ABA, WBTi and ANU Comments on FSANZ P1028 Consultation Paper #3

Authors:

Australian Breastfeeding Association (ABA)

World Breastfeeding Trends Initiative (WBTi) Australia

WBTi assists countries to assess the status of and benchmark the progress in implementation of the Global Strategy for Infant and Young Child Feeding in a standard way. The WBTi Australian team reported an assessment of Australia in May 2018. https://wbtiaus.com/2018/05/24/australia-report-card-2018/

Australian National University (ANU)

[redacted]

Contact details:

[redacted]

Date: 20 October 2021

We welcome the opportunity to comment on the proposals in P1028 Consultation Paper 3. Our specific concerns are made in the context of wider concerns about food regulation and governance that enable the inappropriate marketing of infant formula products. These specific concerns are about:

a. Recategorization of Standard 2.9.1 Division 4 infant formula products for 'special dietary use' (IFPSDU) to IFPSMP ('special medical purposes')
b. Assessment of novel foods and nutritive substances
c. Labelling exemptions from the WHO International Code.

Principles

FSANZ regulates infant formula to ensure it meets minimum standards in its manufacture. However, a fundamental principle that must be recognised by FSANZ in its development of standards for infant formula products is that breastfeeding is a public health issue that requires 'a high standard of public health protection,' in accordance with the overarching objective of the *Food Standards Australia New Zealand Act* (1991). Furthermore, Australian governments cite FSANZ regulation of breastmilk substitutes as one of the three main ways in which Australia gives effect to the obligations it has accepted under the World Health Organization's *International Code of Marketing of Breast-milk Substitutes* and subsequent World Health Assembly Resolutions (WHO International Code).

Protection of breastfeeding therefore requires more than 'the provision of adequate information relating to food to enable consumers to make informed choices,' (as required in objective 3(c) of the Act). The principle to protect breastfeeding as a public health protection measure empowers FSANZ to require manufacturers and retailers of infant formula products to demonstrate how marketing of their products, including through the labelling and packaging of breastmilk substitutes, does not harm breastfeeding.

It is not a sufficient response for FSANZ to await evidence that marketing affects parent/carer purchase behaviour and product sales. Nor is it enough to require that consumers and volunteer and not-for-profit organisations provide such evidence before FSANZ acts in line with the overarching objective of its legislation. The WHO International Code is of itself an acceptance by all WHO Member States, including Australia, that mothers and their infants and young children are uniquely vulnerable to marketing and that usual marketing practices should not apply to these products.

Protection of breastfeeding also requires recognition of its social complexity, and proactive engagement by multiple institutions, as stated in the *Australian National Breastfeeding Strategy: 2019 and Beyond* (COAG Health Council 2019). Accordingly, food standards intersect with the protection of breastfeeding in the health system and by consumer protection agencies to counter the constantly evolving technologies and strategies used to market infant formula products to consumers and health professionals (Grummer-Strawn 2017, Breastfeeding Advocacy Australia 2020, WHO/UNICEF/IBFAN 2020).

We note that Proposal 1028 for infant formula *'aims to ensure that these standards are appropriate, clear and function well now and* ***into the future.'*** (CP#3 page 4 paragraph 2), and the advice of the Food Forum Ministerial Guideline 2011,[1] which states in point (n) that:

'The Authority should:

i. ensure that the prohibitions and restrictions on nutrient content, health, therapeutic, and prophylactic claims in the Food Standards Code are clear and effective for infant formula products; and

ii. consider whether the current labelling regime is leading to consumers being misled about the quality or effectiveness of an infant formula product.'

Infant formula marketing targets both parents/carers and health professionals and includes strategies to segment products into multiple categories (Hastings et al. 2020). Product segmentation is a persistent marketing strategy that exploits the spectrum of food standards for products for infants and young children aged 0-36 months. Product segmentation enables marketing strategies which include line-branding, cross-product marketing and premiumisation that are misleading and exploitative and undermine breastfeeding (ACCC 2021).

Marketing of infant formula products also occurs within the health system, including through health professionals, who have limited breastfeeding education (IBFAN Asia 2018). A further important key principle is that health professionals such as pharmacists, general practitioners and paediatricians cannot be assumed to regulate access to infant formula products in a way that will protect breastfeeding. For example, Australian studies have shown that GPs rely substantially on personal experience rather than professional training to inform their advice on breastfeeding (Brodribb et al. 2008), and a recent survey of pharmacists identified that they have little confidence in their knowledge of breastfeeding (Ryan and Smith 2016). In US community hospitals, paediatricians were found to have lower attitudes to breastfeeding than other professional caregivers (Quinn and Tanis 2020). A 2019 study of paediatric society websites led by WHO researchers found that 60% of paediatric societies received financial support from formula companies (Grummer-Strawn et al. 2019). Recent research shows how formula manufacturers develop relationships with health professionals and fund the development of guidelines though specialist formula milk for allergy to cow's milk protein, resulting in a six-fold increase in sales of these products in the United Kingdom from 2006 to 2016, despite no evidence of increase prevalence of infants with the condition (van Tulleken 2018).

In Australia, rates of full breastfeeding on discharge from maternity hospitals are decreasing across all health districts in NSW and Victoria, and - despite regulatory instruments, policies and strategies to protect, promote and support breastfeeding - are low, stagnant or declining for the country as a whole (Vaz et al. 2021).[2] Urgent action by government authorities, including FSANZ, is required to protect breastfeeding from inappropriate marketing of infant formula products in all settings.

---

[1] AUSTRALIA AND NEW ZEALAND FOOD REGULATION MINISTERIAL COUNCIL 6 May 2011
Policy Guideline on the Regulation of Infant Formula.
Food Regulation Standing Committee, Regulation of Infant Formula Products
https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-Infant-Formula-Products

[2] Before the COVID-19 pandemic, between 2015 and 2019, rates of 'full breastfeeding' at discharge from hospital decreased in all NSW Health Districts. In some NSW public hospitals this rate is less than 60%, and private hospitals in high income areas have some of the lowest rates. (Source: Centre for Epidemiology and Evidence. 2021. New South Wales Mothers and Babies 2019. Sydney, NSW Ministry of Health.)
Department of Health and Human Services (2019). Maternal and Child Health Service 2017-18 annual reports. Melbourne, State Government of Victoria. Retrieved 20 October 2021, from
https://www2.health.vic.gov.au/Api/downloadmedia/%7B00DDAC3E-1CC8-4624-B77E-A98E37A581F4%7D

Consequently, we urge FSANZ to prevent inappropriate marketing of infant formula products that occurs through labelling, health and nutrition claims and novel ingredients.

Further sub-categorization of infant formula products

Health and therapeutic claims are prohibited for infant formula products (e.g. sleep, comfort), yet currently several IFPSDUs in Standard 2.9.1-14 are labelled and marketed as treatments for non-medical conditions that problematize normal infant behaviours (e.g. colic, crying).

We welcome that FSANZ accepts the lack of evidence of effectiveness of these products, (currently classified as IFPSDUs for transient gastroenterological conditions and allergies -P1028 Consultation Paper 3, page 24), consistent with the submission of the Australian Breastfeeding Association on P1028 dated 28 September 2017.

However, we oppose the proposed re-categorization of IFPSDU as IFPSMP. We consider it will result in legitimizing a new category of products with which to mislead or exploit parents and carers. Rather than create a new category of infant formula products IFPSMP, State/Territory Food Authorities should enforce current prohibitions on nutrition content or health claims for infant formula products in Standard 2.9.1 and Standard 1.2.7 (Nutrition, health and related claims) section 4(b) and 8(a).[3]

We consider that the proposed recategorization will allow infant formula manufacturers to use sub-categorisation of food standards to create new products that mislead parents, carers and health professionals and enable marketing through line branding and premiumisation.

There is no evidence that such recategorisation will reduce or eliminate dubious claims on infant formula products. We note that in Europe, the European Commission (EC) regulation of infant formula products for special medical purposes (IFSMPs) has not eliminated products that make dubious health claims as 'comfort milks' and 'anti-reflux' milks (First Steps Nutrition Trust 2020).

The existence of these products also raises doubt about the process of assessment and quality of scientific evidence used to justify these claims. We draw to FSANZ's urgent attention a recent major study by Helfer et al. (2021) and published in the British Medical Journal. The authors conducted a systematic review and meta-analysis of all infant formula trials since 2006, and concluded that these trials '*lack independence or transparency, and published outcomes are biased by selective reporting*'. The vast majority of such trials were funded by industry, three quarters included authors funded by industry, while results were nearly always interpreted in ways favourable to the industry. Other recent publications in leading medical journals have also drawn attention to how cow's milk protein allergy is extending the reach of infant formula manufacturers, and challenge the evidence base for current guidelines that recommend the use of hydrolysed formula to prevent allergic disease in high-risk infants, and the evidence base for health claims on toddler milk products which cross-market to infant formula (Belamarich et al. 2016). The last of these concluded that:

---

[3] Standard 1.2.7 Nutrition, health and related claims
1.2.7—2 Definitions
health claim means a claim which states, suggests or implies that a food or a property of food has, or may have, a health effect.
Note See also subsection 2.10.2—8(3).
health effect means an effect on the human body, including an effect on one or more of the following:
(a) a biochemical process or outcome;
(b) a physiological process or outcome;
(c) a functional process or outcome;
(d) growth and development;
(e) physical performance;
(f) mental performance;
(g) a disease, disorder or condition.
high level health claim means a health claim that refers to a serious disease or a biomarker of a serious disease.
high level health claims table means the table to section S4—4.
serious disease means a disease, disorder or condition which is generally diagnosed, treated or managed in consultation with or with supervision by a health care professional.

1.2.7—4 Nutrition content claims or health claims not to be made about certain foods
A nutrition content claim or *health claim must not be made about:
(b) an infant formula product;
1.2.7—8 Claims not to be therapeutic in nature
A claim must not:
(a) refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition;

'*There is insufficient evidence to support the claims that removing or reducing lactose, using hydrolyzed or soy protein or adding pre-/probiotics to formula benefits infants with fussiness, gas, or colic yet claims like "soy for fussiness and gas" encourage parents who perceive their infants to be fussy to purchase modified formula'*.

To assist Food Authorities enforce Standard 2.9.1, we agree that definitions are required in Division 4. However, we object to exemptions to WHO International Code labelling requirements for any infant formula products:

1. In Standard 2.9.1 Division 4 (Infant formula products for special dietary use), 2.9.1—14 (Products for metabolic, immunological, renal, hepatic and malabsorptive conditions)

   These conditions need medical definitions and to be listed in a table or schedule in the Food Standards Code. Medical conditions would not include normal infant behaviours (e.g. 'sleep' or 'colic' or 'crying' or 'comfort'). Nor would they include common transient illnesses or conditions not requiring a speciality infant formula for treatment (e.g. diarrhoea or constipation).
2. 2.9.1—19 (2) exempts all products for metabolic, immunological, renal, hepatic and malabsorptive conditions from the WHO International Code labelling requirement in 2.9.1-19 (d)[4]

   Only those 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)[5] 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).[6] 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).

   A general exemption is unreasonable, and not consistent with:

   a. 2009 WHO policy *'Acceptable medical reasons for use of breast-milk substitutes'*[7]. For example, inborn errors of metabolism (all types) occur at a prevalence of approximately 50 per 100,000 births (Waters et al. 2018).[8] 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.[9]

---

[4] Standard 2.9.1-19 (d): 'a heading that states 'Important Notice' (or words to that effect), with under it the *warning statement—'Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice'.)

[5] WHO International Code 1981: '9.2 (a) …"Important Notice" or their equivalent; (b) a statement of the superiority of breastfeeding; (c) a statement that the product should be used only on the advice of a health worker as to the need for its use and the proper method of use;'

[6] 2.9.1-19(1)(d)… 'Important Notice' (or words to that effect), with under it the *warning statement—'Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice'.

[7] **WHO (2009) Acceptable medical reasons for use of breast-milk substitutes. Geneva, WHO.** https://www.who.int/publications/i/item/WHO_FCH_CAH_09.01 (page 7):

'Infants who should not receive breast milk or any other milk except specialized formula:

- Infants with classic galactosemia: a special galactose-free formula is needed.
- Infants with maple syrup urine disease: a special formula free of leucine, isoleucine and valine is needed.
- Infants with phenylketonuria: a special phenylalanine-free formula is needed (some breastfeeding is possible, under careful monitoring).

Infants for whom breast milk remains the best feeding option but who may need other food in addition to breast milk for a limited period:

- Infants born weighing less than 1500 g (very low birth weight).
- Infants born at less than 32 weeks of gestational age (very pre-term).
- Newborn infants who are at risk of hypoglycaemia by virtue of impaired metabolic adaptation or increased glucose demand (such as those who are preterm, small for gestational age or who have experienced significant intrapartum hypoxic/ischaemic stress, those who are ill and those whose mothers are diabetic) (5) if their blood sugar fails to respond to optimal breastfeeding or breast-milk feeding.'

[8] Waters, D., et al. (2018). "Global birth prevalence and mortality from inborn errors of metabolism: a systematic analysis of the evidence." Journal of Global Health 8(2): 021102-021102.

[9] About 61% of infants exclusively BF at 4 months and approx. 300,000 infants are born annually in Australia). Source: Breastfeeding and its prevalence in Australia. 2017-18. National Health Survey data. Australian Bureau of Statistics https://www.abs.gov.au/statistics/health/health-conditions-and-risks/breastfeeding/latest-release

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 any 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 Substitutes[4] as implemented in Australia and New Zealand',

We note that the WHO International Code is implemented in Australia in several ways namely via FSANZ, the MAIF Agreement and NHRMC Infant Feeding Guidelines. However, only FSANZ has the legal power to set standards and enforce labelling (as a form of advertising). Consequently, the ANZ Food Standards Code is the ***key*** legal instrument to implement the WHO International Code, and FSANZ is the lead agency with more legal and regulatory responsibility than other authorities (Australian Competition and Consumer Commission or the NHMRC) regarding the labelling and advertising provisions of the WHO International Code.

3. We support pre-market assessment and 'appropriate scientific evidence' for:
    a. Products classified under 2.9.1—14 (Products for metabolic, immunological, renal, hepatic and malabsorptive conditions)
    b. Novel ingredients added to infant formula.

    However, with regard to 'appropriate scientific evidence,' we refer to the concerns stated above about the adequacy of evidence from formula milk trials (Helfer et al. 2021).
4. We further recommend, as a principle, that any milk formula product classified under the proposed provision be required to be supplied to health facilities only in plain packaging, that is, without brand information. This is consistent with the delivery of other products provided for medical indications in health facilities, such as pharmaceutical products.

Concerns regarding reclassification as IFSMP

If introduced, the proposal to reclassify IFPSDUs as IFPSMPs, which 'must be used under medical supervision,' would need to:

1. Define 'appropriate scientific evidence' of efficacy
2. Ensure sale and access is restricted to 'medical practitioners, responsible institutions or permitted sellers' [10] in ways that prevent uncontrolled access, for example via online pharmacies. This may require prescription of IFSMP.

As Consultation Paper 3 notes, IFPSMPs are less regulated in several ways and we anticipate that they will be used to undermine public health and breastfeeding through(a) cross-marketing infant

[10] Standard 2.9.5 Division 2 Sale of food for special medical purposes
2.9.5—5 Restriction on the persons by whom, and the premises at which, food for special medical purposes may be sold
(1) A food for special medical purposes must not be sold to a consumer, other than from or by:
(a) a medical practitioner or dietitian; or
(b) a medical practice, pharmacy or responsible institution; or
(c) a majority seller of that food for special medical purposes.
(2) In this section:
medical practitioner means a person registered or licensed as a medical practitioner under legislation in Australia or New Zealand, as the case requires, for the registration or licensing of medical practitioners.
majority seller: a person is a majority seller of a food for special medical purposes during any 24 month period if:
(a) during the period, the person sold that food for special medical purposes to medical practitioners, dietitians, medical practices, pharmacies or responsible institutions; and
(b) the sales mentioned in paragraph (a) represent more than one half of the total amount of that food for special medical purposes sold by the person during the period.

formula and young child milk drinks and food products; (b) exemptions from the prohibition of claims on infant formula products, and (c) additional regulatory gaps because they have:

a. no age limit specified (allows use beyond12 months)
    i. We recommend that these products carry an age limit of at most 12 months to prevent the creation of a loophole for inappropriate marketing, for example of toddler milk as a ‘specialised formula’.
b. no advice on introduction on timing of introduction of solid foods
c. no compositional requirements
d. are labelled according to EC requirements.

Regarding the prohibition on claims, we note that the WHO International Code prohibits nutrition and health claims for breastmilk substitutes and foods for infants and young children through World Health Assembly resolutions in 2005, 2010 and 2016 (WHA58.32, WHA63.23 and WHA 69/9) '*except where specifically provided for, in relevant Codex Alimentarius standards or national legislation*.' We question the standard of evidence used by FSANZ as the basis for exemptions in Australia's 'national legislation' (ANZ Standard 2.9.1) and the interpretation of what constitutes health and nutritional claims by Food Authorities (K. Gribble, pers. comm).

Human milk fortifiers

We note and agree with the proposals in Consultation Paper 3 that human milk fortifiers (HMFs) of bovine origin will be regulated under Std 2.9.5 (Food for special medical purposes) because they are not 'sole or principal sources of nutrition' and do not comply with Std 2.9.1.

Questions from CP3

How effective do you believe the current regulatory measures for IFPSDU are?
How could they be made more effective? If you think the requirements should be changed to better manage risk, please explain how and why. Please provide supporting detail and data, where available.

Comment

The 'regulatory measures' include enforcement by State/Territory Food Authorities of prohibitions of health and therapeutic claims for infant formula. Food Authorities need definitions of medical conditions for products in In Standard 2.9.1—14 (Products for metabolic, immunological, renal, hepatic and malabsorptive conditions).

1. These conditions need medical definitions and to be listed in a table or schedule in the Food Standards Code. Medical conditions would not include normal infant behaviours (e.g. 'sleep' or 'colic' or 'crying' or 'comfort') (First Steps Nutrition Trust 2020) or common transient illnesses or conditions not requiring a speciality infant formula for treatment (e.g. diarrhoea or constipation).
2. Evidence of efficacy of products for defined medical conditions should be assessed by FSANZ using a high standard of 'appropriate scientific evidence,' noting the evidence of bias in the conduct and reporting of infant formula milk trials (Helfer et al. 2021).

Do you consider that the options proposed in this paper will ensure that IFPSMP are safe, suitable and meet the nutritional requirements of the infants for whom they are intended?
If not, please explain why and provide supporting data and detail, where available.

Comment

Without further detail of the definitions of the medical conditions included in this category, the process of assessment by FSANZ, and the standard of 'appropriate scientific evidence' used to assess these products, marketing of spurious products to consumers and health professionals is likely to continue.

There is no evidence that such recategorisation will reduce or eliminate dubious claims on infant formula products. We note that in Europe, the European Commission (EC) regulation of infant formula products for special medical purposes (IFSMPs) has not eliminated products that make dubious health claims as 'comfort milks' and 'anti-reflux' milks (First Steps Nutrition Trust 2020).

The existence of these products also raises doubt about the quality of scientific evidence used to justify these claims.

How effective do you believe the options proposed for IFPSMP will be?
How could they be made more effective? Do they place an unreasonable cost burden on industry to achieve and/or maintain compliance? Please provide supporting detail and data, where available.

Comment

If introduced, the proposal to reclassify IFPSDUs as IFPSMPs, which 'must be used under medical supervision,' would need to:

1. Define 'appropriate scientific evidence' of efficacy
2. Ensure sale and access is restricted to 'medical practitioners, responsible institutions or permitted sellers' in ways that prevent uncontrolled access, for example via online pharmacies.
3. Providing IFPSMP **on prescription** would increase medical supervision of these products for serious medical conditions and justify reimbursement (PBS or equivalent).
4. We further recommend, as a principle, that any milk formula product classified under the proposed provision be required to be supplied to health facilities only in **plain packaging**, that is, without brand information. This is consistent with the delivery of other products provided for medical indications in health facilities, such as pharmaceutical products.

Other issues
If there are other issues that FSANZ should consider including within the scope of this Paper, FSANZ requests details and the reasons why FSANZ should consider them to be provided.

Comment

2.9.1—19 (2) exempts all products for metabolic, immunological, renal, hepatic and malabsorptive conditions from the WHO International Code labelling requirement in 2.9.1-19 (d)[11]

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)[12] 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).[13]
    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'*[14]. For example, inborn errors of metabolism (all types) occur at a prevalence of approximately 50 per 100,000

[11] Standard 2.9.1-19 (d): 'a heading that states 'Important Notice' (or words to that effect), with under it the *warning statement—'Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice'.)
[12] WHO International Code 1981: '9.2 (a) …"Important Notice" or their equivalent; (b) a statement of the superiority of breastfeeding; (c) a statement that the product should be used only on the advice of a health worker as to the need for its use and the proper method of use;'
[13] 2.9.1-19(1)(d)… 'Important Notice' (or words to that effect), with under it the *warning statement—'Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice'.
[14] **WHO (2009) Acceptable medical reasons for use of breast-milk substitutes. Geneva, WHO.** https://www.who.int/publications/i/item/WHO_FCH_CAH_09.01 (page 7):
'Infants who should not receive breast milk or any other milk except specialized formula:
- Infants with classic galactosemia: a special galactose-free formula is needed.
- Infants with maple syrup urine disease: a special formula free of leucine, isoleucine and valine is needed.
- Infants with phenylketonuria: a special phenylalanine-free formula is needed (some breastfeeding is possible, under careful monitoring).

Infants for whom breast milk remains the best feeding option but who may need other food in addition to breast milk for a limited period:
- Infants born weighing less than 1500 g (very low birth weight).
- Infants born at less than 32 weeks of gestational age (very pre-term).

births (Waters et al. 2018).[15] 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.[16]

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 Substitutes[4] as implemented in Australia and New Zealand'

Novel foods

Questions related to the use of novel foods in infant formula products, food for infants and formulated supplementary food for young children (section 2.2)

1. To manufacturers, please provide information on whether the substances listed in Table 5 are used in infant formula products, food for infants and formulated supplementary food for young children.
No comment

Specialised infant formulas

Questions related to definitions for specialised infant formulas (section 4.3)

2. Is a definition of soy-based formula needed for the purpose of food additive permissions and aluminium requirements?
If so, is the current definition appropriate? If you consider the current definition is inappropriate, please explain why and provide supporting detail and data, where available.

No comment

3. Is a definition of pre-term formula needed for the purpose of food additive permissions and aluminium requirements?
If so, is the current definition appropriate? If you consider the current definition is inappropriate, please explain why and provide supporting detail and data, where available.

4. 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, 60 gastrointestinal disorders, or impairment of the gastrointestinal tract, inborn errors of metabolism etc.?
Comment

- Newborn infants who are at risk of hypoglycaemia by virtue of impaired metabolic adaptation or increased glucose demand (such as those who are preterm, small for gestational age or who have experienced significant intrapartum hypoxic/ischaemic stress, those who are ill and those whose mothers are diabetic) (5) if their blood sugar fails to respond to optimal breastfeeding or breast-milk feeding.'

[15] Waters, D., et al. (2018). "Global birth prevalence and mortality from inborn errors of metabolism: a systematic analysis of the evidence." Journal of Global Health 8(2): 021102-021102.

[16] About 61% of infants exclusively BF at 4 months and approx. 300,000 infants are born annually in Australia). Source: Breastfeeding and its prevalence in Australia. 2017-18. National Health Survey data. Australian Bureau of Statistics https://www.abs.gov.au/statistics/health/health-conditions-and-risks/breastfeeding/latest-release

Authoritative medical definitions of these conditions are necessary and would help prevent products being developed and marketed for non-medical (e.g. normal behavioural) pediatric conditions and manufacturers making health or therapeutic claims for them.

Products for medical uses
Questions related to products for metabolic, immunological, renal, hepatic and malabsorptive conditions (section 5.5.2)

5. To health professionals: Is there any evidence that current practice in relation to low lactose products or the manganese content of products for metabolic, immunological, renal, hepatic and malabsorptive conditions pose a health concern or risk?
If you consider that there is a health concern or risk, please provide relevant details and data, where available.

Comment

Under current regulations, what prevents low lactose infant formula products from being marketed and accessed by parents/carers who self-diagnose this condition or use this product inappropriately?

6. To industry submitters: How many and what types of low lactose IFPSDU are on the market? And what is their maximum level of lactose?
Please provide supporting detail and data, where available.

No comment

Products with a protein substitute
Questions related to products for specific dietary use based on a protein substitute (section 5.5.3)

7. To industry submitters: What types of partially hydrolysed IFP are on the market?
And what is their maximum level of protein denaturation? Are any on the pharmaceutical benefits schemes in Australia or New Zealand? Please provide supporting detail and data, where available.

No comment

8. To health submitters: You have told us that partially hydrolysed IFP are not efficacious in preventing allergy; are they useful in the dietary management of allergy?
Please provide supporting detail and data, where available.

No comment

Compositional requirements
Questions related to specific compositional requirements (section 5.5.3)

9. Regarding options for the regulation of molybdenum and chromium, which option do you prefer and why?
Please provide supporting detail and data, where available.

No comment

10. To industry submitters: What type of products contain MCT oil?
For what purpose and at what levels? Please provide supporting detail and data, where available.

No comment

11. To health submitters: Are there any health concerns from current practice using products that contain MCT oil?
Please provide supporting detail and data, where available.

Comment

Are there examples of claims and marketing based on MCT oil? (e.g. brain, eyes, retina) for infant formula products? (<12 months) or are these claims made for toddler milks?

If appropriate scientific evidence demonstrates that MCT oil improves infant growth or development, then it should be mandatory in all infant formula products.

Evidence for IFPSMP

Questions related to scientific evidence of purpose for IFPSMP (section 5.6.1)

12. To industry submitters: Do infant formula manufacturers hold scientific evidence that supports the purpose of Division 4 products, including for reflux, colic, diarrhoea, and similar products (i.e. for less serious conditions)?

No comment

13. If so, what type of scientific evidence is held by companies and what is its strength of evidence?

No comment

Product use beyond infancy

Questions related to extension of use beyond infancy for IFPSMP (section 5.6.2)

14. What is the maximum labelled age on products suitable for use beyond infancy?

What are the parameters that indicate when the product is no longer appropriate?

We recommend that these products carry an age limit of at most 12 months to prevent the creation of a loophole for inappropriate marketing, for example of toddler milk as a 'specialised formula'.

Labelling of IFPSMP

Question related to labelling of IFPSMP (section 5.7)

15. Do you support FSANZ's preliminary views for ?

Why or why not? Please provide supporting detail and data for your position, where available.

Comment

IFPSMP labelling exempts all products from the WHO Code labelling requirement in 2.9.1-19 (d).

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)[17] 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).[18]
    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.'* [19] For example, inborn errors of metabolism (all types) occur at a prevalence of approximately 50

[17] WHO International Code 1981: '9.2 (a) …"Important Notice" or their equivalent; (b) a statement of the superiority of breastfeeding; (c) a statement that the product should be used only on the advice of a health worker as to the need for its use and the proper method of use;'

[18] 2.9.1-19(1)(d)… 'Important Notice' (or words to that effect), with under it the *warning statement—'Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice'.

[19] **WHO (2009) Acceptable medical reasons for use of breast-milk substitutes. Geneva, WHO.** https://www.who.int/publications/i/item/WHO_FCH_CAH_09.01 (page 7):

'Infants who should not receive breast milk or any other milk except specialized formula:

- Infants with classic galactosemia: a special galactose-free formula is needed.
- Infants with maple syrup urine disease: a special formula free of leucine, isoleucine and valine is needed.
- Infants with phenylketonuria: a special phenylalanine-free formula is needed (some breastfeeding is possible, under careful monitoring).

Infants for whom breast milk remains the best feeding option but who may need other food in addition to breast milk for a limited period:

- Infants born weighing less than 1500 g (very low birth weight).
- Infants born at less than 32 weeks of gestational age (very pre-term).

per 100,000 births (Waters et al. 2018).[20] 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.[21]

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 Substitutes[4] as implemented in Australia and New Zealand'

Labelling of IFSMP in accordance with the WHO International Code is necessary because marketing occurs through the health system, including through health professionals, who have limited breastfeeding education (IBFAN Asia 2018). A further important key principle is that health professionals such as pharmacists, general practitioners and paediatricians cannot be assumed to regulate access to infant formula products in a way that will protect breastfeeding. For example, Australian studies have shown that GPs rely substantially on personal experience rather than professional training to inform their advice on breastfeeding (Brodribb et al. 2008), and a recent survey of pharmacists identified that they have little confidence in their knowledge of breastfeeding (Ryan and Smith 2016). In US community hospitals, paediatricians were found to have lower attitudes to breastfeeding than other professional caregivers (Quinn and Tanis 2020). A 2019 study of paediatric society websites led by WHO researchers found that 60% of paediatric societies received financial support from formula companies (Grummer-Strawn et al. 2019). Recent research shows how formula manufacturers develop relationships with health professionals and fund the development of guidelines though specialist formula milk for allergy to cow's milk protein, resulting in a six-fold increase in sales of these products in the United Kingdom from 2006 to 2016, despite no evidence of increase prevalence of infants with the condition (van Tulleken 2018).

- Newborn infants who are at risk of hypoglycaemia by virtue of impaired metabolic adaptation or increased glucose demand (such as those who are preterm, small for gestational age or who have experienced significant intrapartum hypoxic/ischaemic stress, those who are ill and those whose mothers are diabetic) (5) if their blood sugar fails to respond to optimal breastfeeding or breast-milk feeding.'

[20] Waters, D., et al. (2018). "Global birth prevalence and mortality from inborn errors of metabolism: a systematic analysis of the evidence." Journal of Global Health 8(2): 021102-021102.

[21] About 61% of infants exclusively BF at 4 months and approx. 300,000 infants are born annually in Australia). Source: Breastfeeding and its prevalence in Australia. 2017-18. National Health Survey data. Australian Bureau of Statistics https://www.abs.gov.au/statistics/health/health-conditions-and-risks/breastfeeding/latest-release

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,.

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.

Breastfeeding Advocacy Australia (2020). Submission in response to Application for Authorisation of MAIF 4th December 2020. Australian Competition and Consumer Commission (ACCC).

Brodribb, W., A. Fallon, C. Jackson and D. Hegney (2008). "Breastfeeding and Australian GP registrars—their knowledge and attitudes." Journal of Human Lactation **24**(4): 422-430.

COAG Health Council (2019). Australian National Breastfeeding Strategy: 2019 and Beyond. Canberra, Council of Australian Governments

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

Grummer-Strawn, L. (2017). "A new protocol for monitoring and enforcement of code violations." Annals of Nutrition & Metabolism **71**: 83.

Grummer-Strawn, L. M., F. Holliday, K. T. Jungo and N. Rollins (2019). "Sponsorship of national and regional professional paediatrics associations by companies that make breast-milk substitutes: evidence from a review of official websites." BMJ Open **9**(8): e029035.

Hastings, G., K. Angus, D. Eadie and K. Hunt (2020). "Selling second best: how infant formula marketing works." Globalization and Health **16**(1): 1-12.

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**.

IBFAN Asia (2018). The World Breastfeeding Trends Initiative (WBTi). Australia. Dehli, International Baby Food Action Network (IBFAN),.

Quinn, P. and S. L. Tanis (2020). "Attitudes, perceptions, and knowledge of breastfeeding among professional caregivers in a community hospital." Nursing For Women's Health **24**(2): 77-83.

Ryan, M. and J. Smith (2016). "Breastfeeding knowledge, attitudes and training amongst Australian community pharmacists." Breastfeeding Review **24**(2): 41-49.

van Tulleken, C. (2018). "Overdiagnosis and industry influence: how cow's milk protein allergy is extending the reach of infant formula manufacturers." British Medical Journal **363**: k5056.

Vaz, J. S., M. F. S. Maia, P. A. Neves, T. M. Santos, L. P. Vidaletti and C. Victora (2021). "Monitoring breastfeeding indicators in high-income countries: Levels, trends and challenges." Maternal & Child Nutrition: e13137.

Waters, D., D. Adeloye, D. Woolham, E. Wastnedge, S. Patel and I. Rudan (2018). "Global birth prevalence and mortality from inborn errors of metabolism: a systematic analysis of the evidence." Journal of Global Health **8**(2): 021102-021102.

WHO/UNICEF/IBFAN (2020). Marketing of breast-milk substitutes: National implementation of the International Code. Status report 2020 Geneva, World Health Organization, UNICEF, and the International Baby Food Action Network (IBFAN),.