PUBLIC HEALTH COMMUNICATION CENTRE AOTEAROA

Backing off international infant formula standards: A retrograde step

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Summary

Infant nutrition is a key determinant of health. The International Code of Marketing of Breast-milk Substitutes aims to contribute to the provision of safe and adequate nutrition for all infants through the protection, promotion, and support of breastfeeding, and to ensure the safety of formula fed babies.

Aotearoa New Zealand is opting out of proposed joint Australia/NZ infant formula marketing standards that would have brought NZ more into line with international best practice. This decision is a missed opportunity to protect infant health, to make sure parents and caregivers have accurate information about products, and to support product affordability.

In this Briefing, we describe how the commercial milk formula industry undermines infant health. The NZ Government needs to recognise that industry self-regulation is not working, and that regulations and laws relating to infant and young child nutrition are necessary to protect health

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Breastfeeding is optimal infant feeding and has many short-and long-term health benefits. In New Zealand, only 17-22% of infants are exclusively breastfed to six months with rates consistently lower for Māori and Pacific people.[1] Increasing exclusivity and duration of breastfeeding is one of the most significant cost-effective ways to improve equity and increase population health and wellbeing.[1]

Aggressive marketing of lucrative commercial milk formula, which includes misinformation in the form of claimed benefits, contributes to the undermining and loss of breastfeeding, and the misuse of commercial milk formula products. This can have significant negative effects on infant and maternal health, wellbeing and population health.

A recent article in *The Lancet* highlighted the vast economic power of the commercial milk formula industry, continued under-regulation of industry marketing, and chronic under-resourcing of breastfeeding support services. The marketing of milk formula and the capture of parents, communities, science, and policies have altered the infant and young child ecosystem to the detriment of health. [2]

Industry arguments against regulation and restrictions

The International Code of Marketing of Breast-milk Substitutes seeks safe and adequate nutrition for infants through the protection, promotion, and support of breastfeeding. The Code also aims to ensure the safety of formula fed babies based on adequate information through appropriate marketing and distribution of products. (See Appendix 1)

UNICEF highlights industry arguments against national implementation of the International Code and presents counter arguments to these claims.[3,4] (Figure 1)

Figure 1

United Nations Children's Fund (UNICEF). Countering Industry Arguments against Code Implementation: Evidence and Rights-Based Responses. 2024.

The commercial milk formula industry argues against regulation and restrictions	The International Code of Marketing of Breast-milk Substitutes has the aim of not only contributing to the provision of safe and adequate nutrition for infants through the protection, promotion, and support of breastfeeding, but also to ensure the safety of formula fed babies based on adequate information through appropriate marketing and distribution of products
There are threats from commercial milk formula industry for withdrawal of investments from countries linked to a suggested economic loss	**Argument 15** States that profits generated from foreign investments are, in fact, mostly repatriated to shareholders abroad. Long term benefits for public and population health will offset the short-term economic adjustments.
The commercial milk formula industry states that new FSANZ labelling requirements “do not suit the New Zealand context”. As long as infant formula is safe and the claims on labels are not misleading, consumers should be allowed to make their own informed choices.	**Argument 5** Addresses the legitimate market for formula and how the International Code protects all infants regardless of how they are fed. Information to protect formula fed infants includes accurate product labels and information and protection from misinformation and inappropriate marketing.
The commercial milk formula industry already has voluntary, self-regulated codes of practice which are described by industry as less costly and easier to implement.	**Argument 18** The voluntary, self-regulated codes of practice take a minimalist approach and are fragmented. They are ineffective at protecting infant and population health, reduce standards and rules to the lowest common denominator and serve as a barrier to governments being accountable and meeting their obligations by implementing regulations and legislation to protect infant and young child health.

The New Zealand response to the International Code is underpinned by a voluntary industry code, and a self-regulatory implementation and monitoring process. (See Appendix 2)

Globally, corporate industry lobbying continues to succeed in watering down protections for breastfeeding support as seen at the World Health Assembly in 2018. Experts have written about the resurgent influence of big formula and that education on infant feeding must not be left to industry.[5] Marion Nestle, Professor of Nutrition, Food Studies, and Public Health at New York University, pointed out that “high on the list” of significant and technical trade barriers are country breastfeeding policies, and this reflects industry concern that breastfeeding rates may increase when governments implement policies to support and protect breastfeeding, with a resulting rebound negative effect on infant formula sales.[6]

Blocking infant feeding resolutions that could support governments to implement breastfeeding policies are part of the industry playbook. This also has the effect of reducing protections for infants being fed on formula. The final World Health Assembly resolution in 2018 was significantly weakened by US pressure.[7]

The image above portrays Hine Ahu One, the first female atua and the earth-formed woman. She is depicted breastfeeding her pēpi. It also represents the transference of indigenous knowledge around breastfeeding from tūpuna through to the present and onto the future generations. A special thanks to the illustrator Adele Jackson, nō Ngati Tūkorehe.

Te Tiriti Considerations

Te Tiriti o Waitangi is the constitutional document for Aotearoa New Zealand. It references in Article II, for example, Mana Motuhake enabling the right for Māori to be Māori and to exercise self-determination over their lives and to live in Te Ao Māori terms according to their own philosophies including tikanga Māori. Protections need to be in place to uplift hauora Māori and breastfeeding support for whānau. (Figure 2)

Figure 2

Te Tiriti Considerations

• Whangai ū /Breastfeeding is vitally important to the short and long-term health and well-being of māmā, pepi and whānau.
• Whangai ū is a traditional practice that should be continued. owever, the influence of colonisation and the growing preference for bottle feeding in our society is becoming increasingly evident. [8]
• Whānau, hapū, Iwi should be enabled to exercise their authority to uplift their health and wellbeing, ensuring that they are able to make informed choices around infant feeding choices and maintaining their own cultural practices around whangai ū just like their tūpuna/ancestors.[9]
• Health inequities persist with formula feeding rates for Māori infants at maternity discharge are higher than the national average. [10]
• The milk formula industry harms Papatūānuku: the production of formula leaves a major environmental footprint that contributes to the depletion of natural resources, environmental degradation and greenhouse gas emissions that cause global warming and climate change.[11]
• Aggressive and inappropriate marketing of breast-milk substitutes continues to mislead whānau and undermine efforts to protect the rights of tamariki to health and to ensure sound objective health information for matua/parents.
• It is imperative that governments rebalance the power between commercial and health interests, halt commercial interference with public health measures and prioritise the future of pēpi, māma and whānau health over industry profits. [12]

Conclusion

Parents need access to information about infant feeding that is free from commercial influence (see Appendix 3). Informed decision-making needs accurate, evidence-based infant and young child feeding information on formula products, product information and on digital media. Regulation of industry is a government responsibility as industry self-regulation and voluntary industry codes provide insufficient protection. The proposed standards would have moved Aotearoa NZ a little closer towards international best practice. The International Code of Marketing of Breast-milk Substitutes, and the subsequent relevant World Health Assembly resolutions that update and keep the Code current are regarded as a *minimum* standard to protect infants whether breastfed or formula-fed.

By opting out of the Code, Aotearoa NZ has taken a step in the wrong direction. Population health and wellbeing must take priority over company profits.

What's new in this Briefing

- Aggressive marketing of lucrative commercial milk formula, which includes misinformation in the form of claimed benefits, contributes to the undermining and loss of breastfeeding, and the misuse of commercial milk formula products, both of which have significant negative effects on infant and maternal health, wellbeing and population health.
- Parents are being misled into buying expensive products, choosing products that make unsubstantiated claims, and also into buying unnecessary products such as follow on formula and toddler milks.
- Aotearoa NZ is putting the health of infants at risk by opting out of the new proposed FSANZ standards. The optimal global recommendations for infant and young child feeding continue to be undervalued.

Policy implications

- The New Zealand Government needs to recognise the abundant evidence that an industry voluntary self-regulated code is too weak to protect parents from marketing.
- Regulatory and legislative measures in the area of infant and young child feeding are necessary to protect health.
- Any future work by the government departments regarding food standards must recognise that the International Code of Marketing of Breast-milk Substitutes and subsequent, relevant World Health Assembly resolutions represent a minimum standard of protection.
- These protections apply to all infants regardless of how they are fed.

Correction: This Briefing was updated on 13/09/24 with the addition of the word "exclusively" to the first sentence in the opening paragraph along with an updated reference.

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Appendix 1: The International Code of Marketing of Breast-milk Substitutes and subsequent, relevant World Health Assembly Resolutions

The protection, promotion and support of breastfeeding is a global health priority. The World Health Organization (WHO) and the United Nations International Children's Emergency Fund (UNICEF) recommend that infants be exclusively breastfed for the first six months after birth, with continuation of breastfeeding into the second year of life (and beyond) in combination with age-appropriate complementary foods. It is recognised that not all infants will be breastfed and to mitigate the risks associated with not being breastfed, the International Code advocates that non-breastfed infants be fed safely on the best available nutritional alternative. Infant formula products must be carefully regulated, and parents instructed on how to use formula safely. Recognition of these unique issues has led to the creation of an international standard for the marketing of infant formula products.

The International Code of Marketing of Breast-milk Substitutes has the aim of not only contributing to the provision of safe and adequate nutrition for infants through the protection, promotion, and support of breastfeeding, but also ensuring the safety of formula fed babies based on adequate information through appropriate marketing and distribution of products.[13] A statement from the International Code introduction encapsulates the aim and intent:

"... in view of the vulnerability of infants in the early months of life and the risks involved in inappropriate feeding practices, including the unnecessary and improper use of breast-milk substitutes, the marketing of breast-milk substitutes requires special treatment, which makes usual marketing practices unsuitable for these products" (p.7)

The International Code was adopted by the World Health Assembly in 1981. The World Health Assembly develops and releases relevant resolutions approximately every two years to ensure the International Code remains contemporary and meaningful. The formula industry does not recognise these updates, although they are a legitimate part of the International Code. They aim to keep the Code up to date with challenges to infant and young child feeding such as safe feeding during emergencies, and new industry marketing strategies such as targeted marketing via digital media. Countries who have limited or no legal measures for effective regulation of industry marketing practices, like Aotearoa New Zealand, suffer from a combination of lack of high-level political will, industry interference, poor accountability, and a lack of monitoring and enforcement mechanisms.[14] In 2022, 43 years after the International Code was created, the marketing of formula milk was described as "one of the most underappreciated risks to infants' and children's health".[15]

Baker et al. examined the paradoxical challenges government regulators in low-income countries face when balancing the investments and opportunities for economic development afforded by the transnational milk formula corporations, against the negative public health implications.[16] Baker et al. also reported in another article that these issues are *"...especially the case when companies such as Nestle and Danone are among the*

largest operating in developing countries and when government agencies have only limited capacity to weigh the public health implications".[17]

The infant feeding resolutions passed at the World Health Assembly are important as they update the International Code of Marketing of Breast-Milk Substitutes. This aims to support governments to develop strategies and policies for infant and young child health, and public health. This is about safe infant and young child feeding and controlling misleading industry claims about their products, and not about pressuring women to breastfeed. It is also about governments being held accountable for providing the social conditions that ensure breastfeeding women receive all the support they need, and for providing the information for parents and health professionals to enable support for all parents regardless of how infants are fed.

In 2024, at the Seventy-seventh World Health Assembly in Geneva, guidance for Member States about digital marketing was requested of the WHO Director General due to new technology creating powerfully persuasive marketing tools, extremely cost effective and often not easily recognizable as breast-milk substitutes/commercial milk formula promotion. These developments in digital marketing require governmental regulatory and legal controls. A voluntary industry code cannot provide a disincentive to curb this marketing. There has been a recent consultation on regulatory measures aimed at restricting digital marketing of breast-milk substitutes/ commercial milk formula.[18] The purpose of this consultation was to gather feedback on regulatory measures aimed at restricting the digital marketing of breast-milk substitutes. The rise in digital marketing is of concern. Data on the extent of online social marketing that violates the International Code and resolutions is essential and this work needs to be undertaken by government. It is unlikely that voluntary adherence to an industry code of practice will be sufficient to control these violations.

Studies have found a direct correlation between marketing strategies for follow-on (follow-up) formulae, and the perception and subsequent use of these products as breast-milk substitutes.[19] A similar issue exists with products such as toddler milks.[20,21,22] The World Health Organization has drawn attention to the cross-promotion of products and misleading health and nutrition claims and re-emphasised the updated definition of breast-milk substitutes; "*Products that function as breastmilk substitutes should not be promoted. A breastmilk substitute should be understood to include any milks (or products that could be used to replace milk, such as fortified soy milk), in either liquid or powdered form, that are specifically marketed for feeding infants and young children up to the age of 36 months (including follow-up formula and growing-up milks).*[23]

Appendix 2: The Code in Aotearoa New Zealand

New Zealand's initial response to the International Code was to set up a voluntary, self-regulatory implementation and monitoring process in 1997. The Code in New Zealand, a standard document, which included the Code of Practice for Health Workers and the New Zealand Infant Formula Marketers' Association Code of Practice for the Marketing of Infant Formula, was developed later.[24] Four codes are now included in the New Zealand framework: the Health Workers' Code, the Marketers' Code of Practice (now known as the Infant Nutrition Council Code of Practice which is an industry developed and voluntary code), the Advertising Standards Complaints Board and the Food Standards Code.[25,26] The full scope of the International Code is not recognised under these NZ codes. For example, the International Code now includes products up until 36 months, sales in retail outlets, and feeding bottles and teats. In NZ, violations of the Code in NZ can be reported via a

complaints-based process which relies on health worker and consumer knowledge of the Code/s and relies also on these concerned actors having the time to submit detailed complaints and be actively involved with the industry responses to the reports of their violations.[27] There is no formal, active, or systematic monitoring of formula marketing in New Zealand, and there are no meaningful sanctions imposed for violations.

The WHO/UNICEF/IBFAN (International Baby Food Action Network) national implementation of the International Code, status report made seven recommendations.[28] These include, *Countries should recognize their obligations under international human rights law and international agreements to enact binding legal measures to implement the Code and eliminate inappropriate marketing practices*; and *Countries should ensure that domestically-based companies are held accountable for cross-border activities that violate the Code.* A media report on the day of the 'opt out', the NZ Government announcement included a quote from a formula manufacturer saying how valuable the Asian markets are to New Zealand's infant formula exports.[29] This brings up the question of whether New Zealand has any responsibilities beyond its borders. Judith Galtry discusses whether overseas trade policy is likely to reduce breastfeeding and infant and maternal wellbeing in other nations.[30] Aggressive marketing of lucrative commercial milk formula, which includes misinformation in the form of claimed benefits, contributes to the undermining and loss of breastfeeding, and the misuse of commercial milk formula products, both of which have significant negative effects on infant and maternal health, wellbeing and also population health.

From a Te Ao Māori perspective, babies were sustained on breast milk in pre-European times, and breastfeeding was seen as a taonga/treasure.[31] Continuation of this tikanga is crucial to Māori health and wellbeing. The NZ Breastfeeding Alliance reported last year that 6% of Māori babies leave New Zealand's hospital and community maternity services every year having received formula and no breast milk at all when compared to the national rate of 4%.[32] Government must consider their commitments to deliver equitable services and meet their obligations under Te Tiriti o Waitangi and therefore need to ensure, at a minimum, that Māori health outcomes match those of other New Zealanders.

Appendix 3: What is important for parents to know about infant formula and what is missing?

Protection from misinformation for parents, regardless of their infant feeding decisions, remains limited. Misleading labelling can result in parents purchasing inappropriate products or buying more expensive products that make unsubstantiated claims about benefits. Industry information about products can mislead parents into thinking that common infant feeding challenges can be resolved by using 'special' milk formula and claims that products are linked to 'benefits' such as reduced colic, or increased infant and young child IQ have proved to be very successful industry marketing strategies. Cheung et al. in their research on the health and nutrition claims of 757 formula products found that most had at least one health and nutrition claim and that, "*multiple ingredients were claimed to achieve similar health or nutrition effects, multiple claims were made for the same ingredient type, most products did not provide scientific references to support claims, and referenced claims were not supported by robust clinical trial evidence*."[33] Results from a systematic review of formula milk trials showed that "*formula trials lack independence or transparency, and published outcomes are biased by selective reporting*".[34]

An example of industry influence is seen in the overdiagnosis of cow's milk protein allergy (CMPA) exposed by Van Tulleken.[35] The extensive links between the formula industry, the research, guidelines, medical education, and public awareness efforts around CMPA raised the question of industry-driven overdiagnosis. When a product claims it is beneficial for health conditions it can easily appear to parents that they should use the product in the absence of a medical diagnosis, without considering any risk. Sibson and Westland describe how low-allergy formulas pose health risks above standard infant formulas because the non-lactose carbohydrate sources they contain, such as maltodextrin and glucose syrup are associated with dental caries and early childhood obesity. Other health risks were described, such as increased risk of bacterial contamination due to the addition of probiotics which make proper sterilisation of feeds impossible, and potential adverse effects from phyto-oestrogens in soya formula and thickeners in products labelled "anti-reflux".[36]

Commercial milk formula products conform to the same compositional regulations as determined by the Codex Alimentarius.[37] However, industry marketers compete by making claims about added ingredients which are 'generally regarded as safe' (GRAS) but these ingredients are unnecessary. If they were necessary, they would be included in all products. This practice has a significant effect on the pockets of parents as the products marketed as 'specialised' are more expensive. Such marketing strategies take advantage of the parental natural inclination to do what is best for their babies.In marketing there is a phenomenon called price placebo which is based on consumers believing that if they pay more for a product then it means it must be a better product.[38] Parents using formula milks are trying to decide which product to buy for their babies and they are not only influenced by health and nutrition claims but by price, and they are likely to buy the high-price-high-claim products. Some parents who are struggling financially have been found to practice what is referred to as 'formula-stretching' which involves reducing feed amounts/times and/or watering down feeds. Burkhardt reports that formula stretching practices are associated with serious short and long-term consequences such as failure to thrive and developmental deficits.[39] Another finding by Burkhardt was that 58% of the 144 urban parents in the cross-sectional survey would not use the cheaper generic formulas, and 50% believed that generic formulas and brand name formulas were not equivalent. The reason for this is simple – marketing. Product expense has been an ongoing issue in the U.K and this has recently contributed to a crisis in terms of affordability of formula milks for parents.[40,41,42,43,44] A similar evaluation of these affordability issues in Aotearoa NZ, given the economic stressors on parents, could be viewed as a priority action.

Developing new products which suggest to parents that babies need to move from a stage one milk to a follow-on milk at six months and then on to toddler milks, is another marketing strategy that hits parents' pockets. In reality, stage one formula milks are recommended for infants being fed on formula for the full first year of life and follow-on formula and toddler milks are unnecessary products.[45] Due to exposure to cross branded products/misinformation, and a lack of regulatory measures, parents continue to use commercial milk formula products way past the point they are needed.

Parents and carers also need to know that powdered commercial milk formula products are not sterile. (See Appendix 4).

Appendix 4: Safe preparation of powdered infant formula (PIF)

An important statement missing from commercial milk formula labels is that the powdered products are not sterile. Because the product is not sterile it needs to be reconstituted carefully to avoid the growth of any bacteria that may already be present. Instructions for

optimal reconstitution are also missing on industry information. The World Health Organization recommends using boiled water at a temperature of 70 degrees centigrade or above to ensure any harmful bacteria such as salmonella and cronobacter sakazakii are destroyed.[46] Cronobacter sakazakii, is a species of gram-negative bacteria belonging to the Enterobacteriaceae family, which is known to cause severe and often fatal meningitis and sepsis in young infants. Although infection, morbidity and mortality rates are rare amongst well, full term infants, there is a need to recognise that accurate information may not be collected or reported in some countries, and rates of infant infection due to product contamination may be underreported.

New Zealand Neonatal Intensive Care Units have used ready to feed liquid formula since August 2004 after receiving advice from the Ministry of Health and the Ministry for Primary Industries.[47] Maternity facilities in NZ also use ready to feed liquid formula. Recalls of contaminated powdered products do occur, often after outbreaks of illness.[48,49] Notifications about recalls of contaminated products also occur in New Zealand and although recalled contaminated products are not necessarily on the shelves here, there is always the possibility that parents have purchased products online.[50] A media report in the Washington Post describes how parents are not adequately warned about the risks of cronobacter and the use of ready to feed liquid products is suggested.[51] Utilising the optimal instructions for the reconstitution of powdered infant formula also reduces the risk of illness significantly. For this to happen powdered products need to be labelled as 'not sterile' and optimal instructions for making the formula need to be detailed.

The proposed FSANZ new standards continue to ignore the optimal reconstitution recommendations and instructions will continue to inform users that previously boiled and cooled potable water must be used to reconstitute powdered formula.[52]

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