Comments on 4 April 2022 Call for submissions –Proposal P1028 Infant Formula

Authors:

[redacted]

Australian Breastfeeding Association (ABA)

[redacted]

World Breastfeeding Trends Initiative (WBTi) Australia

[redacted]

Contact details:

[redacted]

Date: 17 June 2022

Principles

Breastfeeding is important to protect the food safety and food security of infants during pandemics and natural disasters, as well as from bacterial contamination (Becker, Zambrano et al. 2022, Doherty, Coutsoudis et al. 2022, M&C Saatchi World Services 2022, WHO/UNICEF 2022). This is an increasing concern for public policy, including in high income countries such as Australia (ACCC 2021).

All products used for feeding infants and young children are to be considered within the scope of the WHO International Code of Marketing of Breastmilk Substitutes 1981 and subsequent relevant WHA Resolutions ("the WHO Code")(WHO 1981). "Marketing" includes, inter alia, product promotion activities targeting health professionals and health channels, as well as to the public.

The ANZ Code is a key mechanism for Australia's implementation of the WHO Code. The role of FSANZ in supporting the implementation of the WHO Code is critical. The ANZ Code must clearly and comprehensively apply the principles of the WHO Code, and implement the recommendations of the WHO Code and subsequent resolutions, and 2017 WHO Guidance on ending the inappropriate promotion of foods for infants and young children (WHO 2016). Prohibiting all nutrition and health claims on all products within the scope of the WHO Code is needed to align Australia's laws with World Health Assembly Resolution WHA58.32 (WHO 2022).

Protecting breastfeeding from being undermined by commercial marketing activities requires regulators to demand the highest standards of evidence in relation to the safety and suitability of these products as breastmilk substitutes. The term 'generally accepted scientific data' is used throughout the P1028 CFS, to support the use of a novel ingredient or additive. However, this is inadequate. The term should be defined to require high quality scientific evidence.

A high standard of evidence for these products is critical, both because of the unique vulnerability of infants and young children, and in the light of systematic reviews that show the biased and inadequate evidence that has been used in the past to justify the use of 'Additional' ingredients (for example long-chain polyunsaturated fatty acids like DHA and AA (Verfuerden, Dib et al. 2020, Helfer, Leonardi-Bee et al. 2021).

Notably, in a recent systematic evaluation of 125 infant formula trials conducted since 2015, Helfer (2021) found that 'formula trials lack independence or transparency, and published outcomes are biased by selective reporting' and that ' some trials might have a marketing aim and no robust scientific aim.' While premarket assessment requirements for novel foods will be considered in another review (P1024), all ingredients must have evidence of functional benefit demonstrated according to high quality scientific evidence (Verfuerden, Dib et al. 2020, Helfer, Leonardi-Bee et al. 2021).

As trade and marketing of formula milk products is globalised, the proposals in P1028 should support Australia's role as a global citizen. This includes responsibilities, as a member of the World Health Assembly, contributor to Codex standards and trading partner, to stop the inappropriate marketing of food products for infants and young children aged 0-36 months, and the promotion of breastmilk substitutes.

There is clear evidence that product labelling of specialised and standard infant or follow up formula products is used for cross-promotion to market milk formula products in breach of the WHO Code (Pereira, Ford et al. 2016, Becker, Zambrano et al. 2022, M&C Saatchi World Services 2022, WHO/UNICEF 2022).

Accordingly, the key objective of the proposals in P1028 should be to ensure Australian food regulators, importers and exporters prioritise WHO Code implementation to protect the health of all infants and mothers. 'Society is not a bystander –everyone must protect the environment in which women and parents feed their infants' (WHO/UNICEF 2022) p.18].

Summary of comments

1. We support the revised regulatory framework into the proposed two categories: IFP and SMPPi but ONLY with a tighter definition of the SMPPi categorisation as detailed.
2. We do not support the current definition of SMPPi and make suggestions to ensure that the product categorisation is not inappropriately exploited to circumvent WHO Code and food law restrictions on health and content claims on infant formula products.
    a. We support retaining the 'Breast is Best statement' on SMPPi except those for inborn errors of metabolism or lactose free formulas.
    b. We support categorising infant formulas that contain hydrolysed protein and/or are low lactose/lactose free as 'infant formula' rather than SMPPi, because it is likely to enable enforcement of the prohibition on nutrition content and health claims (e.g. 'comfort', 'sleep').
3. We support plainer packaging of all infant formula products and the proposal to limit ingredient claims by only permitting 'information about ingredients in the statement of ingredients' (NIS), in a prescribed format.
4. We are concerned that the allowing of 'Additional' ingredients in the NIS supports misleading marketing and 'premiumisation.' We support the principle that 'Any scientifically proven compositional improvements in infant formula should be made mandatory for all relevant products' (Munblit, Crawley et al. 2020).

Detailed comments

We refer you to our previous submission on P1028, and do not object to some of FSANZ 'preferred options' in the 'P1028 CFS.docx'. Hence no comment is made on those proposals.

The following detailed comments and evidence are provided after consideration of the information in Sections 1-8 in 'P1028 CFS.docx' and relevant supporting documents (SDs 1-6) and Attachments. Page numbers in this document refer to 'P1028 CFS.docx,' unless otherwise stated.

2 Regulatory framework

2.5 Preferred option

Infant formula products are proposed to include the following:

1. Nutritionally complete infant formula products with a standard nutrient formulation which, when used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for infants.
2. Nutritionally complete infant formula products with a modified formulation relating only to partially hydrolysed protein and/or low lactose/lactose free which, when used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for infants.

Special medical purpose products for infants are proposed to be:

1. Nutritionally complete with a nutrient-adapted formulation specific for a disease, disorder or medical condition which, when used under medical supervision in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the infants for whom it is intended.

2. Nutritionally incomplete with a nutrient-adapted formulation specific for a disease, disorder or medical condition that is supplementary and is not suitable to be used as the sole source of nourishment.

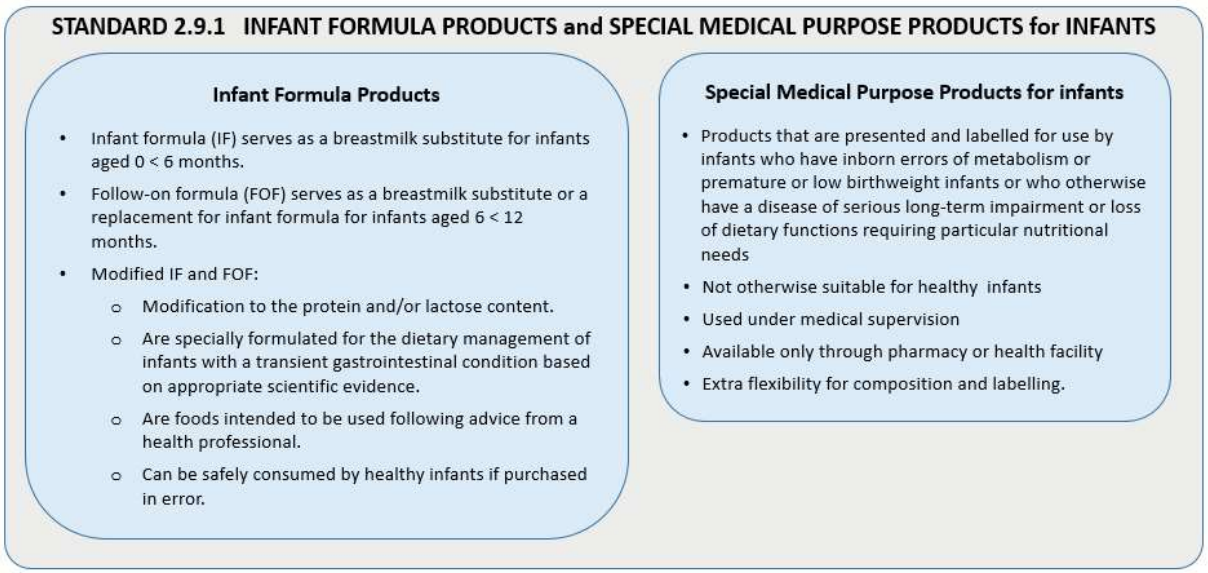

Figure 2: Proposed categories for Standard 2.9.1

To implement the revised regulatory framework, the following changes to Standard 2.9.1 are envisaged:[1]

- remove the Infant Formula Products for Special Dietary Purposes categorisation and the current associated sub-categories
- create a new category and definition in Standard 2.9.1 for Special Medical Purposes Products for infants
- rename Standard 2.9.1 – "Infant Formula Products and Special Medical Purpose Products for infants"
- remove definition of 'protein substitute' with requirements for hydrolysed protein used in infant formula products to be included in Standard 2.9.1

A consequence of the proposed framework is that food additive permissions may apply differently across the infant formula products and SMPPi categories. For infant formula products (including the modified products in this category), food additives will be permitted only at the lower Maximum Permitted Level (MPL) (see SD1).

Comments:

We welcome proposal 2.5 that would categorise infant formulas that contain hydrolysed protein and/or are low lactose/lactose free as 'infant formula' rather than SMPPi. These products are clearly not products to treat an inborn error of metabolism, prematurity or any disease or other serious medical condition. This categorisation would prevent nutrition content and health claims currently made by these products (e.g. 'comfort', 'sleep').

Permission for food additives for infant formula product and SMPPi should be based on high quality scientific data of efficacy, rather than merely 'safe, beneficial and effective for the persons for whom they are intended on the basis of generally accepted scientific data.'

We note that the proposed categorisation means that infant products which are nutritionally incomplete and have a supplementary role (e.g. bovine-derived human milk fortifiers and pre-term supplementary products), will be regulated under Standard 2.9.5 and fall outside the Ministerial Policy Guideline. We agree that these products may require protection of infant health and safety with infant-specific labelling and restrictions for food additives, processing aids, novel foods, contaminants, nutritive substances. We note that these products remain within the scope of the WHO Code, and should not be marketed.

[1] These changes are noted here for explanatory reasons. Proposed drafting for Standard 2.9.1, Schedule 29 and related standards will be covered in the 2nd CFS.

'Lactose free' or low lactose' infant formula

We note from SD3 Section 5.1 the proposal that the product names include 'lactose free' or low lactose' will not be considered a nutrition content claim. However, product labels must contain no other statements other than the amount of lactose and galactose in the NIS table.

Partially hydrolysed infant formulas

We note from SD3 Section 5.2 on partially hydrolysed formula that the preferred option to categorise these products as infant formula (and not SMPPi) would prohibit health claims, for example 'anti-reflux' or 'colic'. We note that 'partially hydrolysed infant formulas are not recommended for dietary management or treatment of allergy' (CPS p. 28), and note that the proposed changes from 'source of protein' to 'origin of protein' (e.g. cow's milk) might reduce misleading marketing. However, the words 'partially hydrolysed' may be required on the label to inform consumers. We would say that that:

- The most appropriate place for this information on the label is the NIS, where the words 'partially hydrolysed' appear as an indented line under 'protein.'
- A label warning is required that partially hydrolysed infant formulas are not recommended for dietary management or treatment of allergy, and to seek medical advice about the appropriateness of the protein in this product for their infant.

3 Definitions

3.2 Definition for SMPPi

3.2.4 Preferred option

The preferred option is a new definition for *Special Medical Purpose Products for infants* (SMPPi), as follows:

A **Special Medical Purpose Product for infants** means a food that is

a. specially formulated for the dietary management of infants
   (i) by way of exclusive or partial feeding, who have special medically determined nutrient requirements or whose capacity is limited or impaired to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food; and
   (ii) whose dietary management cannot be completely achieved without the use of the food; and
b. intended to be used under medical supervision; and
c. represented as being
   (i) a food for special medical purposes intended for infants; or
   (ii) for the dietary management of a disease, disorder or medical condition in infants.

Comments

We note that 'the definition needs to delineate those formulas that are needed for a medically determined disease, disorder, or condition from those that are used for less serious and/or transient conditions' (p.26) and the need to 'reduce the ambiguity surrounding the classification of some products' (p.27) for the purposes of ensuring compliance.

However, the proposed definition is not tight enough. Specifically, there is no clarity on what would constitute 'a disease of long-term impairment or loss of dietary functions requiring particular nutritional needs.' We request that FSANZ considers that infant formula manufacturers and importers have a history of taking liberties in interpreting regulations in this area (Berry and Gribble 2017, Dipasquale, Serra et al. 2020, First Steps Nutrition Trust 2020). For example, the current Standard 2.9.1 allowance for 'Infant formula for special dietary use' is limited to products for premature infants, for cases where a protein substitute is required and for 'metabolic, immunological, renal, hepatic and malabsorptive conditions.' However, products to treat 'colic' and 'sleep' are currently marketed and sold under this allowance. Any proposed definition for SMPPi must prevent such misuse of the categorisation.

Accordingly, we make the following suggestions to the definition of SMPPi to reduce the risk of caregivers misdiagnosing transient digestive disorders and normal infant behaviour through the marketing of these products through product names and label claims. Exposure of consumers to these products and their marketing tactics is likely to occur, given the difficulty of restricting access to these products through online retailers and pharmacies.

- The standard must clearly describe the medical conditions that products under the SMPPi categorisation are for.
- Line (a)(i) the words 'medically determined' should be appear twice, to read:
  by way of exclusive or partial feeding, who have special medically determined nutrient requirements or whose medically determined capacity is limited or impaired to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food; and
- Line (b): require mandatory use under medical supervision and delete the word 'intended' to read:

  b. ~~intended~~ to be used under medical supervision

This will make line (b) consistent with Regulation (EU) No 609/2013 (see table 3.2.1 p. 26), given that most SMPPi consumed in Australia are manufactured in Europe.

3.4 Other definitions

3.4.4 New definitions

In the 2021 CP3, FSANZ asked

Are definitions needed for any of the new terms proposed to be introduced as conditions for the use of food additives in CP1, such as gastrointestinal reflux, gastrointestinal disorders, or impairment of the gastrointestinal tract, inborn errors of metabolism etc.? (Section 4.3).

Comments

We have considered the discussion in SD4 section 3.2.1 on 'the use of mandatory statements in relation to the purpose of SMPPi,' and note that SMPPi will have 'a statement indicating the special purpose of the food, which may include a disease, disorder or medical condition for which the food has been formulated'.

We are concerned that these statements about purpose will be used for marketing products that creep into the SMPPi category and are for less serious and/or transient conditions and not medically determined or if SMPPi products are available through online retailers and pharmacies.

We note that infant formulas that are **not** SMPPi will **not** have a purpose statement on their label, even if formulated as lactose free/low lactose or with partially hydrolysed protein. We note that under EU regulations for 'Food for Special Medical Purposes' (EU 609/2013) that this marketing continues through the product name or mandatory statement of purpose or other text or image that makes a nutrition content or health claim, for example 'comfort,' or 'sleep.' (Belamarich, Bochner et al. 2016, Berry and Gribble 2017, Dipasquale, Serra et al. 2020, First Steps Nutrition Trust 2020, Harris and Pomeranz 2020).

Consequently, unless the risk of misleading marketing is removed through the proposed definition, label statements and access restrictions for SMPPi, we agree with the stakeholder view on p.31 that 'authoritative medical definitions of these conditions are necessary and would help prevent products being developed and marketed for non-medical (e.g. normal behavioural) paediatric conditions and manufacturers making health or therapeutic claims for them'. We refer back to our comments regarding the need to tighten the definition of what products can be included in the SMPPi category and the need to be specific about the conditions for which an SMPPi product can be formulated to treat.

To manage this risk, the revised 2.9.1 Standard for the SMPPi category of products should include authoritative medical definitions for the following diseases, disorders or medical conditions for which the SMPPi products are intended:

- Pre-term
- Low birthweight
- Inborn errors of metabolism
- Disease of serious long-term impairment or loss of dietary functions requiring particular nutritional needs, for example gastrointestinal reflux, gastrointestinal disorders, or impairment of the gastrointestinal tract

7 Labelling

7.2 Provision of information (SD3)

Comments

We support the proposal to limit ingredient claims by only permitting 'information about ingredients in the statement of ingredients' (NIS), in a prescribed format, as stated on CFS pp.44-45. We note that this would 'permit with prescribed wording and format the voluntary listing in the NIS of 'Whey', 'Casein', 'Docosahexaenoic acid', 'Eicosapentaenoic acid' and 'Arachidonic acid' as indicated in Section 3 of SD3' as follows:

From SD3 p. 19:

3.4.5 Preferred option

FSANZ's preferred option is to:

- permit with prescribe wording and format the voluntary listing in the NIS of:

-'Whey' and 'Casein', indented under the macronutrient 'Protein'
-'Docosahexaenoic acid', 'Eicosapentaenoic acid' and 'Arachidonic acid', indented under the sub-group nutrient heading 'Long chain polyunsaturated fatty acids', which is indented under the macronutrient 'Fat'

In response to 'Question 2 to submitters' (SD3 p.16): *How should the subheadings for 'Vitamins, 'Minerals' and 'Additional' be separated from other text (e.g. using lines, bolding)*?

We are concerned to ensure that ingredients are not being used for marketing or health claims to consumers. All ingredients should be written in simple text i.e. **not** in bold text, unless they are part of a prescribed format for a warning e.g. an allergen.

Therefore, the question of how to distinguish 'Additional' ingredients on labels is redundant. This is because supporting the use of additional ingredients e.g. docosahexaenoic acid (DHA) supports 'premiumisation' as a marketing strategy, which is inequitable and misleading for consumers. In summary:

- Ingredients that benefit infants should be mandatory in all formulas. (Munblit, Crawley et al. 2020).
- Additional ingredients are, by definition, non-essential. Non-essential ingredients should not be permitted. Hence the question of how to distinguish 'Additional' ingredients on labels is not relevant (see research by Malek 2017,-2019 in 'Attachment to SD3 – Consumer research on infant formula labelling').
- FSANZ and Codex should ensure that food standards for infant formulas require ingredients shown to be essential using high scientific standards of evidence. 'Any scientifically proved compositional improvements in infant formula should be made mandatory for all relevant products' and support alternative ways for manufacturers to innovate, for example by licencing (Munblit, Crawley et al. 2020).
- Health professionals need confidence that infant formula labelling standards are based on high quality scientific evidence. In the case of the proposed 'voluntary listing' of long-chain polyunsaturated fatty acids (LCPUFA) such as Docosahexaenoic acid (DHA), and Arachidonic acid (ARA), are regulators and health professionals aware of a recent

systematic review and meta-analysis which concluded: *'LCPUFA supplementation of infant formula is not recommended until further robust evidence excludes long-term harm.'* (Verfuerden, Dib et al. 2020). According to these findings, LCPUFA should not be permitted in in Standard 2.9.1.

SD3 Section 6-Representations

6.3.6 Preferred option FSANZ's preferred option is to only permit information about ingredients in the statement of ingredients (except for ingredients (e.g. nutritive substances) that are required to be declared in the NIS).

Comments

We agree and welcome FSANZ's recognition of *'the potential for caregivers to be misled from ingredient claims needs to be addressed in the Code'* and observation that *'government agencies have reaffirmed [that] the intent of the relevant Policy Guidelines is to prohibit all nutrition content and health claims on IFP'* (SD3 p.24). We strongly endorse stakeholder views that *'if the evidence is sufficient to mandate the addition of an ingredient there is no need for a claim'* (p.25) and that *'ingredients should only be declared in the statement of ingredients'* (p.26).

SD3 6.4 Line marketing and proxy advertising

6.4.6 Discussion (p.29) Given FOF is now in scope of P1028, FSANZ is seeking evidence and inviting stakeholder comment about stage labelling and proxy advertising specific to the labelling of IFP (0 - 12 months) noting the labelling of toddler formula is out scope. Questions to submitters: Q4 What evidence can you provide of caregivers' understanding of stage labelling on infant formula products? Q5 What evidence can you provide about caregivers' understanding and behaviours associated with proxy advertising appearing on the labels of infant formula or follow-on formula?

Comments

We welcome FSANZ's recognition of the ACCC final determination dated 27 July 2021 which noted the effect of toddler milks on promoting infant formula and the expected review of the MAIF Agreement by the Commonwealth Department of Health. We agree with the findings of the FSANZ literature review *'SD3 Attachment 1-Consumer research on infant formula labelling,'* which concluded that 'nutrition content claims and health claims influence caregivers' perceptions of infant formula products' (p.iii).

Even though toddler milks are outside the scope of P1028, regulators needs to pay attention to cross-promotion *to* and *from* toddler milks. Cross-promotion from toddler milks to infant formula represents an extreme hazard to 'informed choice' for infant formula products, which can be partly addressed in Standard 2.9.1. Australian toddler milks each have *'an average of six unregulated and eight regulated claims per product'* {McCann, 2021 #9758}, and many of these claims are misleading (*'claims and messages on TMs have little scientific evidence to support them'*) {McCann, 2021 #9758}. In view of these harms, IFP labels should not cross-promote the use of toddler milks. Another recent study showed that structure/function claims on toddler milk changed parent perceptions towards these products (Richter, Duffy et al. 2022). To prevent cross-promotion, infant formula should be labelled differently to toddler milks and not use numbered stages.

We submit the following additional evidence in response to Q4 and Q5:[2]

[2] The summary of each study is an abridged version of the abstract and relevant findings. Not all cited text is in quotations. Refer to original papers for exact wording.

Q4 What evidence can you provide of caregivers' understanding of stage labelling on infant formula products?

Fleming-Milici, F., L. Phaneuf and J. L. Harris (2022). "Marketing of sugar-sweetened children's drinks and parents' misperceptions about benefits for young children." Maternal & Child Nutrition: e13338.

This US qualitative research explored parents' understanding of common marketing tactics used to promote sweetened fruit-flavoured drinks and toddler milks and whether they mislead parents to believe the drinks are healthy and/or necessary for children. Nine focus groups in Washington, DC and Hartford, CT with parents of children (9–36 months) of diverse race/ethnicity and socioeconomic status (N = 50) were conducted.

> 'Confusion between product categories:
>
> 'Parents referred to toddler milks as 'toddler formulas' or used the brand name followed by formula (e.g., 'Enfagrow formula'), although the term 'toddler milks' was used on the concept sheets. Parents were unsure of the difference between infant formula and toddler milks. One participant said she was 'led to believe toddler formulas were the equivalent of infant formula'. As discussions progressed, parents realised that toddler milks were not formula, and some described the labelling as 'misleading' because the product appears to be very similar to infant formula.'
>
> - 'So because my son is almost one year, one year old. So I gave him the first Enfagrow formula as a transition. (Hartford)
> - 'I was certainly led to believe that toddler formulas were the equivalent of infant formula.' (DC)
> - 'I think it's very misleading labeling. The fact that, I thought that, other than the name change from infant to toddler, it was the same product maybe with slightly different ratios of vitamins for what a toddler needs versus what an infant needs. And that's not the case.' (DC)
>
> This confusion about stage labelling intersected with pricing:
>
> 'One parent remembered that toddler milk products from Enfagrow and Similac were less expensive than the same brands' infant formula. She added that parents 'on a budget' may be 'switching to this [toddler milk] earlier' because it is from the 'same company' and lower in price. Another parent said that pricing toddler milks slightly lower than infant formula 'plays into the consumer psychology'
>
> - 'I don't know if some people switched the infant over to the toddler based on price. Because you're like, "it's Enfamil," "it's Similac." But there is a price difference. I think it was like $30 for a similar size of the infant [formula]. And I want to say this [toddler milk] was like $22. If you're on a budget-- I don't know if parents are switching to this earlier and you're thinking, "oh, it's the same company." And I don't think that's a coincidence. I think, probably, from a marketing standpoint, there's probably a strategy there. (DC) (Fleming-Milici, Phaneuf et al. 2022).

Vilar-Compte, M., S. Hernández Cordero, A. C. Castañeda-Márquez, N. Rollins, G. Kingston and R. Pérez-Escamilla (2022). "Follow-up and growing-up formula promotion among Mexican pregnant women and mothers of children under 18 months old." Maternal & Child Nutrition 18(S3): e13337.

> This cross-sectional survey described maternal awareness, beliefs, and normative referents of follow-up formulas (FUF) and growing-up milks (GUMs) among Mexican pregnant women and mothers of children 0-18 months (n=1044). One-third of the participants had heard about FUFs, mainly through health professionals (51.1%) and family (22.2%). Once they had heard about FUFs, the majority (80%) believed older infants needed this product due to its benefits (hunger satisfaction, brain development, and allergy management). Similarly, 19% of the women had heard about GUMs. Mexican women are exposed to FUFs and GUMs, once women know about them, the majority believe older infant and young children need these products, stating perceived benefits that match the poorly substantiated marketing claims of breast-milk substitutes. (Vilar-Compte, Hernández Cordero et al. 2022).

M&C Saatchi World Services. Multi-country study examining the impact of breast-milk substitutes marketing on infant feeding decisions and practices: commissioned report. Geneva: World Health Organization and the United Nations Children's Fund (UNICEF), 2022 (WHO/UHL/MCA/22.01).

> This research investigated the reach and influence of marketing on infant feeding attitudes on a global scale by speaking to women, and those who may influence them using a consumer and market methodology and analysis framework. Data and insights were gathered from eight countries: Bangladesh, China, Mexico City, Morocco, Nigeria, South Africa, the United Kingdom of Great Britain and Northern Ireland, and VietNam. Nine data collection methods were employed to map the marketing of formula milk (In each country this included: Phone diaries (20 women); Focus Group Discussions (FGDs) (12 groups); In-depth Interviews (10 interviews); and a Survey (1,050 pregnant women and mothers). Exposure to formula milk marketing was investigated among pregnant women, mothers, and 'Influencers', including health professionals, partners, family members, and friends. Women's attitudes and beliefs around infant feeding are shaped by several inputs, and practices are

additionally influenced by factors such as work environments, maternity protection, and societal norms and values. This research focuses on one major influence, namely the reach of formula milk marketing, how formula milk marketing messages are perceived by women and Influencers, and how women's exposure to marketing is related to their perceptions of formula milk products.

'Product labels are often the same as, or very similar to infant and other milks, and are promoted under the same brand name. The lack of clear differentiation between products can mislead consumers into purchasing the wrong milk, and some women spoke of how labels were confusing and it was sometimes not clear which formula milk was intended for which age of infant.' (p.22)

- '"I saw these (formula milks) on (website for a store) and they all seemed to be…a more grown-up or follow-on milk. But, I found it all a bit confusing because I can't really say that- I couldn't tell from the packaging immediately what the different types of milk were for." (Breastfeeding mother, London, United Kingdom) (M&C Saatchi World Services 2022).

Cattaneo, A., P. Pani, C. Carletti, M. Guidetti, V. Mutti, C. Guidetti, A. Knowles and G. on behalf of the Follow-on Formula Research (2015). "Advertisements of follow-on formula and their perception by pregnant women and mothers in Italy." Archives of Disease in Childhood 100(4): 323.

This Italian study assessed how follow-on formula milks for infants aged 6–12 months are presented to and understood by mothers that included in-depth semi structured qualitative interviews of 80 pregnant women on their perception of two advertisements for follow-on formula and self-administered questionnaires for 562 mothers to explore their exposure to and perception of formula advertisements. The qualitative interviews to pregnant women showed inability to define the advertised products at first glance due to the ambiguity of the numeral 2 and the presumed age of the portrayed baby; this inability did not disappear after carefully viewing the advertisements and reading the text. When asked in the self-administered questionnaires whether they had ever come across advertisements of infant formula, 81% of mothers reported that they had, despite the legal inexistence of such advertisements, and 65% thought that it was for a product to be used from birth. Conclusions Advertisements of follow-on formula are perceived by pregnant women and mothers as promoting infant formula.

In-depth interviews of pregnant women on shown two advertisements for a follow-on formula:

- 'When asked to define at first glance the product they were being shown (half of them were shown an advertisement of Mellin 2; the other half, of Aptamil 2), 33% said it was formula, 31% milk, 19% a specific brand of milk, 5% infant formula, the remaining 12% gave generic answers such as breastmilk substitute. Two women in this last group thought it was breast milk; only one gave the correct answer: follow-on formula. In the conversation that followed, women said they were misled by the ambiguity of the numeral 2 and by the presumed age of the baby portrayed in the advertisement. Regarding the former (table 1), 65% of the women were unable to assign it its proper meaning." These meanings included: "2 month old babies; "2-year old babies;" 'added value;' '2 cups" "better than 1" and first glance and after careful reading, 38% of women failed to understand that the "2" meant an age category.

Questionnaire for mothers (N=562):

- (81%) stated that they had come across advertisements of formula (Cattaneo, Pani et al. 2015).

WHO/UNICEF (2022). How the marketing of Formula Milk Influences Our Decisions on Infant Feeding. Geneva, World Health Organization and the United Nations Children's Fund (UNICEF).

"Women recalled seeing marketing for stage 1 infant formula products despite the Code and national legislation prohibiting this marketing. Some women spoke of how it was sometimes unclear which formula product was intended for which age of infant:"

- "I saw these (formula milks) on (website for a store) and they all seemed to be … a more grown-up or follow-on milk. But, I found it all a bit confusing because I can't really say that I couldn't tell from the packaging immediately what the different types of milk were for." Mother, London, United Kingdom (p.9)

"Marketing can convince women of the need for a wide range of formula milk products, including stage 2–4 milks, specialized formula milks (e.g. for allergies), comfort formula milks and maternal milks. Exposure to marketing is correlated with the belief that formula milks are necessary for older infants, aligning with the message that breast-milk quality declines over time. In all surveyed countries, apart from the United Kingdom, at least 80% of women who were aware of stage 2 formula believed that it was necessary (Figure 7).

- "If you look at ... stage two and stage three ... It's, kind of, 'Let's continue your journey. Let's help you.'... I felt like... the formula milk is a good thing because it will support your child's growth later on as they're growing… So, I feel like I was tricked into follow-on formula, to be honest." Mother, London, United Kingdom (p. 15) (WHO/UNICEF 2022).

Q5 Evidence can you provide about caregivers' understanding and behaviours associated with proxy advertising appearing on the labels of infant formula or follow-on formula?

Fleming-Milici, F., L. Phaneuf and J. L. Harris (2022). "Marketing of sugar-sweetened children's drinks and parents' misperceptions about benefits for young children." Maternal & Child Nutrition: e13338. (see description of study above)

> '**Cross-branding/product extensions** (p.5)
>
> 'In discussions about toddler milks, parents expressed that similar packaging and product extensions by infant formula brands not only contribute to category confusion but foster trust in these brands' toddler milk products. They described how toddler milk packages 'look just like formula canisters' for brands that 'parents trust already'. Parents described that the connection to an infant formula brand also conveys toddler milks as the 'natural' or 'necessary next step', especially for parents feeding infant formula. Some suggested that perceived similarity to infant formula together with brand trust influence parents' decisions to purchase.'
>
> 'Participants also explained that their grocery shopping occurs under time constraints so, when shopping for drinks for their children, they make 'quick decisions' and 'often with divided attention'. They added that they are 'only looking at the quick front' and do not have the time to 'research every ingredient' or carefully read labels, …Similarly, one parent explained that having toddler milks and infant formula beside each other on grocery store shelves is a way to 'make sure everyone does this', referring to purchasing toddler milk. Another described a display of infant formula and toddler milks in a grocery store and added, 'And I didn't think of it [toddler milk] as something negative then'
>
> Illustrative quotes:
>
> - 'But I know that a lot of the formula companies have started making toddler formulas that they advertise, as like, oh, this is the next step when your kid doesn't need formula anymore-- as a toddler, keep giving them this.' (Hartford)
> - 'They look just like the formula canisters.' (Hartford)
> - 'That's why they keep it right next to the toddler, I mean, the baby's things so that, you know, they want to make sure everyone does this.' (Hartford) (Fleming-Milici, Phaneuf et al. 2022).

M&C Saatchi World Services. Multi-country study examining the impact of breast-milk substitutes marketing on infant feeding decisions and practices: commissioned report. Geneva: World Health Organization and the United Nations Children's Fund (UNICEF), 2022 (WHO/UHL/MCA/22.01).

> 'In all but the United Kingdom, at least 80% of the population who were aware of Stage 2 milks perceived a need for Stage 2 formula.'(p.39).
>
> - ""If you look at...Stage 2 and Stage 2.. It's, kind of, 'Let's continue your journey. Let's help you.'...I felt like...the formula milk is a good thing because it will support your child's growth later on as they're growing…So, I feel like I was tricked into follow-on formula, to be honest." (Formula feeding mother, 6-18 months, London, United Kingdom) (M&C Saatchi World Services 2022).

Appelton (2020) Infant formula feeding and rapid weight gain: parents' infant feeding practice and sources of information, advice and support (PhD Thesis)

> 'The findings described formula feeding practices in an Australian cohort and identified that some formula feeding practices associated with rapid weight gain are more common than others, such as the use of Stage 2 formula and feeding to schedule. While all parents were using an age appropriate formula, many were using Stage 2 formula by nine months. Those who moved from breastfeeding to formula when the infant was older were more likely to use Stage 2 at nine months. This may be due to being exposed to marketing of Stage 2 formula with no information to counter this marketing (such as the health message that Stage 2 formula is not necessary) and/or barriers to using health professional information and support.' (Appleton 2020) p. 219.

8 Special Medical Purpose Products for infants (SD4)

SD4 3.4 Summary of labelling requirements for SMPPi

FSANZ's preferred option is to apply the labelling requirements to SMPPi as listed:

- the requirement to label food as 'genetically modified' in section 1.5.2—4
- inner packages in subsection 2.9.5—8(3)
- transportation outers in subsection 2.9.5—8(4)
- mandatory labelling information in section 2.9.5—9
- mandatory statements and declarations in section 2.9.5—10
- nutrition information requirements in subparagraphs 2.9.5—13(b)(i) and (ii)
- a general requirement to declare the amount of any other nutritive substance that has been added to the product for its intended medical purpose.

Labelling requirements that would not apply to SMPPi, or where SMPPI are exempt are:

- name of business address in section 1.2.2—4
- characterising ingredients and components in Standard 1.2.10
- prescribed names 'Infant formula' and 'Follow-on formula' in section 2.9.1—17
- a prescribed name for SMPPi
- warning statements for IFP in subsection 2.9.1—19(1)
- directions for preparation and use for IFP in subsection 2.9.1—19(3)
- age-related statements for IFP in subsection 2.9.1—19(4)

Comments

Appropriate labelling of SMPPi depends on the product category definition and authoritative medical definitions of the serious medical conditions for which SMPPi are intended. Please note our concerns regarding SMPPi stated in comments on Section 3.2 (Definition for SMPPi) and Section 3.4 (Other definitions) regarding the need for definitions of the serious diseases and medical conditions for SMPPi formulations.

Labelling requirements

From SD4 p.14, We note the proposal for SMPPi labelling includes the following:

- mandatory labelling information in section 2.9.5—9:
  - 'a statement to the effect that the food must be used under medical supervision
  - a statement indicating, if applicable, any precautions and contraindications associated with consumption of the food
  - a statement indicating the medical purpose of the food, which may include a disease, disorder or medical condition for which the food has been formulated
  - a statement describing the properties or characteristics which make the food appropriate for the medical purpose
  - if the food has been formulated for a specific age group–a statement to the effect that the food is intended for persons within the specified age group
  - a statement indicating whether or not the food is suitable for use as a sole source of nutrition
  - for products represented as the sole source of nutrition, the statement to the effect that the food is not for parenteral use, and additional statements about the nutritional modifications made to the product.'

From SD4 pp.14-15, We note the proposal for SMPPi labelling includes the following:

- mandatory statements and declarations in section 2.9.5–10 additional statements indicating:
  - 'the nutrient or nutrients which have been modified, and

- unless provided in other documentation about the food - whether each modified nutrient has been increased, decreased. or eliminated from the food, as appropriate.

These additional statements will apply to SMPPi, when the product has been modified to vary from the baseline compositional requirements for IFP in Standard 2.9.1 and Schedule 29 (see Section 2.1 for the approach for SMPPi composition).'

We note that the label statements listed above and their wording and format should ensure that 'nutrition content claims are prohibited on IFP, including SMPPi' (SD4, Section 3.2.2 Nutrition Information p. 15).

We support the assessment by FSANZ of products in the SMPPi category on the basis of high quality scientific evidence of their efficacy.

Labelling exemptions

We disagree with the proposed exemptions for SMPPi to the warning statement 'Breast milk is best for babies' (paragraph 2.9.2-19(1)(d)) and prohibited representations (Section 2.9.1-24). Defining the serious diseases and medical conditions will enable products to be identified for which breastmilk is appropriate or contraindicated.

Breastmilk, and breastfeeding wherever possible, are the standard of clinical care for feeding pre-term infants. Given that about 8% of infants are born prematurely, this represents a large proportion of infants whose care may require pre-term formulas and other products in the SMPPi category. FSANZ could require, for preterm formula products, that a modified statement is required as follows: 'Breast milk is best for babies, unless contraindicated.'

Measures to protect breastfeeding are relevant to caregivers and health professionals supervising the use of SMPPi. We ask how informed decision making by a health professional is improved by 'pictures of infants, pictures idealising infant formula use; humanised / maternalised words; words promoting human milk oligosaccharides etc' (SD4 p.19).
Health professionals are not immune to marketing and subject to influence from manufacturers of infant formula products through conferences, sponsorships and research funding (Dykes, Richardson-Foster et al. 2012, M&C Saatchi World Services 2022, Vilar-Compte, Hernández Cordero et al. 2022, WHO/UNICEF 2022). In Australia, health professionals working in NICUs and special care nurseries, where SMPPi are likely to be used, may not have the knowledge and skills in lactation to support mothers to provide breastmilk, despite this being policy.

Accordingly, we reiterate the comments from our submission on P1028 CP3 in October 2021:

1. Only products for medical conditions for which breastmilk is medically contraindicated may be considered eligible for modification of labelling requirements in WHO International Code clause 9.2(a-b) that all breastmilk substitute labels should state the superiority of breastfeeding and that the product be used only on the advice of a health worker, currently implemented in Australia in Standard 2.9.1-19(1)(d).
A list of diagnosed medical conditions that can be considered medical contraindications to breastfeeding should be listed in a table or schedule in the Food Standards, and based on the highest quality evidence published by recognised independent medical authorities such as WHO or the Centre for Disease Control (CDC).
2. A general exemption is unreasonable, and not consistent with:

a. 2009 WHO policy 'Acceptable medical reasons for use of breast-milk substitutes.' For example, inborn errors of metabolism (all types) occur at a prevalence of approximately 50 per 100,000 births (Waters et al. 2018). This means that annually in Australia, a WHO International Code labelling exemption is relevant for less than 150 infants. In contrast,

protection of breastfeeding and WHO International Code labelling is appropriate for the majority of infants fed infant formula.

b. The WHO International Code and subsequent resolutions, and 2017 WHO Guidance on ending the inappropriate promotion of foods for infants and young children, which state that 'Any milk product that is marketed or represented as suitable as a partial or total replacement of the breastmilk part of the young child's diet is a breast-milk substitute and thus falls under the scope of the International Code.' In other words, WHO does not consider specialised formulas different from other breastmilk substitutes, and all are covered by the WHO International Code and its provisions for labelling.

c. The 2011 ANZ Food Regulation Ministerial Council Policy Guidance to FSANZ which states:
'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
'k) The labelling and advertising of infant formula products should be consistent with the World Health Organization International Code of Marketing of Breast Milk Substitutes4 as implemented in Australia and New Zealand',

9 FSANZ Act assessment requirements

9.1 Section 59

9.1.1 Consideration of costs and benefits

1. Conclusion

Based on consultation and engagement to-date, FSANZ currently concludes that the following benefits are likely to outweigh the costs of this proposal:

1. further ensuring that infant formula products and SMPPi remain safe and suitable into the foreseeable future for almost 3 million infants a decade
2. regulatory clarity for producers and enforcement agencies
3. greater international alignment and fewer trade barriers enabling longer-term production-cost savings, and improving sustainability of supply. Fewer trade barriers will particularly benefit the most vulnerable infants that depend on continued access to special formula products for high-risk health conditions.

However, FSANZ will take into account any extra feedback received during this CFS, noting the extensive consultations already undertaken.

2. Questions

1. To what extent do you agree with FSANZ's conclusion on benefits outweighing the costs?
2. Do you agree with FSANZ's summary of industry costs and that the main costs will be:
    a. one-off product reformulation to meet new domestic standards
    b. processes to further reduce contaminant levels, and
    c. one-off product label changes to meet new standards?
3. Do you agree with FSANZ's current estimates of relabelling costs in SD5 (pg.4 - 6)?
4. Do you agree with FSANZ's current estimates of reformulation costs in SD5 (pg. 3 – 4)?
5. Do you agree that reformulation costs would be lower for multinational companies than domestic companies, if there is an adequate transition period?
6. Do you have any further information on estimated numbers of products that:
    a. sell in Australia and New Zealand
    b. would need to reformulate?
7. Do you have any further information on the numbers of companies that would need to reformulate, or how many products your company would need to reformulate?
8. Do you have any other comments on costs and benefits as presented in this section or in SD5?

Please provide any relevant evidence to support your comments on any of the above questions.

Comments

SD5: Consideration of costs and benefits

FSANZ Cost analysis vastly undervalues the financial benefits of restricting marketing that undermines breastfeeding (through IFP product categorization, non-essential ingredients, nutrient content or health claims, exemptions from the WHO Code Statement).

The costs of inadequate regulation fall on individual consumers as well as on the health system, and more broadly the environment, and are poorly measured.

Preventing unnecessary infant formula consumption will save the costs of 'harm it causes for child and maternal health, human rights, for societies, for economies and for the environment' (WHO/UNICEF 2022 p. 18).

There is a considerable literature documenting the economic and financial costs of premature weaning from exclusive and continued breastfeeding. This is reflected in the Australian Dietary Guidelines which include economic and financial aspects as part of the benefits of breastfeeding. Numerous studies are available at global and national level. Recent pertinent examples include studies from other countries (Renfrew, Pokhrel et al. 2012, Pokhrel, Quigley et al. 2015, Rollins, Bhandari et al. 2016, Walters, Horton et al. 2016, Bartick, Schwarz et al. 2017, Santacruz-Salas, Aranda-Reneo et al. 2019, Walters, Phan et al. 2019, Quesada, Méndez et al. 2020).

A number of studies now also document the high environmental costs of not breastfeeding (Karlsson, Garnett et al. 2019, Dadhich, Smith et al. 2021, Long, Mintz-Woo et al. 2021, Pope, Karlsson et al. 2021, Andresen, Hjelkrem et al. 2022). Protecting breastfeeding is particularly pertinent for achieving public health objectives in the context across the policy imperatives for mitigating, resilience building, and responding to emergencies and disasters (Gribble and Berry 2011, Gribble, McGrath et al. 2011, Smith 2019). These costs for public health and safety of undermining breastfeeding should be taken into account through consideration of the potential adverse impacts of insufficient regulation of marketing through labelling of food for infants and young children.

References

ACCC (2021). Final Determination and Interim Authorization Decision. Applicaton for revocation of authorisations A91506 and A91507 and the substitution of authorisation AA1000534 lodged by Infant Nutrition Council Limited in respect of the Marketing in Austrtalia of Infant Formula: Manufacturers and Importers Agreement, and associated guidelines 27 July 2021. Canberra, Australian Competition and Consumer Commission,.

Andresen, E. C., A.-G. R. Hjelkrem, A. K. Bakken and L. F. Andersen (2022). "Environmental Impact of Feeding with Infant Formula in Comparison with Breastfeeding." International Journal of Environmental Research and Public Health **19**(11): 6397.

Appleton, J. (2020). Infant formula feeding and rapid weight gain: parents' infant feeding practice and sources of information, advice and support. Doctor of Philosophy, University of Sydney.

Bartick, M. C., E. B. Schwarz, B. D. Green, B. J. Jegier, A. G. Reinhold, T. T. Colaizy, D. L. Bogen, A. J. Schaefer and A. M. Stuebe (2017). "Suboptimal breastfeeding in the United States: Maternal and pediatric health outcomes and costs." Maternal & child nutrition **13**(1): e12366.

Becker, G. E., P. Zambrano, C. Ching, J. Cashin, A. Burns, E. Policarpo, J. Datu-Sanguyo and R. Mathisen (2022). "Global evidence of persistent violations of the International Code of Marketing of Breast-milk Substitutes: A systematic scoping review." Maternal & Child Nutrition **18**(S3): e13335.

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

Berry, N. J. and K. D. Gribble (2017). "Health and nutrition content claims on websites advertising infant formula available in Australia: A content analysis." Maternal & child nutrition **13**(4): e12383.

Cattaneo, A., P. Pani, C. Carletti, M. Guidetti, V. Mutti, C. Guidetti, A. Knowles and G. on behalf of the Follow-on Formula Research (2015). "Advertisements of follow-on formula and their perception by pregnant women and mothers in Italy." Archives of Disease in Childhood **100**(4): 323.

Dadhich, J., J. P. Smith, A. Iellamo and A. Suleiman (2021). "Climate change and infant nutrition: estimates of greenhouse gas emissions from milk formula sold in selected asia pacific countries." Journal of Human Lactation **37**(2): 314-322.

Dipasquale, V., G. Serra, G. Corsello and C. Romano (2020). "Standard and Specialized Infant Formulas in Europe: Making, Marketing, and Health Outcomes." Nutrition in Clinical Practice **35**(2): 273-281.

Doherty, T., A. Coutsoudis, D. McCoy, L. Lake, C. Pereira-Kotze, J. Goldhagen and M. Kroon (2022). "Is the US infant formula shortage an avoidable crisis?" The Lancet.

Dykes, F., H. Richardson-Foster, N. Crossland and G. Thomson (2012). "'Dancing on a thin line': Evaluation of an infant feeding information team to implement the WHO code of marketing of breast-milk substitutes." Midwifery **28**(6): 765-771.

First Steps Nutrition Trust (2020). Comfort infant milks suitable from birth. London.

Fleming-Milici, F., L. Phaneuf and J. L. Harris (2022). "Marketing of sugar-sweetened children's drinks and parents' misperceptions about benefits for young children." Maternal & Child Nutrition: e13338.

Gribble, K. D. and N. J. Berry (2011). "Emergency preparedness for those who care for infants in developed country contexts." International breastfeeding journal **6**(1): 1-13.

Gribble, K. D., M. McGrath, A. MacLaine and L. Lhotska (2011). "Supporting breastfeeding in emergencies: protecting women's reproductive rights and maternal and infant health." Disasters **35**(4): 720-738.

Harris, J. L. and J. L. Pomeranz (2020). "Infant formula and toddler milk marketing: opportunities to address harmful practices and improve young children's diets." Nutrition Reviews **78**(10): 866-883.

Helfer, B., J. Leonardi-Bee, A. Mundell, C. Parr, D. Ierodiakonou, V. Garcia-Larsen, C. M. Kroeger, Z. Dai, A. Man and J. Jobson (2021). "Conduct and reporting of formula milk trials: systematic review." British Medical Journal **375**.

Karlsson, J. O., T. Garnett, N. C. Rollins and E. Röös (2019). "The carbon footprint of breastmilk substitutes in comparison with breastfeeding." Journal of Cleaner Production **222**: 436-445.

Long, A., K. Mintz-Woo, H. Daly, M. O'Connell, B. Smyth and J. D. Murphy (2021). "Infant feeding and the energy transition: A comparison between decarbonising breastmilk substitutes with renewable gas and achieving the global nutrition target for breastfeeding." Journal of Cleaner Production **324**: 129280.

M&C Saatchi World Services (2022). Multi-country study examining the impact of marketing of breast-milk substitutes on infant feeding decisions and practices: commissioned report. Geneva, World Health Organization and the United Nations Children's Fund (UNICEF),.

Munblit, D., H. Crawley, R. Hyde and R. J. Boyle (2020). "Health and nutrition claims for infant formula are poorly substantiated and potentially harmful." BMJ **369**: m875.

Pereira, C., R. Ford, A. B. Feeley, L. Sweet, J. Badham and E. Zehner (2016). "Cross-sectional survey shows that follow-up formula and growing-up milks are labelled similarly to infant formula in four low and middle income countries." Maternal & Child Nutrition **12**: 91-105.

Pokhrel, S., M. A. Quigley, J. Fox-Rushby, F. McCormick, A. Williams, P. Trueman, R. Dodds and M. J. Renfrew (2015). "Potential economic impacts from improving breastfeeding rates in the UK." Archives of disease in childhood **100**(4): 334-340.

Pope, D. H., J. O. Karlsson, P. Baker and D. McCoy (2021). "Examining the environmental impacts of the dairy and baby food industries: are first-food systems a crucial missing part of the healthy and sustainable food systems agenda now underway?" International Journal of Environmental Research and Public Health **18**(23): 12678.

Quesada, J. A., I. Méndez and R. Martín-Gil (2020). "The economic benefits of increasing breastfeeding rates in Spain." International breastfeeding journal **15**(1): 1-7.

Renfrew, M. J., S. Pokhrel, M. Quigley, F. McCormick, J. Fox-Rushby, R. Dodds, S. Duffy, P. Trueman and A. Williams (2012). "Preventing disease and saving resources: the potential contribution of increasing breastfeeding rates in the UK."

Richter, A. P. C., E. W. Duffy, L. Smith Taillie, J. L. Harris, J. L. Pomeranz and M. G. Hall (2022). "The Impact of Toddler Milk Claims on Beliefs and Misperceptions: A Randomized Experiment with Parents of Young Children." Journal of the Academy of Nutrition and Dietetics **122**(3): 533-540.e533.

Rollins, N. C., N. Bhandari, N. Hajeebhoy, S. Horton, C. K. Lutter, J. C. Martines, E. G. Piwoz, L. M. Richter, C. G. Victora and T. L. B. S. Group (2016). "Why invest, and what it will take to improve breastfeeding practices?" The Lancet **387**(10017): 491-504.

Santacruz-Salas, E., I. Aranda-Reneo, Á. Hidalgo-Vega, J. M. Blanco-Rodriguez and A. Segura-Fragoso (2019). "The economic influence of breastfeeding on the health cost of newborns." Journal of Human Lactation **35**(2): 340-348.

Smith, J. P. (2019). "A commentary on the carbon footprint of milk formula: harms to planetary health and policy implications." International Breastfeeding Journal **14**(1): 1-7.

Verfuerden, M. L., S. Dib, J. Jerrim, M. Fewtrell and R. E. Gilbert (2020). "Effect of long-chain polyunsaturated fatty acids in infant formula on long-term cognitive function in childhood: A systematic review and meta-analysis of randomised controlled trials." PloS one **15**(11): e0241800.

Vilar-Compte, M., S. Hernández Cordero, A. C. Castañeda-Márquez, N. Rollins, G. Kingston and R. Pérez-Escamilla (2022). "Follow-up and growing-up formula promotion among Mexican pregnant women and mothers of children under 18 months old." Maternal & Child Nutrition **18**(S3): e13337.

Walters, D., S. Horton, A. Y. M. Siregar, P. Pitriyan, N. Hajeebhoy, R. Mathisen, L. T. H. Phan and C. Rudert (2016). "The cost of not breastfeeding in Southeast Asia." Health policy and planning **31**(8): 1107-1116.

Walters, D. D., L. T. Phan and R. Mathisen (2019). "The cost of not breastfeeding: global results from a new tool." Health policy and planning **34**(6): 407-417.

WHO (1981). International Code of Marketing of Breast-milk Substitutes. Geneva, World Health Organization.

WHO (2016). Guidance on ending the inappropriate promotion of foods for infants and young children. A69/7 Add.1. Geneva, World Health Organization.

WHO (2022). Marketing of breast-milk substitutes: national implementation of the international code, status report 2022. Geneva, World Health Organization,.

WHO/UNICEF (2022). How the marketing of formula milk influences our decisions on infant feeding. Geneva, World Health Organization and the United Nations Children's Fund (UNICEF).