

RESPONSE

POLICY OPTIONS FOR THE REGULATION OF INFANT FORMULA PRODUCTS

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1. Please comment under any or all of the following questions:

Question 1: Do you have any comments on the definitions used?

- Suggest use the term human milk instead of breast milk in the definitions and throughout the document. Human milk is the species-specific milk for human infants and human milk should be the specific reference milk for comparison with infant formula, cow's milk, etc. Breast milk refers to the gland, which is irrelevant in this document and can also have negative connotations.
- Suggest use internationally recognised definitions where possible. That is, the WHO indicators^{1,2} for infant and young child feeding practices.
- Avoid the use of the word 'benefit' throughout the document as it is confusing and potentially misleading. Breastfeeding is the biological norm; any component of infant formula that results in similar physiological outcomes to breastfeeding may be improving an inferior product, but is not conferring a "benefit". This term is also inappropriate in marketing.
- Add a definition of 'Infant growth' which states that the biological norm is the growth standards for exclusively breastfed infants in the first 6 months, and predominantly breastfed infants in the second 6 months³, as documented in the WHO Child Growth Standards. Formula fed infants deviate from this biological norm and there are implications for obesity, elevated cardiovascular risks, and diabetes^{4,5}.

Question 2: Are there any international standards of relevance that have not been provided here? Please provide references.

- Global Strategy for infant and young child feeding (WHO) http://www.who.int/nutrition/topics/global_strategy/en/index.html
- Safe preparation, storage and handling of powdered infant formula: guidelines, (WHO)⁶ <http://www.who.int/foodsafety/publications/micro/pif2007/en/index.html>
- Child Growth Standards (WHO) <http://www.who.int/childgrowth/en/>.

Question 3: *Are there any impacts to consumers, industry, government, and public health stakeholders that have not been included here? Please provide details.*

- The key priority . . . is to protect public health and safety. The use of infant formula, where breastfeeding was possible, has major individual and public health implications. Every aspect of the regulatory system, availability, labelling, marketing, etc. should be considered for its potential impact on the optimal health of infants in Australia and New Zealand.
- While affordability is an important aspect, it should never compromise optimal quality and the optimal health of infants – even if some sectors of the community have to be subsidised, e.g. through the PBS, when breastfeeding is not possible. When use of infant formula is a lifestyle choice, a less affordable product may be a disincentive (as shown for alcohol and cigarettes).
- Ensuring that infant formula products on the market in Australia and New Zealand are not perceived by health professionals and the public to be ‘superior’ to human milk or even close to ‘equivalent’. While the regulatory framework may need to focus on individual components or outcomes which may sometimes approach equivalence, there should be nothing in the policy documents or the standard which suggests superiority or equivalence on a complete product basis, or permits labelling or marketing which might imply superiority or equivalence on the basis of one or more components or outcomes. The perception that ‘infant formula is so close to breastfeeding that it doesn’t really matter’ has an adverse impact on consumer breastfeeding rates.

Question 4: *What criteria should underpin the essential nutritional composition requirements?*

- The consideration of the addition of any components to infant formula products should be based on unbiased evidence (research not funded by infant formula companies)
- Whether there is an RDI or absence that can cause a ‘deficiency’ or a negative health outcome.
- While short and long term health outcomes are important, should also consider bioavailability and comparison between human-milk-fed and formula-fed infants on parameters such as serum levels, physiological outcomes, normal growth (using WHO Standards) and side-effects which differ from the biological norm.

Question 5: *Should any ingredients other than additives, processing aids and nutritive substances that are being used in infant formula products, require pre-market assessment?*

- Yes all components / ingredients should require pre-market assessment.

Question 6: *Is the health and physiological outcome of the full term, breast fed infant (at relevant age) a useful benchmark in considering the composition of infant formula products? Why? Why not?*

- Yes, these are useful benchmarks, but should also include growth and development (using WHO Standards). Both short and long term outcomes should be included.
- For infants up to 6 months, the benchmark should be specified as full term, exclusively breastfed infants as that is the biological norm. For infants greater than 6 months, the benchmark should be full term infants who were exclusively

breastfed up to around 6 months and then predominantly breastfed and receiving appropriate complementary foods.

- Where possible, all assessment trials should be conducted on infants in settings similar to Australia and New Zealand in terms of nourishment, disease prevalence, etc. Improved infant outcomes in some settings may not be relevant or demonstrable in Australia and New Zealand. The local applicability of all trials should be assessed.

Question 7: *Is consideration of health benefit (as defined in this paper) a useful benchmark in considering the composition of infant formula products? Why? Or why not?*

- As in Question 1, there are no ‘health benefits’ in the composition of infant formula. Revise language to ‘improved outcomes’ or similar.
- Components should demonstrate either a nutritional or technological purpose to justify inclusion, with an end result of getting closer to the physiological norm of a breastfed infant. Improved health outcomes are important, but should not be the only criteria. Biologically normal growth should be another criteria.

Question 8: *Should ingredients not present as components in breast milk be permitted to be used in infant formula products? If so, under what circumstances and with what, if any limitations placed on such additions?*

- Because the overall composition of infant formula is inevitably very different to human milk, some additional ingredients may be necessary to counteract differences in bioavailability and problems inherent with deviating from the biological norm (e.g. constipation, reflux).
- We recognise that components also need to be added to infant formula to ensure safety and stability of the product. Infant formula will never be able to replicate human milk in this regard (that is, no additives needed!). However, this should only be done when absolutely necessary and in a safe manner and clearly labelled.

Question 9: *When should an optional ingredient become a mandatory ingredient? What criteria should be required?*

- When it can be demonstrated that an ingredient/component is safe and results in improved health or developmental outcomes for formula fed infants or enables closer to biologically normal growth, and when an RDI has been developed, then it should be considered mandatory. This is an equity issue. If an ingredient/component is deemed to improve health, growth and/or development then all infants who are being fed with infant formula should have access to it.
- Once safety and other relevant considerations have been established, a novel ingredient/component could have a time-limited transitional status until it becomes mandatory or is deemed unnecessary.
- The existence of the category ‘premium infant formulas’ with optional additional ingredients serves to increase the cost to the public. Their availability creates pressures on parents who feel guilty if they don’t buy these premium products for their babies.

Question 10: *Do you think that the policy principles for infant formula should be the same for follow on formula? If not, please provide details.*

- Should be the same policy principles (although recognising that because it is for infants greater than 6 months the benchmark should be based a different reference group, as above).
- We also think the same policy principles should apply to toddler formula.

Question 11: *Are there any policy principles that should specifically guide the regulation of infant formula products for premature or low birth weight infants? Please provide details.*

- The policy principles should incorporate higher standards for this particularly vulnerable group, because the differences in health outcomes of formula fed vs. breastfed pre-term or low birth weight infants are enhanced, compared to full term or normal birth weight infants.
- The compositional benchmarks should be set to be appropriate for the physiologic, growth and other norms of exclusively or predominantly human-milk-fed pre-term or low birth weight infants, with particular reference to long term outcomes.
- A higher level of food safety is required. The policy principles should incorporate the relevant WHO recommendation regarding powdered infant formula products and vulnerable infants, including: Where feasible, sterile liquid infant formula should be used in care settings, especially when feeding high-risk infants. These feeds do not contain harmful bacteria. Care settings, such as neonatal intensive care units, provide care for infants at greatest risk of *E. sakazakii* infection, i.e. neonates and those less than two months of age. However, sterile liquid infant formula is not always available (e.g. for infants who have special dietary needs), and PIF might be used instead.⁶

Question 12: *Should pre-market assessment of infant formula products for premature or low birth weight infants require the same level of evidence and assessment standards as infant formulas for general use?*

- There should be a higher level of evidence and assessment because this is a vulnerable group of infants that need protecting.
- There should be independent review of all pre-market assessment trials (not just those for these infants)
- There should be a requirement to include all assessment trials of infant formula on the international trial register, prior to the trial commencing.

Question 13: *Are there any specific policy principles that should specifically guide the regulation of infant formula products for infants with specific health conditions? Please provide details.*

- As per Question 11, taking special nutritional needs of these groups into account.
- As per Question 11, the policy principles should incorporate the relevant WHO recommendation regarding powdered infant formula products where infants are immune compromised or otherwise more vulnerable.
- We recommend restricting access to these infant formula products so that they are available through prescription only, or at the very least restricted to pharmacist-only. Parents should not be in a position to self-diagnose and determine the best management of conditions such as lactose intolerance, reflux, etc., especially at the expense of unnecessarily abandoning breastfeeding.

Question 14: *Should pre-market assessment of infant formula products for infants with specific health conditions require the same level of evidence and assessment standards as infant formulas for general use?*

- A higher level of evidence is needed because they are such a vulnerable group.

Question 15: *If an ingredient is proposed to be added to an infant formula product with the intention of achieving a health benefit, is a pre-market assessment of that health benefit warranted? If so, what type and level of evidence might you expect to be appropriate to support such an assessment?*

- As above, there are no health ‘benefits’ – only improved outcomes for infants whose health is already compromised by not being breastfed.
- Yes, a pre-market assessment is warranted.
- Best available evidence of effectiveness available e.g. RCT or NRT or population cohort studies:
 - Using a reference group of healthy breast fed infants.
 - Independent systematic review of existing studies.
 - All studies to declare funding and note potential conflicts of interest
 - Inclusion on the international trial register
 - Clear general principles, design, methodology and data analysis to identify short and long term risks and improved outcomes
 - Independent review of trial and results.

Question 16: *Do you think post-market surveillance has a place in the regulatory framework for infant formula products? If so, what would you consider an appropriate trigger for post market surveillance? If not, why not?*

- Pre-market surveillance needs to be strengthened (see previous responses)
- An independent register of adverse effects, with compulsory notification by companies, should be set up to monitor adverse outcomes and used as the basis for triggering post-market surveillance and/or withdrawal if appropriate.
- Cost of any post-market surveillance is justified if we value infant health. Use of infant formula is a deviation from the biological norm and can be expected to have consequences.

Question 17: *Do you think conditional approvals should be given so long as post-market surveillance is undertaken?*

- No definitely not. This would be treating infants as guinea pigs in uncontrolled experiments.

Question 18: *What do you consider would be a major formulation change to infant formula? Please provide details.*

- Any change to the level of an essential ingredient, a new form of an essential ingredient or addition of a new ingredient.
- Any change to the source of ingredients or the composition.
At <http://www.stuff.co.nz/national/639798> there is a report of an infant in New Zealand who had a severe reaction when Heinz changed the supplier (and therefore some ingredients) of its Nurture Follow-on Formula, when the parents thought

they were using the same product. The company also had other complaints. Apparently there was no legal notification requirement to the NZ Food Safety Authority – there should be. Clearly this ‘minor’ change had serious implications for at least one infant.

Question 19: *Do you think existing guidelines, standards, and measures deal effectively with labelling and advertising in relation to infant formula? Please provide details.*

- No – existing measures need to be both amended and strengthened
- The WHO recommendations⁶ regarding the reconstitution of powdered infant formula (PIF) should be incorporated on the labels as a matter of urgency – this is a safety issue. The information should be amended to include:
 - the information that powdered infant formula is not a sterile product
 - an instruction should be added about clean surfaces and equipment as this is a known source of contamination inherent with reconstituting powdered infant formula, which then becomes the growth medium and source of bacterial contamination.
 - WHO recommends reconstitution with water at 70°C. We support this recommendation because it is based on extensive safety analysis and reduces the risk of bacterial proliferation, especially when PIF is prepared or stored less than optimally, the reality in many homes.
 - unless the 70°C instruction is implemented, the information about storing and use within 24 hours should be deleted and replaced with the instruction that each bottle should be prepared individually and used immediately.
- Labelling should implement the spirit and intention of the WHO Code as clearly outlined in the preamble. The images on current labels are inherently promotional and idealise the use of infant formula.
- Ditto advertising, which idealises the use of infant formula and conveys the impression of greater similarity to human milk, and less risks associated supported by the body of scientific evidence.
- Very grey line between advertising and provision of ‘scientific and factual’ information to health professionals. Also marketing and promotion seem to fall outside the definition of ‘advertising’
- Freely advertised to the public on the internet.
- Manufacturers indirectly promote infant formula using brand recognition by promoting ‘toddler milks’ as Step 3, with infant formula and follow-on formula being steps 1 and 2.
- The language used on websites and on labels can undermine breastfeeding.
- Health claims and trademarked fancy names of ingredients with implied health ‘benefits’ should not be permitted on infant formula. There should be no reference on labels or in any materials to health ‘benefits’, as above.
- There should be mandatory warnings on the label for potential adverse affects in the same way other food stuffs are required to do. For far too many mothers, the use infant formula is a lifestyle choice rather than an “emergency use only” product when they cannot breastfeed.

Question 20: *Are there any policy options that have not been considered here? If so, please provide details.*

- No.

Question 21: Can you provide data to support the potential costs and/or benefits of impacts of policy options? If so please provide this in relation to comments on the key issues and relevant options.

- While option 1 may be the most expensive to implement from an industry perspective it is the option that best protects infants and children who are not breastfed. The savings in cost from adverse health impacts will far outweigh any implementation costs.
- As above, if infant formula has to cost more to provide a product which improves health and other outcomes for infants who are not breastfed, then that is a necessary consequence which the baby bonus could be used to pay for. When an infant has to be fed on infant formula for maternal or infant medical reasons, it could be supported through the PBS or similar. An increase in breastfeeding rates would indirectly offset costs.

Question 22: Please **indicate** your preferred option (as stated or otherwise) and provide details as to why you consider this option suitable.

- Option 1 as:
 - In the best interests of infant health
 - Provides confidence for consumers re safety and physiologically closer to breast milk
 - New ingredients added will have a demonstrated benefit
 - Provides clarity and certainty for industry
 - Clarity for government re assessment and enforcement

General comments

- We need to ensure that breastfeeding is not undermined in any way by any policy option.
- Infants who are not breastfed rely on infant formula as the sole source of nutrition for the first 6 months and as a predominant source of nutrition for the second 6 months. They are a vulnerable group that needs protecting with this policy.
- There needs to be equity in the way that infants who are not breastfed receive infant formula. If ingredients are tested and deemed to be beneficial then *all* infants who are not breastfed need to have access to this formulation, not just those whose families can afford it.

References and resources

1. WHO/UNICEF. Indicators for assessing infant and young child feeding. *Child and adolescent health and development*. Geneva: WHO/UNICEF, 2007.
2. WHO/UNICEF. Indicators for assessing breastfeeding practices. Geneva, Switzerland: WHO Division of Child Health and Development, 1991.
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4. Butte NF, Hopkinson JM, Wong WW, Smith EO, Ellis KJ. Body composition during the first 2 years of life: an updated reference. *Pediatr Res* 2000;47(5):578-85.
5. Dewey KG. Growth patterns of breastfed infants and the current status of growth charts for infants. *J Hum Lact* 1998;14(2):89-92.

6. Safe preparation, storage and handling of powdered infant formula: guidelines, WHO 2007
<http://www.who.int/foodsafety/publications/micro/pif2007/en/index.html>
 7. Singhal A, Farooqi IS, O'Rahilly S, Cole TJ, Fewtrell M, Lucas A. Early nutrition and leptin concentrations in later life. *Am J Clin Nutr* 2002;75(6):993-9.
 8. Lucas P, Arai L, Baird J, Kleijnen J, Law C, Roberts H. A systematic review of lay views about infant size and growth. *Arch Dis Child* 2007;92(2):120-7.
 9. Lucas A, Bishop NJ, King FJ, Cole TJ. Randomised trial of nutrition for preterm infants after discharge. *Arch Dis Child* 1992;67(3):324-7.
 10. Lucas A. Long-term programming effects of early nutrition -- implications for the preterm infant. *J Perinatol* 2005;25 Suppl 2:S2-6.
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The Tasmanian Breastfeeding Coalition is made up of the following organisations and services:

- Australian Breastfeeding Association
- Australian College of Midwives Inc. Tas Branch
- Baby Friendly Hospital Initiative, Tas Committee
- Calvary HealthCare Hospitals
 - St Lukes Campus
 - Lenah Valley Campus
- Department of Health and Human Services
 - Beaconsfield District Health Service
 - Community Nutrition Unit, Population Health
 - Child, Health and Parenting Service
 - Maternity Services, Royal Hobart Hospital
 - Nutrition Department , Royal Hobart Hospital
 - Maternity Services Launceston General Hospital
 - Oral Health Services Tasmania
- Healthscope
 - Hobart Private Hospital, Maternity Services
 - St Helens Private Hospital
- HealtheCare
 - North West Private Hospital
- Birth Centre, Launceston
- National Association of Childbirth Educators
- Pharmaceutical Society of Australia (Tasmanian Branch)
- Tasmanian Lactation College Inc.
- Eat Well Tasmania
- Child Health Association Tasmania Inc.
- Good Beginnings Australia
- Tasmanian Early Years Foundation
- Diabetes Australia, Tasmania
- Australian Medical Association, Tasmanian Branch
- Women Tasmania
- Glenorchy City Council