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Response to consultation discussion paper on FSANZ revision and review of regulatory standard for infant formula - P1028

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"To the extent that competitive markets succeed in delivering he more efficient satisfaction of freely chose preferences, they will more efficiently produce bads as well as goods – however bad and good are defined"

Braithwaite, J. 2005 *Markets in Vice Markets in Virtue*, p8, Federation Press.

The Author

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Executive Summary

The objective of P1028 is to revise and clarify standards relating to infant formula in the ANZ Food Standards Code. The following comments focus on how proposed changes meet the primary statutory objectives of the Code, and in particular how they influence marketing and representation of infant formula.

Revision of the Standard to assist achievement of objectives of the *FSANZ Act*, and to clarify prohibition and enforcement regarding nutrition or health claims on infant formula products is timely in the light of new WHO guidelines on inappropriate marketing of foods for infants and young children, and a WHA resolution calling for countries 'to take all necessary measures in the interest of public health to end the inappropriate promotion of foods for infants and young children'.

However failure of P1028 to initiate timely action on inappropriate marketing of other milk formula products marketed for infants and young children is disappointing. Nutrition and health claims on these food products currently confuse and mislead the public. The delay in addressing this problem perpetuates a culture which is detrimental to exclusive and ongoing breastfeeding, and to protecting food safety and public health.

It is concerning that the stated objectives specified by FSANZ in assessing issues under P1028 are not the primary, statutory objectives of 'protection of public health and safety'', provision of 'adequate information… to enable informed choice, and; prevention of misleading or deceptive conduct'. Any revisions to the standard must give precedence to these primary statutory objectives.

Infant formula can only reflect such attributes as 'safe' and 'nutritious' to the extent permitted by current scientific knowledge; in the context of infant formula, such attributes are relative not absolute, and are comparative to breastfeeding as the traditional and

optimal food for infants. On the role of the infant formula standard, FSANZ's statement that 'the standard provides a 'safe and adequate' breastmilk substitute' needs modification along the lines that it aims for 'formulation of infant formula products which are as safe and as nutritious as possible given the current state of scientific knowledge on the superiority of breastfeeding'.

Breastfeeding is important to mothers' health, infant health is not the only concern of the Code in regard to infant formula. There are short and long term reproductive health implications for mothers from replacing breastfeeding with infant formula, such as heightened risk of breast cancer.

Infants are rightly recognised by FSANZ as a vulnerable population group. However, pregnant and new mothers are also vulnerable consumers, both because of the adverse women's health implications of formula feeding, and because of mothers' particular vulnerability to infant formula marketing which is confusing, misleading, or deceptive. The development of standards for regulating foods for infants and young children (0-36 months) including infant formula should recognise the unique vulnerability of mothers and infants both as a dyad, and as separate persons.

The statement that 'breastmilk is best for babies' is inaccurate and misleading, and is inadequate for informed choice or preventing the deception or misleading of consumers on the attributes of infant formula. The statement is inconsistent with the well established evidence on the superiority of breastfeeding. 'Breastfeeding' is not the same as 'breastmilk' feeding. Emerging evidence reinforces the superiority of breastfeeding over breastmilk feeding. The 'breast is best' statement should be urgently revised to 'breastfeeding is best for babies'.

Advances in scientific knowledge have identified that infant formula is not a sterile product. Warning labels regarding safe preparation and use should include a statement about the non sterility of infant formula, and its innate risks of contamination even when prepared as directed. Parents should be informed, by prominently located labelling, regarding the source of protein in infant formula being dairy milk, as numerous sources report that parents are confused, think formula is human milk, or believe that infant formula is not dairy food. Parents should be advised through infant formula labelling that scientific evidence does not support the effectiveness of hydrolysed formulas in reducing allergy, nor the reproductive health safety of soy formula.

Nutrition and health claims on infant formula are specifically prohibited by Australian food regulation, but are encouraged and facilitated by being permitted to include novel foods, nutritive substances, or optional ingredients. Advertising is not information. Excessive information on labels or packaging can inappropriately promote infant formula and confuse and/or mislead caregivers about the comparative nutrition and health attributes of infant formula brands, as well as on about the comparative benefits of breastfeeding and components of breastmilk.

The objectives of the Code and the latest evidence based international regulation and guidance support from WHO support FSANZ giving an overriding public health priority in ensuring and enforcing the prohibition of nutrition and food claims anywhere on the product packaging and in any form including implied in trademarks. Protecting public health is not constrained by WTO or similar trade agreements.

Children's human rights to be protected from marketing of infant formula is supported by the Convention on the Rights of the Child regarding the right to the highest standard of health, including breastfeeding.

Industry sustainability– benefits of standards in relation to industry compliance

Many more infants are fed on infant formula than would be the case if the product was provided only where human milk was not suitable for the infant. Market competition provides many benefits but has the downside of resulting in innovation and product development focussed on meeting and expanding product demand especially targeting more affluent consumers, rather than on meeting the requirements of the most vulnerable, including infants. This points to the need for stronger regulation of inappropriate promotion of infant formula through the various forms of information provision or advertising, alongside any competition-enhancing industry efficiency and innovation to the benefit to consumers.

While regulatory supervision of infant formula is clearly essential and benefits public health and safety, the existence of such standards indirectly contributes to sustaining and expanding the infant formula industry. In the absence of the standard, the market for such products would be much smaller, due to the greater perceived risks of infant formula compared to breastfeeding under the hypothetical unregulated regime. Hence regulation of infant formula provides benefits to industry, and by its nature risks underpinning or validating inappropriate marketing of infant formula in competition with breastfeeding. As the development and promulgation of the infant formula standard privileges the infant milk formula industry, industry has a responsibility to strictly adhere to the letter and the spirit of the law, and significant or repeated breaches should attract a strong enforcement response.

With the convergence of the food and pharmaceutical industries,(1) and continued advances in scientific knowledge on the superiority of breastfeeding, regulation of infant formula manufacture and sale brings together a number of conceptual and practical challenges for FSANZ and food regulatory authorities globally. This submission reflects on some elements of an alternative regulatory framework for infant formula and related food products for infants and young children which substitute for, and compete with breastfeeding.

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Introduction

1. The scope of the present proposal P1028 is limited to 'infant formula' (and hence excludes 'follow on' or 'toddler formula' or those for 'special dietary use' that are otherwise covered by of the infant formula products standard (2.9.1). Issues for consideration include category definitions, composition, microbiological safety, and labelling and representation of infant formula.
2. FSANZ has stated an overarching purpose of addressing problems and providing clarity regarding the intent of relevant standards for infant formula, specifically, 'there is scope to improve the clarity of some standards and to consider the application of Ministerial Policy Guidance and alignment with international regulations'.
3. The focus of the following comments is on labelling and representation of infant formula, specifically on how proposed changes protect public health and safety, prevent misleading and deceptive conduct including nutrition and health claims. Some comments are also offered below on the definition of infant formula, on composition regarding optional ingredients and on safety aspects.
4. SD1 and SD2 discuss composition and safety and food technology including in relation to novel foods or optional ingredients or substances and their characterisation, while SD3 discusses information provision, including labelling and representation of infant formula such as through nutrition and health claims. There is some overlap between these areas, reflected in the structure adopted below, because how the composition and safety of infant formula is regulated may either facilitate or inhibit inappropriate marketing of infant formula, such as through prohibited nutritional and health claims on infant formula products or such as by whether it promotes an informed choice about not purchasing these foods, i.e. to breastfeed.

The Scope and Purpose of the proposal

5. It is disappointing that the scope of the current proposal FSANZ fails to initiate timely action to address important concerns regarding infant formula produced for special dietary use (IFPSDU), or the line marketing and proxy advertising of other milk formula products for infants and young children (0-36 months. Recent research raises questions about whether there is any evidence for the use of specialised formula products, soy or hydrolysed formula.(2-4)
6. Through marketing segmentation and promotion strategies involving such products, industry's nutrition and health claims confuse and mislead the public, caregivers and health professionals about the properties of infant formula compared to breastfeeding, as well as in relation to other brands or product lines. Industry practice of avoiding regulatory restraints on labelling and advertising of breastmilk substitutes through market segmentation and creating new product categories is well documented.(5-7)
7. Such ongoing exposure of the public to inappropriate marketing through nutrition and health claims on food for infants and young children results in a normalisation or even valorisation of formula feeding over breastfeeding, and creates an culture for infant and young child feeding decisionmaking which is detrimental to exclusive and ongoing breastfeeding as recommended by health authorities (8, 9).
8. Companies engage in marketing because it increases sales. The onus should be on industry to demonstrate that marketing activities related to food for infants and young children do not influence decisions about initiating or continuing breastfeeding, rather than this burden being on the wider community or regulators.
9. While recognising the limitation of existing FSANZ resources, the extended delay in addressing the problem of marketing of such products for uniquely vulnerable infants and young children is significantly detrimental to achieving the primary objectives of the Food Code. It illustrates with stark clarity the lack of Australian Government priority given to protecting the health and safety of women and children compared to promoting food industry interests.

Regulatory Objectives and Approach to assessing issues under P1028

Objectives and approach

10. As FSANZ notes in the consultation paper (p.9), statutory requirements define the objectives of any changes to the standard. Hence the overriding objectives for p1028 are to be interpreted as; 1) 'protection of public health and safety'', 2) provision of 'adequate information… to enable informed choice, and; 3) prevention of misleading or deceptive conduct'. Any other considerations including ministerial policy are only relevant where proposed changes are consistent with the statutory objectives, and furthermore with the overriding precedence of protecting public health and safety.

11. However, the consultation document fails to consistently state that these objectives are paramount. It is particularly concerning that the objectives specified by FSANZ for assessing issues under P1028 in some of the consultation documents are not the statutory objectives stated in the FSANZ Act. For example, at p. 6 of the consultation document and on page 1 of SD 1, FSANZ purports to present 'objectives' for the assessment of issues in the proposal as protecting the 'health and safety of infants', 'consistency with advances in scientific knowledge', and 'not hindering innovation or trade'.
12. In this context, it should be noted that the purported objective for P1028 of protecting the 'health and safety of infants' - rather than 'public health and safety' ignores the health risk for mothers of infant formula where its labelling or representation results in earlier cessation of breastfeeding (see below). Several hundred women a year in Australia are diagnosed with breast cancer attributable to premature cessation of breastfeeding,(10) hence any revision of the standard must take this as an important consideration and any revisions must be consistent with protecting maternal as well as infant health.
13. Thus it is appropriate and consistent with the Act for FSANZ to apply policy guidance and international guidance to improve statutory objectives such as protect public health and safety and other statutory objectives regarding adequate information and prevention of misleading or deception, but it is not able to apply such guidance to enable the revision of 2.9.1 to weaken the standard's contribution to achieving these objectives, even if this promotes 'consistency with advances in scientific knowledge' or 'not hindering innovation or trade'.
14. FZANZ is nevertheless to be congratulated on its initiative to revise the Infant Formula Standard to help ensure its proper enforcement in line with the objectives of the FSANZ Act, and in line with the clear intent of guidance which prohibit any nutrition or health claims on infant formula products. This submission notes FSANZ's interpretation of the Ministerial Policy Guidance as guiding 'a more rigorous standard of assessment of product composition', and that this includes premarket evaluation of optional ingredients. The guidance also included a specific policy principle for labelling and advertising infant formula products which included a clear intent to not allow any nutrition or health claims on infant formula products.
15. Industry continues to market infant formula products to vulnerable consumers using nutrition and health claims, despite this being contrary to the Food Code. Such claims confuse and mislead consumers about both the superiority of breastfeeding, and about the relevance of differences between different brands and types of infant formula products. The recent proliferation of nutrition and health claims for infant formula and other milk products for infants and young children makes it crucial that, even if a proposed change is consistent with advances in scientific knowledge or not hindering innovation in trade, any such revisions must achieve the objective of providing

'adequate information for informed choice' about infant feeding (which would include adequate information on breastfeeding as well as infant formula), and the objective of 'preventing misleading or deceptive conduct'. Furthermore, marketing of infant formula using nutrition or health claims facilitates the exploitation of vulnerable consumers, as mothers buying such formulas are required to pay higher prices for such 'premium' or 'gold' products despite the lack of any evident effect on nutrition or health outcomes compared to using other brands or product lines. This is a matter of urgent concern for enforcement of consumer law by jurisdictions as well as for the infant formula standard.

16. The increasingly ubiquitous practice of marketing infant formula and related infant formula products through nutrition and health claims suggests companies are not acting in good faith regarding compliance with community standards and regulatory requirements. Rather than regulators negotiating continually with industry on redefining and clarifying definitions and standards, a more effective compliance approach may be achieved through detailed monitoring of industry behaviour within a framework such as that proposed recently for breastmilk substitutes by international agencies including WHO (11). Enforcement of financial and other penalties might include public 'naming and shaming' of the companies which are the most regular and worst offenders regarding non-compliant nutrition content and health claims.

International regulations, standards, and agreements

17. FSANZ (p.7) draws attention to 2007 Codex standards as an example of international regulations triggering a review for consistency as part of P1028. Reflecting the primary objectives of the standard, consistency with Codex should not take precedence over WHO Code or other WHA Resolutions or WHO guidance on infant feeding or marketing, or over national infant feeding guidance such as the Australian NHMRC Infant Feeding Guidelines, where such consistency with Codex is adverse to public health and safety, adequate information for informed choice, and preventing consumers from being deceived or misled.
18. Standing alongside the secondary objectives for consistency with international food standards such as with Codex, is the 2011 Ministerial guidance. This states that the infant formula standard should be consistent 'to the greatest extent possible with relevant WHO and WTO agreements and Codex standards', thus indicating the comparable status for the food standard of such international agreements with Codex. 'Relevant WHO agreements' with regard to P1028 include the 1981 WHO Code and subsequent relevant WHA Resolutions, and the WHO *Global Strategy on Infant and Young Child Feeding* (9), as well as most recently, the May 2016 WHO guidance on Inappropriate Marketing of Food for Infants and Young Children (12).
19. It is important to note in this regard that notwithstanding provisions in WTO or other trade agreements, countries can freely regulate to protect public health, including

regulating the use of trademarks (or other IP such as patents) where this violates regulatory restraints on nutrition content or health claims.

20. As well as being timely for updating for changes to Codex, P1028 is timely to consider alignment with the international agreement encompassed in the WHA Resolution of May 2016 (13) on the aforementioned new WHO guidelines addressing inappropriate food marketing for infants and young children. This Resolution was agreed to by all WHO member countries and included welcoming WHO's call for countries 'to take all necessary measures in the interest of public health to end the inappropriate promotion of foods for infants and young children'.(12) The WHO guidance is based on a thorough review of the available evidence on the effects of marketing on IYCF practices, and caregivers' attitudes and preferences. It reiterates the importance of both governments and industry taking responsibility for preventing promotion of infant formula. For example,

    "Products that function as breast-milk substitutes should not be promoted. A breast-milk substitute should be understood to include any milk products (or products that could be used to replace milk, such as fortified soy milk), in either liquid or powdered form, that are marketed for feeding infants and young children up to the age of 3 years (including follow-up formula and growing-up milks). It should be clear that the implementation of the International Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly resolutions covers all these products."

Also;

"The messages used to promote foods for infants and young children should support optimal feeding and inappropriate messages should be avoided. Messages about commercial products may be conveyed in multiple forms, through advertisements, promotion and sponsorship, including brochures, online information and package labels. Specifically, messages should always:

- *include a statement on the importance of exclusive breastfeeding for the first 6 months and of continued breastfeeding for up to two years or beyond;*
- *include the appropriate age of introduction (this must not be less than 6 months) and a statement on the importance of not introducing complementary feeding until about 6 months of age;*
- *be easily understood by parents and other caregivers, with all required label information being visible and legible.*

Messages should not:

- *include any image, text or other representation that might suggest use for infants under the age of 6 months (including references to milestones and stages and images of bottles or teats);*

- *include any image, text or other representation that is likely to undermine or discourage breastfeeding, that makes a comparison to breast-milk, or that suggests that the product is nearly equivalent or superior to breast-milk; recommend feeding the product in a bottle or otherwise promote bottle feeding;*
- *convey an endorsement or anything that may be construed as an endorsement by a professional or other body, unless this has been specifically approved by the national or international regulatory authorities."*

21. Finally, it should also be noted that in assessing P1028, industry marketing agreements on infant formula are not an international agreement or a national regulation or standard, in either Australia or New Zealand, and the definitions and provisions of such industry agreements should not be accorded any status by FSANZ with regard to objectives of achieving consistency. The MAIF is an industry agreement, and industry compliance with its restraints on marketing of infant formula is voluntary, not enforced by public statute or regulation. Furthermore, the 1992 MAIF expired in Australia in 2014 and the proposed replacement industry agreement of the same name but different nature has not been approved by the relevant competition policy regulatory agency, the ACCC. It is therefore circular and inappropriate to refer to MAIF definitions in order to assess the appropriate age definition for the purpose of regulating infant formula in the Food Code.

The food regulatory framework and the 'necessity' for infant formula

22. The growth of 'functional foods' along with the convergence of the pharmaceutical and food industry presents a major regulatory challenge for FSANZ and global food regulators. Nowhere is this more evident than in the case of infant formula. Infant formula products, and to a somewhat lesser degree, food for infants and young children, are at the cutting edge of this regulatory dilemma because of the unique health and consumer vulnerabilities of both infant and mother, and the interaction of those vulnerabilities. These vulnerabilities are discussed further below, but in summary, the infant consumer of infant formula is at the most physiologically vulnerable stage of development and sensitivity to dietary intake, the health impacts of infant formula intake may not be evident for 20-50 years, and the infant is not able to make an informed choice as the caregiver necessarily makes virtually all dietary choices on its behalf. Equally, the mother is uniquely vulnerable to any marketing of infant formula during this major and stressful life transition, yet may have to make decisions to address her own needs in conflict with avoiding risk to the health or development of the infant, as well as maternal health including in later life.
23. There are also important dilemmas for competition policy in this regard, as greater market efficiency at producing 'goods' also results in greater efficiency in producing 'bads', however these are defined from a social perspective. For example, it has been argued (14) that the nature of market competition is that innovation and product

development focusses on meeting and expanding product demand by affluent consumers, rather than on addressing, for example, the safety, nutrition and health requirements of the most vulnerable consumers. Thus a 'virtuous' good (such as infant formula as originally intended to meets the needs of infants who were unable to tolerate human milk, or children deprived of a mother) can be turned by greater competition and marketing into a bad ('vice') which displaces breastfeeding through enhancing the efficiency of supply of breastmilk substitutes and responding to for newly created or identified consumer product demands.

24. FSANZ states in the consultation document that 'a safe and nutritious substitute for breastmilk is needed for infants who are not breastfed'. The strongest arguments for regulation of infant formula products relate to ensuring the availability of a breastmilk substitute product for infants who cannot be breastfed, such as those few infants with galactosemia. Many infants are fed infant formula products even though this is not necessitated by a dietary requirement for the infant to avoid human milk. From this perspective, the FSANZ framing statement that infant formula is 'needed' distracts from the primary food policy regulatory goal in this area of infant feeding of more prevalent optimal infant and young child feeding. In most cases optimal infant and young child feeding is defined by WHO and NHRMC to be exclusive breastfeeding for 6 months and continued breastfeeding to at least 12-24 months. Breastfeeding is the only food for infants that is not, in a human evolutionary and physiological sense, a 'novel food'.
25. Thus the FSANZ framing statement regarding the role of the standard for infant formula can be considered to reinforce a focus on 'behaviours' of the individual mother, whilst distracting attention away from crucial necessity for social, economic and health policy and practice as well as food regulation to protect, support, and promote breastfeeding, and thereby make 'informed choice' on infant and young child feeding real. Informed choice in the context of infant feeding is primarily about providing adequate information to enable an informed choice to breastfeed. In the context of food regulatory framework, this means that information to promote informed choice in the context of food purchasing decisions for infants and young children will promote informed choice enabling comparison with the option of <u>not</u> purchasing infant formula/breastmilk substitutes, i.e. the informed choice of breastfeeding. The most accurate framing of the role of food standards for infant formula would therefore be focussed on its necessity for *the small number of infants who cannot tolerate human milk, and for situations where a mother experiences it as necessary to feed her infant a breastmilk substitute*.
26. To protect breastfeeding from displacement by inappropriate marketing of infant formula products, whilst also ensuring that infant formula is as safe and nutritious as feasible, assessment of revisions to the standard in line with Code objectives should give important consideration to how any changes better protect, support and promote breastfeeding whilst regulating infant formula primarily to ensure industry incentives are

directed at most efficiently addressing the needs of infants who cannot tolerate human milk, and must be fed a breastmilk substitute to ensure their health and survival.

27. To avoid unnecessary institutional incentives for industry to expand the market for suboptimal infant and young child feeding products such as infant formula, it is generally desirable that industry, not the regulator, carryis public and legal responsibility for deficiencies or detriment caused by manufacture, sale or consumption of these 'novel food' product for infants. Consistent with this, consumers would also be fully informed that a decision not to breastfeed or to reduce breastfeeding through using infant formula, carries individual health and safety risks against which food regulation or industry compliance with the food regulatory standard does not protect them.
28. The difficulty with defining and enforcing regulation regarding novel foods, nutritive substances and optional ingredients, and nutrition and health claims in relation to these, in the context of 'functional foods' and 'pharmaceutical and food industry convergence (1) suggests consideration of such issues within an alternative regulatory framework. In such a framework, for example, infant formula might include a label indicating that infant formula is a novel food for human infants, that the traditional food is provided by breastfeeding, and that manufacturers retain future liability for any adverse public health or safety consequences of infants consuming a non-traditional, 'functional food' which has not been scientifically proven safe and healthful for use as the sole or predominant food source for human infants.
29. In this context, secondary objectives of P1028 such as 'consistency with advances in scientific knowledge', and 'not hindering innovation or trade' might usefully be applied – entirely consistently with primary public health and safety objectives of the Code – to explore and develop an alternative regulatory framework for the composition, safety and representation of infant formula products. Such an alternative framework, in line with advances in scientific knowledge about infants' traditional first food, might encourage innovation or trade directed at the protection, support and promotion of 'optimal breastfeeding' as defined by health authorities (8, 9), and at supporting a sustainable industry in breastfeeding related goods and services such as breastfeeding and lactation support services, and even commercial wet-nursing, human milk banking, and the exchange or trade in human milk. In such an alternative regulatory framework (and noting the previously identified distinction between breastfeeding and breastmilk feeding), attention would of course need to be given to protecting breastfeeding by the mother from other modes of feeding infants breast milk, in the light of emerging scientific knowledge of breastfeeding's superiority, and to protect informed choice and prevent consumers from being deceived or misled into not optimally breastfeeding her infant.

Definitions, nutrient composition and safety and food technology of infant formula, [including consistency with advances in scientific knowledge]

The definition of infant formula

30. FSANZ reports confusion about the age range for infant formula in relation to 'follow on' formulas. The risk of confusion has been created by industry, arising from infant formula manufacturers' deliberate strategies of avoiding regulatory restraints on marketing of breastmilk substitutes by market segmentation and creation of new 'follow up' or 'growing up' milk product categories for infants and young children, such as 'follow-on formula' and 'toddler milk' in Australia.(5-7)
31. WHO stated in 2013 that 'as well as being unnecessary, follow-up formula is unsuitable when used as a breast-milk replacement from six months of age onwards'.(15) WHO also stated that follow up formula is being 'marketed in a way that may cause confusion and have a negative impact on breastfeeding'. The NHMRC Infant Feeding Guidelines which were recently updated likewise stated (p.74) that; 'the use of 'follow-on formula' for infants aged 6–12 months is not considered necessary and no studies have shown advantages over using 'infant formula'.(8)
32. Regarding the definition of infant formula (Q1.2), I therefore offer the following comments.

- the current definition of infant formula is now unsatisfactory because of confusion over whether 'follow-up' formula is necessary or superior to infant formula. Hence this submission does not support the 'no change' option.
- Of the options offered, Option 3 being Option 1 followed by 'and as part of a progressively diversified diet of infants from 6 months of age' is the <u>least unsatisfactory</u> definition of infant formula as it specifies infant formula is also suitable from 6 months of age. However, this does not adequately clarify the role and scope of infant formula as it does not clearly indicate the intent of the standard that infant formula be suitable for consumption by an infant up to 12 months.
- A new modified version of the policy guideline definition is submitted by Government (Table 2.2, p.10): 'infant formula: means an infant formula product which is formulated to meet, as the sole source of nourishment, the nutritional requirements of infants up to six months of age, and, as part of a progressively diversified diet, from six to 12 months of age.' This is a better definition as it specified to 12 months of age.
- Furthermore, this definition also reflects the important consideration that infant formula is '<u>formulated to'</u> satisfy… rather than '<u>satisfies</u>' the nutritional requirements of infants'. That is, the safety and nutritional adequacy of infant formula products as a breastmilk substitute is relative not absolute, and hence infant formula can only reflect such attributes as 'safe' and 'nutritious' <u>to the extent permitted by current scientific knowledge</u>. Stating that infant formula <u>satisfies</u> the nutritional requirements of infants

may be considered inaccurate and misleading because there is more than sufficient evidence of nutrition and health disadvantages of formula fed infants.(16)

33. The state of knowledge on the contribution of breastfeeding to human health and development is continually advancing. Thus, it would also be desirable for the definition of infant formula to also indicate that the product is formulated 'as indicated by current scientific knowledge'. In summary, a suggested wording for the definition of 'infant formula' in the standard for infant formula products is therefore:

    'is formulated as indicated by current scientific knowledge to satisfy by itself the nutritional requirements of infants less than 6 months of age and as part of a progressively diversified diet of infants from 6 months to up to 12 months of age.

The nutrient composition, safety and food technology of infant formula

34. FSANZ reports that formula manufacturers are seeking to introduce different composition requirements for infant formula and follow up formula. FSANZ also reports from the 2012 consultations on P1028 that jurisdictions are calling for greater clarity about adding optional substances, and noting that the intent of Ministerial guidance on the regulation of IF products is that a premarket assessment be required for all new substances (FSANZ March 2013). There is also ministerial guidance regarding appropriate evidence to link the effects of the substance for specific health outcomes (SD1 p.4), requiring particular caution where such links are less clear.
35. Below I comment in particular in relation to questions (including Q1.4, Q1.5 and Q1.27-29) regarding the regulatory approach to lead contamination, sources of fat in infant foods and regulatory approaches to novel foods, or nutritive substances, optional ingredients. As these questions overlap with issues regarding nutrition content and health claims, to a degree these are considered together.
36. It is appropriate that where there is sufficient evidence that ingredients are safe and essential for the normal growth or development of infants, such ingredients are mandated in all infant formulas. Conversely, standards must change when new evidence comes to light regarding significant adverse effects of exposure to ingredients or contaminants. This applies for example, regarding the question of lead contamination of infant formula, where FSANZ proposes reducing maximum permitted levels. In view of the revocation of the Codex maximum level of lead in infant formula, based on current scientific knowledge suggesting there is no threshold below which lead exposure is safe, along with findings of around 3 IQ points in children aged 5-6 years at comparatively low levels of exposure of 2 ug/kg, the preliminary view of FSANZ to ensure the level of lead in infant formula is as low as is achievable is supported. Given the vulnerability of infants and the existing levels of lead in infant formula samples as identified in Att A2.4, (p.132), this change should be implemented immediately, without consideration of cost to industry. Further reductions foreshadowed as more evidence regarding infants' exposure to lead through infant formula becomes

available. It is noteworthy that cognitive losses of around 3 IQ points from infant formula feeding were estimated by Rollins and colleagues to imply productivity losses of around $300 billion a year globally, mostly in industrialised countries.(17)

37. It is also appropriate that a premarket assessment be required of all new substances, as per the Ministerial guidance noted above.
38. This raises the question as to the point at which it can be concluded there is insufficient evidence to justify ongoing permission for optional ingredients or nutritive substances or there is sufficient evidence to justify withdrawing such permission (such as for added LC-PUFAs like DHA, or nucleotides). Despite considerable research over an extended period of time, there does not appear to be sufficient evidence to support that they be mandatory, yet they are still permitted in infant formulas. If there is still insufficient evidence of benefit, and links with specific health outcomes remain unclear, should they still be permitted, or should this permission be reassessed?
39. There also remains a question as to why post-marketing surveillance is not also required for such substances in infant formula products given the unique nutrition and health vulnerability of infants and young children, and the lack of any systematic process for documenting and reviewing the safety and effectiveness of infant formula in its intended use substituting for breastfeeding and breastmilk as the sole or main food for infants. With the rise of ‘functional foods’ more generally the issue in the context of regulation of infant formula takes on a greater significance.
40. FSANZ has formed a preliminary view that including LC-PUFAs notably DHA should not be mandated, because of insufficient evidence to establish their effectiveness or benefit. On the other hand, FSANZ has permitted these to be added as ‘optional’ ingredients or substances on the basis that there is no evidence of risk to infant health from the addition of these ingredients. However, ‘no evidence of risk’ is not the same as ‘evidence of no risk’. In light of the unique vulnerability of infants who are not breastfed, and ethical considerations regarding the lack of informed consent for experimentation with human participants (18) ‘evidence of no risk’ should be a requirement for determining if novel foods, nutritive substances or optional ingredients in infant formula should be permitted in the future.
41. The example of DHA is an example of how permitting optional ingredients in infant formula facilitates and motivates inappropriate marketing of products containing these ingredients. Use of such ingredients in nutrition content or health claims undermines informed choice to breastfeed, by implying breastfeeding does not contain such ingredients and is equivalent to infant formula. It also undermines caregivers’ informed choice about infant formula purchases, by implying that the product provides nutrition or health benefits compared to other products.
42. Where the evidence does not support the health effectiveness of the product (as distinct from its efficacy in generating comparable physiological responses to specific ingredients in breastmilk), caregivers are being deceived or misled into purchasing.

Where scientific evidence from properly designed and conducted trials is sufficient to support the health effectiveness of the product compared to infant formula without such ingredients, the question is raised as to why they are not mandated ingredients.

43. It is a concern that such ingredients are of uncertain benefit to children, and may not be safe but are included in current formulas without warnings to caregivers that the purported or inferred benefits for health outcomes are not supported by scientific research. The risk to informed choice and the likelihood of deceiving or misleading purchasers by permitting such ingredients, as well as potential concerns about adherence to ethical standards regarding experimentation with human participants, reinforces public health and safety arguments for not permitting such ingredients or 'information provision' about them. Extensive post market surveillance and long term accumulation of scientific evidence would be necessary for sufficient evidence that novel or optional ingredients in infant formula are not harmful. On this basis of uncertain benefit and potential risks to public health and safety, it is submitted novel or optional ingredients should not be permitted in infant formula.

Provision of information (warnings, advisory and other statements, claims and declarations)

Protecting public health includes mothers' health

44. Consistent with the Code objective of protecting public health, P1028 assessments must consider women's health, not just that of infants. This is because breastfeeding is important to mothers' as well as to children's health. Recent studies published in leading medical journals reinforce the accumulation of evidence on adverse child and maternal health effects of formula feeding (which reduces the duration of breastfeeding), and the public health importance of protecting, supporting and promoting breastfeeding.(10, 17, 19-22) For example, as well as documenting the higher rates of infectious illness and death, cognitive disadvantage and later life chronic disease among infants who are formula fed, such studies note the substantial health implications for mothers such as around 20% higher maternal breast cancer risk where breastfeeding during the first 6-12 months is replaced or reduced by infant formula use.

The unique vulnerability of infant formula 'consumers' includes their mothers

45. Infants are rightly recognised by FSANZ as a vulnerable population group. However, the consultation documents appear unaware of evidence that mothers, especially pregnant and new mothers, are vulnerable consumers. This is both because of the adverse health implications for women of formula feeding, and because of mothers' particular vulnerability to marketing. For example, research has identified the 'liminal' vulnerability of pregnant and new mothers at this major transitional stage in their lives, as well as arising because they are inexperienced consumers entering a new marketing 'space'.(23) Other research has also documented that mothers face

particularly high levels of anxiety and concern for children's health because of highly gendered social expectations about the mothering role and responsibilities.(24)

46. In developing standards for foods for infants and young children (0-36 months) including infant formula, it is important that FSANZ also recognises the unique vulnerability of mothers and infants both as a dyad, and as separate persons, with such vulnerability in terms of their health and also in relation to marketing and product information on infant formula which is confusing, misleading, or deceptive.
47. Irrelevant or unnecessary information, as well as lack of information, undermines mothers' informed choice about infant and young child feeding, and contributes to premature cessation of optimal breastfeeding as defined by WHO and the NHMRC (8, 9), and public health detriment.

Preventing promotion of infant formula including through labelling and advertising

48. As well as Codex, FSANZ must have regard to Ministerial guidance including that labelling and advertising of infant formula should be consistent with the WHO Code (as implemented in Australia (SD2, p5). The WHO Code provisions on labelling and advertising of breastmilk substitutes are partly implemented in Australia through the FSANZ and the Food Code, but as noted earlier, are otherwise not implemented in Australia (11).*

'Breast milk is best' statement SD2 (5.6)

49. FSANZ proposes retaining the current warning statement on infant formula that 'breast milk is best for babies'. However, this statement is inadequate for informed choice, as well as inaccurate and potentially misleading. The evidence relating to WHO Code requirements is based on the superiority of breastfeeding compared to formula feeding. 'Breastfeeding' is not the same as 'breastmilk' feeding. The literature demonstrating the health impacts of breastfeeding and formula feeding is not based on comparison of feeding breastmilk with feeding formula milk, but rather compares breastfeeding populations with those fed formula milk usually in bottles.
50. Recently the number of women who feed expressed breastmilk has increased especially by mothers in the US returning to paid employment because of inadequate paid maternity leave; concerns have arisen in that country about differential outcomes for breastfed compared to infants fed bottled breastmilk as well as in comparison to infants fed bottled infant formula.
51. Such concerns about breastmilk feeding vis a vis breastfeeding arise from both the higher potential for contamination compared to breastfeeding, as well as differential immunological and mental or physical development impacts of expressed or pasteurised breastmilk rather than breastfeeding; the effects identified range from

* Notwithstanding the existence of a proposed voluntary industry agreement, which has not been approved by the Australian Competition and Consumer Commission. If Ministerial guidance is inconsistent with the primary objectives of the Code, the primary objectives of the Code have precedence.

effects on maternal-child bonding, and on infectious illness such as otitis media and gastrointestinal infection, to malocclusion and speech development, as well as poorer appetite self-regulation among breastmilk fed compared to breastfed, and relatedly to risk of maternal overfeeding leading to obesity.(25-31) Breastfeeding duration may also be shortened by breastmilk feeding.(31)

52. The emerging evidence reinforcing the superiority of breastfeeding over breastmilk feeding (alongside the well-established superiority of breastfeeding in relation to formula feeding/bottle feeding) points to the urgent need to adequately reflect the WHO International Code regarding requirements for a statement on the superiority of breastfeeding. Hence, the 'breast is best' statement should be urgently revised to 'breastfeeding is best for babies', otherwise this statement misleads and deceives mothers about comparisons with breastfeeding, and does not support informed choice of infant and young child feeding method.

Protein source statement and its location - dairy in infant formula

53. FSANZ has raised questions regarding the usefulness of information on protein source, and aspects of its location on the product. Regarding the statement on protein source and its location (Q2.6-2.8) the SD2 provides information which suggests that caregivers value and seek information on whether the protein source in infant formula is dairy milk in order to identify products which may not meet their infant's dietary requirements. FSANZ also notes that that protein source information is usually prominent only on the labels of infant formula where cows' milk is not the protein source. Previous submissions on P1028 contained reports of ignorance or misunderstanding that the source of powdered milk used for most infant formula products is cows' milk. This suggests that parents are confused, may believe infant formula is human milk, or believe that infant formula is not dairy food.
54. The above would suggest benefit in terms of public health and safety and informed choice if this protein source information was consistently placed on in a prominent place on the front of the package. Parents would then be appropriately informed that dairy milk not human milk is the protein source for infant formula, and would not be not deceived or misled into believing that infant formula is free from dairy products, or that infant formula is manufactured from human milk or any of its components.
55. Where the protein source is soy, the regulatory objective of informed choice and related consumer protection considerations would suggest that parents should be advised through labelling requirements that current research is uncertain on whether concerns over soy-based formula and reproductive health are justified (4). Likewise, for hydrolysed formula, parents should be advised of recent evidence of no significant reduction in rates of allergy from using such products (3).

Powdered infant formula is not a sterile product

56. WHO advises that powdered infant formula is not a sterile product, even if it has been manufactured to meet current hygiene standards, and so may occasionally contain pathogens that can cause serious illness (WHO 2007). Although the consultation documents report evidence of a lack of awareness by parents that powdered infant formula is not sterile (Att A2.2, p. 3-4), FSANZ has stated it is not considering an advisory statement under P1028 (p.36).
57. Addressing the inherent risk of bacterial contamination of powdered infant formula has necessarily focused on improving caregiver practices. However, it can be argued that not providing information to caregivers about potential pathogens in infant formula misleads and deceives parents about the safety of using infant formula and the superiority of breastfeeding, with potentially serious consequences for (infant) health and safety. The absence of such information may also contribute to negative effects including guilt about infant formula use where the infant becomes sick, as the inherent contamination risks of infant formula are not widely known, and incidence of illness associated with such risks is understated due to lack of systematic monitoring and reporting processes.
58. A statement providing information on the inherent risks of contamination in powdered milk formula, even when prepared, handled and stored as directed, is needed to meet statutory objectives for informed choice about using powdered infant formula, and to avoid misleading and deceiving parents on its safety, by clarifying that pathogens in infant formula are not necessarily due to inadequate caregiver practices. This submission therefore suggests FSANZ give further consideration to requiring a statement on the non-sterility of infant formula, and its inherent risks compared to breastfeeding or using ready-to-feed infant formula.

Nutritive substances and novel foods in infant formula, and nutrition content and health claims

59. From an evolutionary and therefore physiological perspective, infant formula (comprising all its nutritive substances) is a 'novel food' when consumed by human infants, and breastfeeding is the only suitable 'traditional food'. This perspective may provide a potential basis for developing an alternative regulatory framework for prospective regulation of infant formula and associated nutrition and health claims. Such issues are canvassed below, for exploration and consideration in the context of discussion of nutrition and health claims.
60. Recognising the lack of clarity on which nutritive substances and novel foods are covered by pre-marketing assessment requirements for infant formula, FSANZ has invited comment on whether all such substances should require pre market assessments and if not, how these substances should be distinguished. FSANZ also raises questions on whether macronutrient subcategories should be permitted in nutrition information statements.
61. Industry seeks permission to label infant formula regarding its nutrition content claims, while the intent of guidance is clear that claims are prohibited, pre-market assessment should be required for all new substances, and relevant WHO standards (not the industry's MAIF) should be implemented to the extent possible. It is noteworthy that the position of industry is in the direction of weakening regulatory restraint of marketing of infant formula products, while the policy guidance is in the direction of strengthening it.
62. The issue of defining coverage of premarket assessment requirements is a difficult question because of conflicting aims of minimising the detriment to infants deprived of breastfeeding by permitting improvement and innovation in infant formula composition where there is sufficient evidence of its safety and benefit, as against the risks to health and safety and the need to protect breastfeeding from inappropriate marketing (which promotes infant formula as being close to breastmilk and thereby risks reducing breastfeeding and maternal breastfeeding duration. Without mandatory implementation and enforcement of the WHO Code and relevant WHA/WHO agreements and guidance, marketing and nutrition or health claims would likely be facilitated by not requiring premarket assessment for all such substances. Novel food, nutritive substances or optional ingredients can be, and sometimes are used to promote infant formula.
63. Prohibition of nutrition and health claims on infant formula by Australian food regulation is in line with well-established evidence and international and national regulation, agreements and guidance about the specific harm to optimal infant feeding of infant formula promotion arising from the unique vulnerability of both mothers and infants. Ensuring and enforcing this prohibition in Australia in the interests of public health and safety has precedence over other objectives, even such as adequate information and prevention of deception or misleading consumers, as well as achieving 'consistency' or

innovation or industry development, ministerial guidance etc. As noted earlier, WTO or trade agreements are not a barrier to achieving public health and safety regulatory objectives.

64. Specifically FSANZ has posed the question of whether macronutrient subcategories should be permitted in nutrition information statements (SD3 Q3.2-3.6). However, it is submitted in response that information about the composition of all infant formulas is adequate for informed choice if it accurately reflects their broad macronutrient composition. Allowing additional macronutrient or other information mainly allows infant formula to be promoted by reference to its ingredients, without comparable, countervailing promotion of the superior ingredients available from breastfeeding or breastmilk. Likewise, information about reformulation of an infant formula is likely to facilitate marketing of new products rather than provide necessary information to parents using such products.
65. Permitting unnecessary additional unnecessary information in nutrition information statements or on product labels serves primarily as a marketing strategy to gain attention and differentiate brands from competitors, without advancing public health or food safety.
66. Current permissions for optional ingredients and difficulties of enforcement regarding novel foods or substances, similarly can be argued to be an unethical experiment on infants. As is the case with tobacco products, unnecessary information on labels or packaging is used by industry to promote a product not informed choice, and in the case of infant formula is likely to confuse and/or mislead mothers both about the comparative characteristics of the brand, and about the superiority of breastfeeding and the valuable, non-replicable, constitution of breastmilk.
67. As noted earlier, mothers and babies are uniquely vulnerable consumers on several counts. Advertising is not information. Providing additional ‘information’ on ingredients or nutritive substances will tend to bias caregiver ‘choice’ towards purchasing infant formula - and away from optimal breastfeeding which is not promoted with similar vigour or sophistication.
68. FSANZ has cited difficulties regarding rejecting nutrition and health claims implicit in trademarks. It reports that Australian government agencies are unable to properly assess and automatically reject nutrition and health claims implicit in trademarks. This is perhaps not a concern because a trademark is only a right to protect against competitors use of this ‘intellectual property right’. It does not amount to an inhibition on governments regulating the use of such trademarks such as for the protection of public health and safety, in the case where trademarks are used to make implicit nutrition or health claims for infant formula. However, this difficulty does suggest the need for more strongly punitive and deterrent approaches to compliance, but is not an argument for the de-facto acceptance of nutrition and health claims on infant formula and infant

formula products via trademarks. The latter approach is inconsistent with the statutory objectives set for the infant formula standard.

Responsibility for provision of information on infant formula use

69. Consistent with children's human right to the highest attainable standard of health and for their caregivers to have access to relevant independent information, consideration might be given to the extent to which government has responsibility for providing access to independent information on infant formula. This might take the form of an independently prepared brochure or information booklet on formulas, available through health professionals, health services and supermarkets or wherever infant formula is supplied (as was suggested by submissions to the previous consultation). This could inform caregivers any necessary information on the ingredients or changes to the formulation of all infant formula products, so that caregivers can identify a formula which individual infants can tolerate, and could advise caregivers of the significance or otherwise of ingredients in infant formula for protecting or contributing to the product's safety or healthfulness.

Benefit to industry of regulation of infant formula standards

70. In the same way that legalisation and regulation of gambling results in it being perceived as safer and will be more engaged in by consumers, the market for infant formula products is expanded by government regulation which for consumers implies a warranty of its safety.
71. The earlier discussion regarding framing regulation in the context of some infants' need for a safe and nutritious infant formula illustrates that the existence of standards for infant formula has an inherent risk of, in itself, indirectly contributing to expanding the infant formula industry. In the absence of the standard, the market for these products would be much smaller, due to the perceived unregulated risks compared to breastfeeding. It would be more the case that only babies who could not tolerate human milk would not be breastfed, and governments would find it necessary to introduce health, employment and other measures to better enable mothers to breastfeed.
72. By reducing consumer concerns about the safety and adequacy of infant formula, the regulation of infant formula provides benefits to industry, as well as providing the starting point for their marketing of infant formula in competition with breastfeeding. The development and promulgation of the infant formula standard privileges the infant milk formula industry and this should be reciprocated by industry adherence to the letter and the spirit of the law.
73. That industry does not meet ethical or regulatory standards in force globally or nationally is evident in a recent report published jointly by the WHO, UNICEF and IBFAN.(11) The report along with concerns leading to the call for new WHO guidance

on preventing inappropriate promotion of infant and young child foods shows the extent to which industry has breached its obligations to comply with national law and regulation, as well as its obligations to behave ethically in line with the highest global community standards; the WHO report on WHO Code implementation recorded that a key challenge to implementation globally was 'continued interference from manufacturers and distributors in governments' efforts to initiate or strengthen Code monitoring and enforcement measures' (p.2).

74. It is crucial both for food safety and for public health that the regulation of infant formula
    - fully protects breastfeeding against the expansionary tendencies of competitive productive markets such as for infant formula products, and
    - reflects a perspective which ensures that manufacture, marketing and use of infant formula is as safe and healthy as possible for all infants whether they are currentlly breastfed or not breastfed,
    - As many infants are, have been, or will be at some stage 'mixed fed', the standards regulating infant formula affect the safety and health of currently breastfed infants and are not only directed at the health and safety of those who are currently exclusively formula fed.
75. An alternative regulatory framework needs to be explored and developed which prospectively encompasses all infant formula products marketed after a certain date (for example 1958). The regulatory framework for future infant formula products' could adopt elements of the framework for pharmaceutical and therapeutic goods, including more substantial premarket trialling and assessment, and post-market surveillance and evaluation. Under such a framework, breastmilk substitutes including infant formula marketed prior to a specified date could be defined and regulated separately as a 'traditional' food which has been proven (after a 20-50 year time lag) as providing adequate protection for public health and safety. This would be subjected to food regulation allowing no new nutritive substances, no novel foods, and no nutrition content or health claims, in line with the current food policy and regulatory intent and standards for infant formula products.

Conclusion

> ***"A paradox of a more effectively liberal economy is that it forces us to make more judgements about vices we wish the state to regulate. Because a perfectly competitively economy produces vice, indeed innovation into vices yet to be invented (such as designer drugs) it creates a greater demand from citizens for state regulation.***

Braithwaite, J. 2005 *Markets in Vice Markets in Virtue*, p8, Federation Press.

If the benefits of a more competitive economy are to be realised, regulation may need to be strengthened. This is nowhere more true than in the case of foods marketed for infants and young children, as has been accepted at the highest levels of global health governance.

Regulation benefits industry by giving consumers confidence that food products are as safe and healthy as possible, given the current state of knowledge. Irresponsible industry uses the shield of such regulation to promote the product, create new consumer demand and expand sales beyond the levels that are socially beneficial, making the virtue of competition, efficiency, and innovation in product development and promotion, into a vice. Responsible industry players recognise the benefits for shareholders of achieving the highest standards of self regulation in line with community standards, as well as the reputational harm and loss of shareholder value due to community perceptions that they are not good corporate citizens adhering to high ethical standards. Industry has a long way to go to repair its tarnished image of inappropriately promoting breastmilk substitutes.

In the meantime, FSANZ is to be supported and endorsed in its efforts to strengthen the regulation of infant formula towards achieving the greatest possible protection of public health and safety including of mothers, and through protecting breastfeeding. It is also to be supported in any efforts to import ministerial and international guidance which offer the opportunity to strengthen Australian infant formula standards in line with the best available scientific evidence.

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