF Agreement:

- a. The World Health Organization (WHO) *Consultation on the public draft of the Clarification and guidance on inappropriate promotion of foods for infants and young children* 20 July-10 August 2015. Following this consultation the document will be submitted to the WHO Executive Board in January 2016 in preparation for consideration by Member States at the World Health Assembly (WHA) meeting in May 2016.
- b. Renegotiation of Australia's National Breastfeeding Strategy, which expires in 2015.
- c. Ongoing FSANZ review of Food Standard 2.9.1 which includes labelling requirements for infant foods that fall within the scope of the WHO Code.

In order to consider such evidence, we contend that the MAIF agreement should be given interim approval, for a maximum period of one year (to expire 31st Dec 2016).

¹⁰ Euromonitor International 2014. Baby Food In Australia.

¹¹ WHO Consultation on the public draft of the *Clarification and guidance on inappropriate promotion of foods for infants and young children* <http://www.who.int/nutrition/events/inappropriate-food-promotion-consultation/en/> Accessed 9 August 2015

2. The scope of the MAIF Agreement as described by the Infant Nutrition Council (INC) for this reauthorisation does not protect optimal breastfeeding effectively in Australia.

The INC application states that the MAIF Agreement applies to Starter Infant Formula and Follow-On Formula, but excludes Toddler Milks, Growing Up Milks and complementary foods being sold as suitable for introduction before six months of age.

In 2013, the World Health Organization stated that follow on and toddler formulas are marketed in a way that confuses consumers, and reduces breastfeeding.¹² Further, the WHO Scientific and Technical Advisory Group (STAG) on Inappropriate Promotion of Foods for Infants and Young Children, stated in July 2015 that:

- *'Complementary foods have been shown to displace the intake of breast milk if the amounts provided represent a substantial proportion of energy requirements.'*¹³ and
- *'Evidence from numerous countries has shown that foods are being sold as suitable for introduction before six months of age, breastmilk substitutes are being indirectly promoted through association with commercial complementary foods, and inaccurate claims are being made that products will improve a child's health or intellectual performance.'*¹⁴

In addition, distributors and retailers (i.e. supermarkets and pharmacies) are not included in the MAIF Agreement and neither is pricing of breast milk substitutes.

The Best Start report in 2007¹⁵ and prior to that the Knowles report in 2003¹⁶ made recommendations to include retailers in Australia's implementation of the WHO Code and subsequent WHA resolutions. The current retail environment includes regular in-store promotions, price discounting and the internet is now also a major mechanism for sales and promotion. These practices, intensified by the growth of electronic media, highlight the gaps and inadequacy of the MAIF agreement to protect consumers from inaccurate, misleading and potentially harmful advertising of breastmilk substitutes.

We ask that any reauthorisation of the MAIF Agreement also consider that the pricing of breastmilk substitutes be included. Price competition is a significant driver of consumer choice.

3. The MAIF Agreement and MAIF Complaints Tribunal are inadequate as Australia's official application of the World Health Organization's (WHO) International Code of Marketing of Breast Milk Substitutes and subsequent World Health Assembly (WHA) resolutions.

The Australian Breastfeeding Association strongly disputes the claim by the Infant Nutrition Council that the MAIF Agreement is an effective regulatory instrument for marketing of breast milk substitutes and would like to see it replaced with a mandatory regulatory instrument giving full effect to the WHO Code and subsequent World Health Assembly resolutions, as

¹² http://www.who.int/nutrition/topics/WHO_brief_fufandcode_post_17July.pdf

¹³ *ibid.* Page 1

¹⁴ Discussion Paper: Clarification and Guidance on Inappropriate Promotion of Foods for Infants and Young Children. Report of the Scientific and Technical Advisory Group (STAG) on Inappropriate Promotion of Foods for Infants and Young Children <http://www.who.int/entity/nutrition/events/draft-inappropriate-promotion-infant-foods-en.pdf?ua=1>

¹⁵ Commonwealth of Australia 2007. *The Best Start*. Report on the inquiry into the health benefits of breastfeeding. House of Representatives Standing Committee on Health and Ageing. Pages 138-142.

http://www.aph.gov.au/parliamentary_business/committees/house_of_representatives_committees?url=haa/breastfeeding/rreport.htm

¹⁶ Knowles 2003. *Independent advice on the composition and modus operandi of APMAIF and the scope of the MAIF Agreement*. Department of Health and Ageing. Pages 10-15.

<http://www.health.gov.au/internet/main/publishing.nsf/Content/health-publth-publicat-document-brfeed-knowles.htm>

recommended in *The Best Start 2007* report of the Parliamentary inquiry into the health benefits of breastfeeding.

Specifically:

- a. The MAIF Agreement is voluntary and not all industry members are signatories
- b. Oversight of the MAIF Agreement by the Advisory Panel on the Marketing in Australia of Infant Formula ceased in 2013¹⁷ without public consultation. It was replaced by a MAIF Complaints Tribunal administered by the St James Ethics Centre.
- c. The MAIF Agreement is not enforceable and the Tribunal has no power to impose penalties.
- d. There is a lack of clarity about processes for bringing a complaint about a breach of the MAIF Agreement via the Department of Health and then to the MAIF Complaints Tribunal reporting of decisions and outcomes to the public.
- e. The lack of transparency and appropriateness of industry funding arrangements of the MAIF Complaints Tribunal and the make up of the Tribunal. It is imperative that any regulatory body has transparent processes, is truly independent of industry and absolutely free of conflict or perceived conflict of interest.
- f. Any regulatory authority must table public reports annually, that include outcomes and consequences of significance.
- g. The definition of the 'infant formula market' adopted in MAIF does not capture substitutable products, including toddler and follow-up formulas (consumers cannot differentiate these products)¹⁰
- h. The MAIF Agreement applies only to companies that are signatories to the Agreement.

Given the abysmal failure of the MAIF agreement to protect breastfeeding, as evidenced by the growing breastmilk substitute sales in Australia. It is clear that a broader, stronger legislative regulatory instrument is required ensuring all manufacturers, importers, marketers and retailers of infant formula and breast milk substitutes would be required to comply.

The Australian Breastfeeding Association believes that the full adoption of the WHO Code and subsequent WHA resolutions into legislation is the logical next step in protecting breastfeeding and improving the health and prosperity of the Australian community.

ABA acknowledges the contribution of Dr Julie Smith and Libby Salmon to the development of this submission

¹⁷ Department of Health <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-publth-publicat-document-brfeed-complaints.htm>, accessed 8 August 2015



Health outcomes associated with infant feeding

A summary of evidence - August 2015

When it comes to health outcomes associated with infant feeding, the longer the total duration of breastfeeding and the longer the period of exclusive breastfeeding within the first 6 months, the lower the risks.

An increasing amount of research shows that there are health risks associated with either not breastfeeding or with early weaning.

The following are health outcomes associated with infant feeding for which there is scientific evidence. This list includes results from studies where all types of breastfeeding (including partial breastfeeding), not just exclusive breastfeeding, are included. For all of the following, there is a dose-response relationship between breastfeeding and the health outcome, meaning that the less breastfeeding that occurs, the higher the risks.

For infants, not being breastfed or being breastfed for shorter lengths of time increases the risk of:

- Infections in the first year of life – gastrointestinal, respiratory and ear (otitis media)¹⁻⁴
- Doctor's visits due to infections^{4,7}
- Antibiotic use⁵
- Hospitalisation due to infections⁶⁻⁸

For children, not being breastfed or being breastfed for shorter lengths of time increases the risk of:

- infections at 6 years of age – ear, nose and throat⁹
- overweight and obesity^{3,10}

The National Health and Medical Research Council's (NHMRC's) 2012 Infant Feeding Guidelines¹¹ indicates that not breastfeeding is associated with an increased risk of various health outcomes. The NHMRC indicates that not breastfeeding is associated with the following excess health risks for the following health outcomes, see table below.

Table 1.

Health outcomes associated with not breastfeeding (NHMRC) ¹¹	Cost of hospitalisation in ACT (Australia) in 2002 ¹²
Childhood illness	
Gastrointestinal infection – 178%	\$492,667 (\$20.96 million)
Hospitalisation for lower respiratory tract diseases in the first year – 257%	\$730,132 (40.38 million) all respiratory
Ear infection (otitis media) – 100%	\$198,953 (11.9 million)
Eczema – 47%	\$3,910 (0.23 million)
Necrotising enterocolitis in premature babies – 138%	\$96,686 (5.8 million)
SIDS – 58%	
Asthma (with family history) – 67%	
Childhood obesity – 32%	
Mother	
Breast cancer – 4%	
Ovarian cancer – 27%	

The financial and human cost of not breastfeeding exclusively to 6 months:

Australia¹²

- Exclusive breastfeeding for less than 6 months, added around \$1 to \$2 million annually to ACT hospitalisation costs of treatment of infants and children (aged 0–4 years) for gastrointestinal illness, respiratory illness, otitis media, eczema and NEC in 2002.
- Nationally between \$60 and \$120 million could be saved annually across the Australian hospital system, just for these childhood illnesses.

USA¹³

If 90% of infants were exclusively breastfed to 6 months, the United States would save at least \$13 billion per year and prevent 911 deaths, mostly infants.

UK (UNICEF)¹⁴

A moderate increase in breastfeeding rates would lead to:

- 3,285 fewer gastrointestinal infection-related hospital admissions and 10,637 fewer GP consultations, with over £3.6 million saved in treatment costs annually
- 5,916 fewer lower respiratory tract infection-related hospital admissions and 22,248 fewer GP consultations, with around £6.7 million saved in treatment costs annually
- 21,045 fewer acute otitis media related GP consultations, with over £750,000 saved in treatment costs annually
- 361 fewer cases of necrotising enterocolitis, with over £6 million saved in treatment costs annually
- 865 fewer breast cancer cases with cost savings to the health service of over £21 million

This could result in an incremental benefit of more than £31 million each year.

Chronic disease in later life

Australian researchers calculated the proportion of chronic disease in the adult population that can be attributed to being formula fed, that is, not being breastfed.¹⁵

Table 2. Percentage of chronic disease in the population caused by not being breastfed.

% of population not being breastfed	% of chronic disease in the population caused by not being breastfed							
	Obesity	Type 1 diabetes	Type 2 diabetes	Cardio-vascular disease	Asthma	Coeliac disease	Irritable bowel disease	Childhood cancer
90	20	28	37	15	25	48	26	18
30	8	11	16	6	10	24	11	7
10	3	4	6	2	4	10	4	2

For example if 90% of the population are not breastfed, then 20% of obesity in that population can be attributed to artificial infant feeding. If 10% of the population are not breastfed, then only 3% of that population's obesity can be attributed to artificial infant feeding.

In addition, many large studies around the world are currently being conducted to determine the effect of breastfeeding on long-term health outcomes for mothers and infants as they grow:

SEARCH for diabetes in youth - 6-centre observational study conducting population-based ascertainment of physician-diagnosed diabetes in youth in the US

- Breastfeeding appears to be protective against development of type 2 diabetes in youth, mediated in part by current weight status in childhood.¹⁶

CARDIA (Coronary Artery Risk Development in Young Adults) Study - an ongoing multicenter, population-based, prospective observational cohort study conducted in the US

- Longer duration of lactation was associated with lower incidence of the metabolic syndrome years after weaning among women with or without a history of gestational diabetes.
- Lactation may have persistent favourable effects on women's cardiometabolic health.¹⁷

SWAN (The Study of Women's Health Across the Nation) - SWAN is a multisite, multiethnic longitudinal study of 3,302 mid-life women developed to characterise patterns of health in women as they traverse the menopausal transition conducted in the US.

- Duration of lactation is associated with lower prevalence of metabolic syndrome in a dose-response manner in midlife, parous women.¹⁸

¹ Duijts, L., Jaddoe, V. W., Hofman, A., & Moll, H. A. (2010). Prolonged and exclusive breastfeeding reduces the risk of infectious diseases in infancy. *Pediatrics*, 126(1), e18-e25.

² Duijts, L., Ramadhani, M. K., & Moll, H. A. (2009). Breastfeeding protects against infectious diseases during infancy in industrialized countries. A systematic review. *Maternal & Child Nutrition*, 5(3), 199-210.

³ Hornell A, Lagstrom H, Lande B, Thorsdottir I 2013, Breastfeeding, introduction of other foods and effects on health: a systematic literature review for the 5th Nordic Nutrition Recommendations. *Food Nutr Res* 57:10.3402/fnr.v57i0.20823.

⁴ Ladomenou, F., Moschandreas, J., Kafatos, A., Tselentis, Y., & Galanakis, E. (2010). Protective effect of exclusive breastfeeding against infections during infancy: a prospective study. *Archives of Disease in Childhood*, archdischild169912.

⁵ Mangrio E, Wremp A, Moghaddassi M, Merlo J, Bramhagen A-C, Rosvall M 2009, Antibiotic use among 8-month-old children in Malmo, Sweden – in relation to child characteristics and parental sociodemographic, psychosocial and lifestyle factors. *BMC Pediatr* 9: 31. doi: 10.1186/1471-2431-9-31

⁶ Quigley MA, Kelly YJ, Sacker A 2009, Infant feeding, solid foods and hospitalisation in the first 8 months after birth. *Arch Dis Child* 94: 148-150.

⁷ Yiengprugsawan, V., & Hogan, A. (2013). Ear Infection and Its Associated Risk Factors, Comorbidity, and Health Service Use in Australian Children. *International journal of pediatrics*, 2013.

⁸ Talayero JMP, Lizán-García M, Puime AO, Muncharaz MJB, Soto BB, Sánchez-Palomares M, Serrano LS, Rivera LL 2006, Full breastfeeding and hospitalization as a result of infections in the first year of life. *Pediatr* 118: e92-e99.

⁹ Li, R., Dee, D., Li, C. M., Hoffman, H. J., & Grummer-Strawn, L. M. (2014). Breastfeeding and Risk of Infections at 6 Years. *Pediatrics*, 134 (Supplement 1), S13-S20.

¹⁰ Horta BL, Victora CG 2013, Long-term effects of breastfeeding: a systematic review, Geneva: World Health Organization.

- ¹¹ National Health and Medical Research Council 2012, *Infant Feeding Guidelines: Information for Health Workers*. Canberra: National Health and Medical Research Council
- ¹² Smith, J. P., Thompson, J. F., & Ellwood, D. A. (2002). Hospital system costs of artificial infant feeding: estimates for the Australian Capital Territory. *Australian and New Zealand Journal of Public Health*, 26(6), 543-551.
- ¹³ Bartick, M., & Reinhold, A. (2010). The burden of suboptimal breastfeeding in the United States: a pediatric cost analysis. *Pediatrics*, 125(5), e1048-e1056.
- ¹⁴ Renfrew et al for UNICEF UK 2012, *Preventing disease and saving resources: the potential contribution of increasing breastfeeding rates in the UK*.
- ¹⁵ Smith, J. P., & Harvey, P. J. (2011). Chronic disease and infant nutrition: is it significant to public health?. *Public Health Nutrition*, 14(02), 279-289.
- ¹⁶ Mayer-Davis, E. J., Dabelea, D., Lamichhane, A. P., D'Agostino, R. B., Liese, A. D., Thomas, J., ... & Hamman, R. F. (2008). Breast-Feeding and Type 2 Diabetes in the Youth of Three Ethnic Groups The SEARCH for Diabetes in Youth Case-Control Study. *Diabetes Care*, 31(3), 470-475.
- ¹⁷ Gunderson, E. P., Jacobs, D. R., Chiang, V., Lewis, C. E., Feng, J., Quesenberry, C. P., & Sidney, S. (2010). Duration of lactation and incidence of the metabolic syndrome in women of reproductive age according to gestational diabetes mellitus status: a 20-Year prospective study in CARDIA (Coronary Artery Risk Development in Young Adults). *Diabetes*, 59(2), 495-504
- ¹⁸ Ram, K. T., Bobby, P., Hailpern, S. M., Lo, J. C., Schocken, M., Skurnick, J., & Santoro, N. (2008). Duration of lactation is associated with lower prevalence of the metabolic syndrome in midlife—SWAN, the study of women's health across the nation. *American journal of obstetrics and gynecology*, 198(3), 268-e1.