



australian
breastfeeding
association

Submissions – Infant Formula Products
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Submission by the Australian Breastfeeding Association on the

FOOD REGULATION POLICY OPTIONS CONSULTATION PAPER for the Regulation of Infant Formula Products

The Australian Breastfeeding Association (ABA) welcomes the opportunity to comment on the 'Food Regulation Policy Options Consultation Paper for the Regulation of Infant Formula Products' and was pleased to be represented at the consultation meeting on 25 August, 2009 (Sydney). We appreciated the approval for a late submission, in consideration of our role and circumstances as related to Carole Inkster.

The Australian Breastfeeding Association is recognised as Australia's leading authority on breastfeeding. It is a national not-for-profit organisation, primarily volunteer based, which includes in its charter raising community awareness of the importance of breastfeeding and human milk to infant and maternal health.

More information about the Australian Breastfeeding Association can be found on the organisation's website at www.breastfeeding.asn.au.

Please contact me if you would like further information about the Australian Breastfeeding Association or this submission.

Yours sincerely,

Querida David
National President
Australian Breastfeeding Association

RESPONSE SHEET

OPTIONS FOR THE REGULATION OF INFANT FORMULA PRODUCTS

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The Australian Breastfeeding Association acknowledges that the primary objective of regulation of food standards is public health and safety. The policy and standards should reflect, throughout, the inherent fact that breastfeeding and breastmilk are the biological norm for infants and children.

The policy principles applying to the future composition and labelling of infant formula products (p 53-54) and objectives (p 37) require amendment to delete reference to a healthy well-nourished mother, and add reference “to minimise the deficits associated with formula feeding”; “not distort decision making” and “encourage appropriate and safe use”.

An objective of Food Standards is the need for standards to be based on risk analysis using the best available scientific evidence. In any standard for infant formula, risk analysis would take account of the particular vulnerability of non-breastfed infants; of formula being the sole food; and of formula being experimental in human history, as well as the particular vulnerability due to this consumption occurring at a critical stage of development with potential lifelong effects.

Infant formula products compete in the same market as breastmilk and breastfeeding. The market share of formula products is not fixed by women choosing to breastfeed; rather it reflects daily decision-making for women to continue breastfeeding. This is susceptible to a range of external factors, including advertising. A significant factor in change or reformulation of formula products is to increase market share — often at the expense of breastfeeding.

It is of concern that current Food Standards require lower standards for infant formula, follow-on formula and toddler milk than other nutritional/dietary supplements (under the Therapeutic Goods Administration). This is despite the fact that infants are vulnerable to significant risks if they are neither breastfed nor receiving human milk.

In the absence of effective regulation of the marketing of infant formula products, current standards for infant formula allow false and misleading advertising of these products.

It is important that labels on formula products provide full information to consumers on the risks associated with the product, even if used as instructed, and any claims are without embellishment. No health claims should be allowed in labelling and marketing of formula products.

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

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

Definitions within the Interpretations section of the document are inconsistent with the body of the document in respect to infants, infant formula, and follow-on formula.

The preferred definition for infant formula is as referenced to standard 2.9.1 on page 14 of the consultation paper:

“In Standard 2.9.1, infant formula products are classified into three sub categories:

1. infant formula;²¹
2. follow-on formula;²² and
3. infant formula products for special dietary use. etc ”

“Infant formula is intended to be the sole source of nutrition for the infant until such time as complementary feeding is introduced (at around six months) but is suitable for infants at all ages. Follow-on formula is marketed to infants over the age of six months.”

Standard 2.9.1 states that ‘infant formula product’ means a product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve as the principal liquid source of nourishment for infants.

The definition of ‘Follow-on formula’ is inconsistent with international terminology.

The Australian Breastfeeding Association (ABA) recommends that the definition as outlined in the Codex is used to maintain consistency throughout the paper. ie:

2.1.1 *Follow-up (follow-on) formula* means a food intended for use as a liquid part of the weaning diet for the infant from the 6th month on and for young children.

2.1.3 The term *young children* means persons from the age of more than 12 months up to the age of three years (36 months).¹

The definition of the term ‘Health benefit’ is problematic. See response to Question 7 for further details.

The terms effectiveness and efficacy should have the accompanying word ‘health’ removed and be expressed in terms of a reduction in risk when compared to breastmilk.

¹ Codex Standard for Follow-Up Formula (CODEX STAN 156-1987)

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

World Health Assembly Resolutions 33.32, 34.22, 35.26, 37.30, 39.28, 41.11, 43.3, 45.34, 46.7, 47.5, 49.15, 54.2 and 55.25 have further clarified or extended certain provisions of the International Code of Marketing of Breast-milk Substitutes.

Other international standards of reference include:

1. Global Strategy for Infant and Young Child Feeding ²
2. Acceptable medical reasons for use of breast-milk substitutes³
3. Infant formula and related trade issues in the context of the international code⁴
4. United Nations Convention on the Rights of the Child (CRC)⁵
5. 2005 Innocenti Declaration on Infant and Young Child Feeding⁶
6. WHO Child Growth Standards.⁷

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

The population health impact of formula feeding is not included and should be included. Artificial feeding substantially increases an infant's risk of obesity, hypertension, diabetes and hypercholesterolemia throughout his/her life. Formula-fed infants are also significantly more susceptible to gastrointestinal illness, respiratory illness and infection, eczema, and necrotising enterocolitis.

Evidence of an association between artificial feeding and other chronic or serious illnesses or conditions such as urinary tract infection, certain types of cancers, diseases of the digestive system, such as coeliac disease and Crohn's disease, liver disease and SIDS is strengthening. Infants who are not breastfed are known to have poorer cognitive development and lower IQ, inferior central nervous system development, impaired visual acuity and problems with speech and jaw development. For the mother there is increased risk of breast cancer, other cancers of the reproductive organs and osteoporosis.

The health costs associated with illnesses linked to premature weaning to formula are substantial. The NHMRC has noted the high costs of hospital care associated with early weaning. Based on Australian research, the attributable hospital costs of premature weaning would be at least \$60–120 million per year nationally for just **five** illnesses. The main reason for these high costs is that babies are more likely to become ill and they have more difficulty in

² WHO/UNICEF (2003) Global Strategy for Infant and Young Child Feeding WHO/NMH/NHD/09.01 Available at: http://www.who.int/nutrition/topics/global_strategy/en/index.html

³ WHO (2009) Acceptable medical reasons for use of breast-milk substitutes. Available at: http://www.who.int/nutrition/publications/infantfeeding/WHO_NMH_NHD_09.01/en/index.html

⁴ WHO (2001) Infant Formula and Related Trade Issues in The Context of the International Code of Marketing of Breast-milk substitutes Available at: http://www.who.int/entity/nutrition/publications/infantfeeding/infant_formula_trade_issues_eng.pdf

⁵ Available at: <http://www2.ohchr.org/english/law/crc.htm>

⁶ 2005 Innocenti Declaration Infant and Young Child Feeding. Available at: http://www.unicef.org/nutrition/files/innocenti2005m_FINAL_ARTWORK_3_MAR.pdf

⁷ WHO (2005) WHO Child Growth Standards <http://www.who.int/childgrowth/en/>

recovering from illness when they are formula fed. Consequently, the protection, promotion and support of breastfeeding are important preventative health strategies.

For both public health and health equity considerations, infants and young children should not be disadvantaged by the addition or omission of an ingredient to infant formula, follow-on formula or toddler milks nor be subject to “premium” product marketing. If an ingredient is proven to improve the formula then it should be required in all of the products.

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

The first section on the composition of infant formula includes a statement about the infant feeding recommendations. This section quotes selectively from the statement from the WHO.

The complete statement is relevant to the scope of the Regulation — that is, that *‘infants should be exclusively breastfed for the first six months of life to achieve optimal growth, development and health. Thereafter, to meet their evolving nutritional requirements, infants should receive nutritionally adequate and safe complementary foods while breastfeeding continues for up to two years of age or beyond’*⁸

The goal of infant formula production should be to achieve the health, growth and development of a child who is exclusively breastfed.

Sale of formulas in Australia and New Zealand that are designed to ‘treat’ problems which are not diseases or pathological conditions should be prohibited. This practice encourages parents to self-diagnose health issues in their child and may result in them not seeking appropriate medical advice.

For example, an infant formula manufacturer in the US has recently begun promoting an infant formula called ‘Restful’. This formula is marketed to make babies sleep more at night. It essentially contains rice cereal which introduces food other than milk to baby’s diet much earlier than is recommended by health authorities. Further, this particular type of formula is of great concern because promotion of deep sleep in infants has been associated with an increased risk of SIDS. The manufacturer has not conducted studies to establish whether this formula further increased the risk of SIDS compared to standard formula.

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?

Any ingredient added to a current infant formula may have unintended consequences on the growth and development of infants and young children. As such, a pre-market assessment should be required for all new ingredients.

⁸ WHO (2003) Global Strategy for Infant and Young Child Feeding.

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

The World Health Organization identifies the full term, exclusively breastfed infant as the standard for normal health, growth and development⁹. The health and physiological outcomes associated with exclusive breastfeeding are a goal, so that the artificially fed infant achieves as near as possible outcome to that of breastfed infants, but cannot be considered the benchmark for composition of infant formula products.

In considering the composition of new infant formula products, benchmarks should reflect that the product must be shown to improve the health outcomes for the infant compared to existing formula products, not compared to the healthy breastfed infant or breastmilk. The standard should relate to whether the particular composition of the new product reduces the health disadvantage of formula fed infants, not whether it produces health outcomes which bring it closer to breast milk.

Benchmarks will be used in marketing. Marketing practices equating formula to breastmilk and breastfeeding inevitably undermine breastfeeding, and regulations should restrict opportunity for a company to claim the product as being closer to breastmilk. There is considerable evidence that this marketing strategy is becoming more widespread.

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?

Health benefits as defined in this paper are not useful in considering the composition of infant formula products.

The use of the term health ‘benefit’ in relation to infant formula is misleading when the breastfed infant is considered the norm, as all infant formulas are inferior to breastmilk.

There is little doubt that research should be conducted to improve the composition of infant formula.

Labelling can include the added ingredients but they should not be addressed in terms of a benefit or improvement, but in terms of a reduction of a deficit. It is the only comparison to be made, as breastfeeding is the biological and physiological norm for infants.

Australian and New Zealand recommendations are that infants and young children should be breastfed. The introduction of infant formula has an adverse affect on the health of the child and mother. It is only when breastmilk is not available that infant formula is necessary. Parents should be aware that the unnecessary use of infant formula increases the likelihood of their baby becoming sick and can compromise their normal development.

When considering the adverse health consequences of introducing formula to an exclusively breastfed child, the terms ‘health’ or ‘functional benefit’ as used in the consultation paper should be changed to reflect that there is no ‘benefit’ in any formula.

⁹ Berry, N & Gribble, K (2008) Breast is no longer best: promoting normal infant feeding. *Maternal & Child Nutrition* 4 (1), 74 – 79.

Infant formula is not a health ‘benefit’ for infants compared to breastfeeding.

Therefore no health or functional benefit of any kind should be allowed to be used in labelling of infant formula. To answer the intent of the question and ignore the language used to describe reductions of deficits in formula, manufacturers should continually seek to improve the quality of infant formulas to minimise the adverse health consequences associated with artificial feeding.

Comments that adverse health consequences are not readily seen in our community can be answered by the general quality of our health system and availability of medical intervention and the community’s willingness to accept that ‘childhood illnesses’ including gastroenteritis and auto-immune disorders such as asthma and type 1 diabetes are ‘normal’ for children.

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?

Most of the components in artificial milk formulas are not present in human milk — ie cows’ milk proteins, vegetable oils. Where plant and animal products and other substances are used there must be research-based evidence that they are safe and suitable for continuous consumption by infants.

Ingredients added to animal milks or plant derivatives may behave differently when digested by the infant and therefore cannot be compared with human milk.

Both nutritional value and safety should be considered. This is particularly important because the fully formula fed infant’s exposure to the components will be constant for the first 6 months of life, when brain and body development is critical.

In recent years many components have been added to formula in an attempt to copy human milk without gaining any benefits for the infants using that formula. Human milk and artificial milk can never be equivalent.

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

If a particular composition of formula is shown to be effective in reducing the health disadvantage of infants who are not breastfed, then it should, within a period of time, be mandated for all infant formula products.

It is ethically unacceptable that a market advantage and price premium be obtained for reducing the health disadvantage of infants who are fed one type of formula whilst others are fed an inferior formula which increases their disadvantage compared to all other infants.

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.

Yes, policy principles for infant formula should be the same for follow-on formula.

The health and safety of infants is of paramount importance and there should be no differentiation in standards for formulas.

The World Health Organization recommends that breastmilk continue to form about half of an infant's energy needs up to the age of one and up to one third during the second year of life. As such, the use of formula or toddler milk is likely to be a significant part of an infant and young child's diet. On this basis, the Australian Breastfeeding Association believes that regulation should not be specific to infant formula but consistently applied to all formula products ie: infant formula; follow-on formula and toddler milks as they replace breastmilk when it is not available.

The definition of follow-on formula must be made consistent throughout the regulation.

Families who combine breast and formula feeding, as may occur when the mother of a breastfed baby returns to work, need to be confident that the infant formula they are using has been developed with the same high standards that are applied to formula intended for younger babies.

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.

As with any other health policies, the first principle is to do no harm, therefore infants who have compromised health should ideally have access to human milk from their mother or a human milk bank.

If an infant needs modified milk this should be prescribed in consultation with the infant's medical adviser and not be a choice in a retail outlet.

The ABA recommends that advice be sought from the professional body representing paediatricians in Australia and New Zealand.

World Health Organisation and UNICEF (2009) *Acceptable medical reasons for use of breast-milk substitutes* http://whqlibdoc.who.int/hq/2009/WHO_FCH_CAH_09.01_eng.pdf provides relevant reference material.

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?

To maintain an ethical standard, pre market assessments of all infant formula products should all require proof of effectiveness in reducing the health (infection, immunological, chronic disease), growth (obesity risk) and development (IQ and bonding etc) disadvantage of infants compared to breastfed or breastmilk fed infants with the same health condition.

The ABA recommends that advice be sought from the professional body representing paediatricians in Australia and New Zealand.

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 specified in Q 11 above, infants with identified health conditions should have access to human milk as a first option and if modified formulas are necessary, this should be a prescription item, provided under the health care rebate scheme.

The ABA recommends that advice be sought from the professional body representing paediatricians in Australia and New Zealand.

World Health Organisation and UNICEF (2009) *Acceptable medical reasons for use of breast-milk substitutes* http://whqlibdoc.who.int/hq/2009/WHO_FCH_CAH_09.01_eng.pdf provides relevant reference material.

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?

To maintain an ethical standard, pre market assessments of all infant formula products should require proof of effectiveness in reducing the health (infection, immunological, chronic disease), growth (obesity risk) and development (IQ, bonding, etc) disadvantage of infants compared to breastfed or breastmilk fed infants.

The ABA recommends that advice be sought from the professional body representing paediatricians in Australia and New Zealand.

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 discussed previously there are no health benefits to infant formula. If research and pre-market assessment shows that adding an ingredient will reduce the health risk or deficit of the formula then consideration should be given to adding the ingredient to all infant formulas.

Industry may suggest that it is not possible to conduct expensive effectiveness studies when considering the addition of a new ingredient. However, the committee should be aware that there are currently trials being conducted in Australia by infant formula manufacturers (eg the TRIGR randomised control trial is part of an international study and another on premature formula).

Infants have been seriously harmed by the use of infant formula and some have died from brain damage as a result of the composition of infant formula. The low salt formula used in the 1970s, when salt was considered an unhealthy additive, caused brain damage and deaths and led to the development of the Codex Alimentarius (Codex). In Israel, thiamine deficient formula led to

deaths and brain damage just a few years ago (Remedia). Further to this, it has been reported that Health Ministry Food and Nutrition Service director, Dr. Dorit Nitzan-Kalusky, said that Remedia, an Israel-based food distributor owned by Heinz, 'had not informed the ministry when the formula was changed in April. This change resulted in the powder being produced without a trace of the vital vitamin. Since the company did not ask for approval, the ministry didn't make a special check of the formula.' Most recently, infant formula widely distributed by a trusted manufacturer in China caused severe illness and death for many formula-fed babies.

Whilst the focus of this consultation is on Australia and New Zealand, export practices should also be considered by the committee and regulations should incorporate export practices. Infant formula that does not meet Codex standards (deficient in some minerals) is currently being exported from Australia to developing countries and this should not be permitted.

The highest level of peer-reviewed evidence should be required as a pre-market assessment for any added ingredient with a period of post market surveillance as the minimum consideration before an addition of any ingredient.

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?

Yes. Post-market surveillance should be conducted following the introduction of any new ingredient and in the case of any concern with existing formula being identified (eg in the case of the thiamine deficient formula quoted above).

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

Conditional approvals should not be given even if post-market surveillance is undertaken.

Infants are vulnerable consumers and parents rely on the regulation process to provide a safe food that does not adversely affect their health more than the formulas currently available.

A post-market surveillance without a pre-market assessment could potentially mislead consumers who will presume that additional ingredients have been demonstrated to be safe for infants and young children.

To allow conditional approval for introduction of new ingredients is allowing experimentation on infants and young children.

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

The addition of new ingredients, the removal of existing ingredients and/or a change in the relative composition of ingredients should be considered a major formulation change.

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, they do not. In the absence of effective regulation of the marketing of infant formula products, current standards for infant formula products allow false and misleading advertising of these products in two ways:

- Firstly, the Regulations create ambiguity about the need to comply with consumer law eg the Trade Practices Act on false and misleading advertising, as the Code permits advertising except where it is prohibited.
- Secondly, the Regulations allow the promotion of some products with additives etc based on claims of their efficacy. This means they are marketed to consumers as if they were effective in reducing health risk when there is no evidence that supports this.

It is therefore important that labels on formula products provide full information to consumers on the risks of the product even if used as instructed and on its inferiority compared to human milk.

It should be clear to all parents (including those with low literacy) that replacing breastmilk feeding with formula milk can negatively impact the health of their child.

Under the current advertising arrangements, it is entirely possible for consumers to be misled and think that formula is a health food. It is the responsibility of FSANZ to ensure that the use of formula is minimised and that it is understood that all the sophisticated, scientific production of infant formula does not make it better than the milk of even poorly nourished mothers.

Current labelling warns of adverse consequences if formula is improperly prepared but does not warn that there are adverse consequences even if it is prepared according to instructions. There needs to be such warnings. Without this information parents are unable to make informed decisions about how to feed their baby.

The International Code of Marketing of Breastmilk Substitutes is recognised as being the minimum standard required for ethical marketing of infant formula. The current industry code, MAIF, is ineffective in curtailing the unethical marketing of infant formula; follow-on formulas and toddler milks to parents and health professionals and legislative restrictions are required to address this issue.

As FSANZ is concerned with labelling issues, it should ensure that labelling requirements meet the minimum standards required by the International Code of Marketing of Breastmilk Substitutes and subsequent WHA resolutions to which Australia is a signatory.

The Code prohibits labelling that includes images or text that idealise the use of infant formula.

Australian labelling of infant formula breaches the Code, according to the International Code Documentation Centre (ICDC) which is the organisation delegated by WHO to monitor Code compliance worldwide.

Some examples of breaches include:

- Use of scientific and pseudo-scientific terms like ‘bio factors’; ‘opti-pro’; ‘bio-factors system’; ‘NDP System’, ‘Alpha-Pro’; ‘Nucleotides’; ‘Casein-dominant’; ‘Bifidus BL’; ‘Omega 3 DHA’. The ‘scientification’ of infant formula is a proven effective marketing tool.
- Images — cuddly toy images; cute little booties; use of a shield of protection.
- General terms — ‘caring’; ‘protect’; ‘support’; ‘premium’; ‘nurture’; ‘Nourishment, Protect; Development’; ‘Advanced’; ‘nutritious’; ‘trusted for generations of mums’; ‘gentle’.
- Gold labelling; ‘gold’ in the name; gold bows gives the impression that the product is ‘as good as gold’ (valuable, reliable, highly prized).
- Functional claims that parents would consider to be health claims eg: ‘helps support immunity’; ‘helps support growth’; ‘helps support brain and eye development’; ‘easily digested’; ‘healthy digestive system’.
- The labelling of products with helpline numbers that solicit contact with parents. For example, ‘Wyeth Nutrition Careline — with you at every step’.

FSANZ should require companies to have labelling consistent with the Code which we reiterate is the *minimum standard of ethical marketing*.

Based on advertising claims and social influences, parents often chose to add infant formula to their baby’s diet without realising that the introduction of infant formula to an exclusively breastfed baby is a health risk.

This risk is a result of altered gut flora and pH levels which promote the growth of pathogens that predispose infants to infection. For mothers who are breastfeeding, the introduction of formula products also reduces the quantity of human milk and therefore the protective passive and active components of breastmilk which again, makes infants more vulnerable to infection. Furthermore, the introduction of infant formula products into the diet of a breastfed child is associated with shortened breastfeeding duration.

Gutierrez-Castrellon, P., I. Mora-Magana, et al. (2007). ‘Immune response to nucleotide-supplemented infant formulae: systematic review and meta-analysis.’ British Journal of Nutrition 98 Suppl 1: S64-7.

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

Recent COAG policy regarding early childhood development and breastfeeding promotion, and the National Breastfeeding Strategy (Australia) contain policy options that have not been considered here.

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.

The costs of regulation to industry, government and consumers need to be balanced against the costs of not regulating - to infants, families, the community and health system. This includes the costs to the health system in increased hospitalisation and treatment as a result of the health detriments associated with formula feeding. Data on this was outlined in our response to Question 3.

In conducting a cost-benefit evaluation of policy options it is also essential to include all parties and all costs, reflecting that it is about the distribution of costs within stakeholders — and these extend beyond the industry and government regulators — and not just the level of immediate cost and resource usage.

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

Option one, ensuring that new ingredients are evaluated in a real life setting, is the safest for infants, which should be our primary consideration. However, the reference to health benefit comparing to breastfeeding or breastmilk should not be used – rather reduced risk.

We support the need for pre-marketing assessment and post-market surveillance in measuring effectiveness. The latter is particularly important in identifying adverse effects of new or substituted components, as in the Chinese formula scandal of 2008, and in industry marketing practices.

Reference to industry disincentives based on loss of financial incentive to develop new formulations ignores the substantial amount of money spent on product advertising.

Properly regulated and monitored, this option would save time when moving through regulatory stages as it will eliminate unnecessary additions and marketing or cost-driven changes to the content of infant formulas. It would provide for improvements when a demonstrated improved outcome for formula fed infants is identified; and reduce investment in adding ingredients that are not proven to reduce the health deficits of formula fed infants.

It is acknowledged that Option 1 may increase the pre-market assessment burden on FSANZ and increase post-market surveillance. The cost-benefit analysis must take into account the risks and burdens of not ensuring optimal safety and public health – and include the medium and longer-term costs to the health and social welfare system associated with reductions in breastfeeding. Greater attention must be given to the International Code of Marketing of Breast-milk Substitutes.

Ethical considerations should over-ride commercial considerations when regulating the food for infants and young children - our most vulnerable consumers.

Comments should be provided by **1 September 2009 (NB Extension Granted)**

Submissions – Infant Formula Products

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Would you like to receive future information about food regulatory issues?

Yes, please.

If so, please indicate your main areas of interest and provide your e-mail address in your submission.

Infant and toddler formula, milks and foods.