IBFAN / IACFO COMMENT on the PROPOSAL TO REVIEW THE CODEX STANDARD FOR FOLLOW-UP FORMULA (CODEX STAN 156-1987)  
BACKGROUND PAPER prepared by New Zealand

GENERAL COMMENTS:

1. The rationale for a revised separate standard gives disproportionate emphasis to the need to facilitate trade and is based on projections of maintained and increased consumption of follow-up formula (FUF) and growing up milk (GUM). No health argument is given other than the need to address composition. Reports from New Zealand and Ireland confirm the importance of exports of formulas as a “huge opportunity.” ¹

2. IBFAN believes that there is no nutritional need for formulas to be marketed especially for older babies, so no need for a separate standard which would legitimise a whole range of unnecessary and expensive products.² The marketing and composition requirements of existing products can more safely be accommodated as a footnote in the infant formula standard.

3. As the background paper points out, the Codex standard is certainly out of date. However there is no evidence that the composition of milks for older babies and young children should be different from infant formulas and no evidence that the products currently on the market provide any additional nutritional value to infant formula which is suitable for infants up to 12 months and beyond. The Codex Infant Formula Standard already permits a wide compositional range of nutrients that meet the requirement for formulas for older infants and young children.³ Recent studies indicate that infants with high iron levels at 6 months, who

¹ Radio New Zealand report: Processed foods key to NZ earnings rise – 29.10.2010. A report, commissioned by the Economic Development Ministry, says New Zealand will need to double the value of its exports if it’s to reach the Government’s goal of lifting per capita GDP by more than 60% in 15 years, to catch up with Australia. It says a key to that is processing more farm products into added value foods before they’re exported. The report, from Coriolis Research, focuses on Australia as New Zealand’s biggest export market, and analyses the potential for increasing returns from processed foods such as infant formula.

² Economic Development Minister Gerry Brownlee says a kilo of infant formula is worth ten times the value of a kilo of milk powder, so it’s obvious which product New Zealand should be selling. The report says New Zealand earned more than $750 million from milk formula exports last year - three quarters of the value of wine exports - and suggests there's the potential for New Zealand to export five times as much infant formula as it does now. Chinese interests seeking to buy the Craflar farms want to import formula here for export to China. The Synlait-Chinese joint venture in Canterbury will also be processing infant formula for that market. http://www.radionz.co.nz/news/rural/60638/processed-foods-key-to-nz-earnings-rise-report

³ A survey by the German consumer centres on the products being sold as “Kindermilch” ("milk for children") targeting the age from 12 months found that Kindermilch was up to four times more expensive than normal milk, costing parents up to 245 euros more each year. http://www.vzhh.de/ernaehrung/129727/kostenfalle-kindermilch.aspx
were fed iron-fortified formulas were shown to have IQ levels 10 points lower at the age of 10 years than infants who had low-iron levels. 4

4. Having a separate standard increases the likelihood that the marketing of these products will be less strictly regulated than infant formula. The aggressive promotion of these products, which often share brand and logos with infant formulas, exacerbates nutrition problems and runs counter to national health and nutrition policies. No health argument has been made to have a separate standard for these products. 5

5. FUFs and GUMs currently contain high levels of sugar, often twice as much as normal cow’s milk, increasing the risk of obesity. 6

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4 Iron-Fortified vs Low-Iron Infant Formula Developmental Outcome at 10 Years Betsy Lozoff, MD; Marcela Castillo, PhD; Katy M. Clark, MA; Julia B. Smith, EdD Arch Pediatr Adolesc Med. Published online November 7, 2011.

Infant Milks in the UK. Caroline Walker Trust “Growing-up milks are aimed at young children, who should be obtaining the majority of their nutrients from the food that they eat. It is generally recommended that toddlers eat a good variety of foods to supply the majority of their nutrients, rather than relying on fortified milk products to supply them. Current UK infant feeding guidelines recommend that the weaning diet should include iron-rich foods, that exclusive breastfeeding should continue for at least 6 months and that the introduction of cow’s milk, which has a lower iron content than breast milk, should be postponed until 12 months of age. There is some evidence that high iron intakes among iron-replete toddlers may actually have an adverse affect on growth (Ojardinata et al, 1994) and a large trial of nearly 500 infants and toddlers given follow-on formula between 9-18 months of age in the UK found that there were no developmental or growth advantages in children given iron-supplemented follow-on formula (Morley et al, 1999). “Increasing the iron content of follow-on formula beyond that typically found in first formula has only a limited effect on increasing the net amount of iron absorbed, and it is generally agreed that follow-on formula offers no advantage over standard infant formula after the age of 6 months (May, 2000) 2011 “There is some evidence that excess iron intakes may result in a reduced uptake of other trace metals including copper and oxidation of lipids, due to the pro-oxidant effects of excess iron (Aggett et al, 2002b)

5 UK Scientific Advisory Committee on Nutrition (SACN) 2007 review of infant feeding states “There is no published evidence that the use of any follow-on formula offers any nutritional or health advantage over the use of whey-based infant formula among infants artificially fed” (SACN, 2007). For this reason follow-on formula are not included in the UK Healthy Start Scheme.


UK Independent Review Panel Report on the controls on the marketing of formulas (Feb 2010 ) included a report by Department of Health, 2005 Attitudes to Feeding Report of Survey Findings. “In 2005 the Department of Health commissioned NOP World to carry out a survey of pregnant women and those mothers with a child under one year of age to explore their perceptions and understanding of infant formula and follow-on formula.” The outcome of that survey showed that of 67 per cent of women surveyed who had seen advertising for formula on television and in magazines, about 39 per cent stated this was infant formula advertising, which is prohibited in the UK, and around the same number - 38 per cent - said it was advertising for follow-on formula. 4 out of 10 women who are aware of both [Infant formula and Follow On formula] think there is no difference between them or don't know if there is a difference. 11 per cent of mothers reported giving babies under six months of age follow-on formula (BMRR Social Research, 2005) www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4118853 Also included was research by commissioned by the National Childhood Trust (NCT) and UNICEF in 2005 showing that 60 per cent of the sample reported having seen infant formula advertising (which is banned in the UK) indicating that parents were not clear about the difference between infant formula and follow-on formula. (NCT/UNICEF, 2005). The Baby Feeding Law Group (BFLG) provided evidence of marketing strategies in the UK in 2006, which undermined breastfeeding and research from Canada and Austria, suggesting that some infants under six months are being fed follow-on formula in those countries. Research from the United States also indicated that the marketing of formula can affect breastfeeding rates and/or duration. An opinion from the Institute of Advertising Practitioners in Ireland, showed that the advertising of follow-on milk, increased both its brand share and contributed to growth in the total formula market. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_113825


6 Infant Milks in the UK. Caroline Walker Trust The change from infant formula to cows’ milk involves a taste transition for infants who should become accustomed to a less sweet taste in their main milk drink. Growing-up milks contain almost twice as much sugar per 100ml as cows’ milk. Given that the development of taste preference is influenced by both genetic factors and experience, parents can influence their children’s taste preferences through the food choices they make for them (Savage et al, 2007; Benton, 2004). It is unclear whether repeated exposure to sweet drinks in infancy and toddlerhood might contribute to the
6. Global policy setting for foods for infants and young children must prioritize optimal health outcomes for infants and young children, and the recommendations of the World Health Assembly and UNICEF should be the overarching guiding principles in this area. The majority of governments all recommend, as an essential priority intervention, the protection of exclusive breastfeeding for the first six months and sustained breastfeeding thereafter with the gradual introduction of complementary foods to two years and beyond. 7

7. Increased trade, marketing and availability of such unnecessary products, threaten sustained breastfeeding and increase health risks associated with formula feeding, compromising optimum infant and young child feeding practices. FUFs when marketed as suitable for use with bottles can compromise oral health and facial development. 8

8. The Hygienic Code of Practice for Powdered Follow-up Formula permits a higher tolerance level for Salmonella and Chronobacter sakazakii contaminants, increasing risk of illness from these pathogenic bacteria. The FAO/WHO reports on the E sakazakii note that there are virtually no production differences between powdered infant formula and powdered follow-up formula and notes: “Thus, in reality, there is not adequate data available to make a comparison between PIF and FUF in terms of microbiological quality. This ultimately means that any assessment of the impact of microbiological criteria on the prevalence of contaminated FUF in the market place and ultimately the risk of illness associated with this product is going to be based on a set of assumptions regarding the levels of contamination….E. sakazakii (Cronobacter spp.) infection is a notifiable condition in two countries, and invasive E. sakazakii (Cronobacter spp.) disease is notifiable using a mandatory, passive system in another country and one state in the USA. Such a limited number of systems cannot be expected to provide an overview of E. sakazakii (Cronobacter spp.) disease from the global perspective….Most E. sakazakii (Cronobacter spp.) infections were identified by hospital outbreak investigations or voluntary passive reporting. Thus it can be concluded that existing surveillance systems may not be capturing potential cases.” 9

**COMMENTS ON THE DOCUMENT:**

**1. INTRODUCTION**

In the introduction of the Background paper, the assumption is made that a decision to revise the standard has already been made by the Committee.

“At the 32nd session of the CCNFSDU, it was agreed that the New Zealand Delegation would prepare a discussion document on the revision of all or part of the Standard for Follow-up Formula (CODEX STAN 156-1987),”

This does not accurately reflect the conclusions of the Committee: The CCNFSDU 2010 report notes: “Standard for Follow-up formula 125. The Delegation of New Zealand proposed to prepare a discussion document for the Committee to consider the revision of part or all of the Standard for Follow-up Formula (CODEX STAN 156-1987). The Committee agreed with this proposal. “ (IBFAN emphasis).

devlopment of a preference for sweet drinks in later life. Growing-up milks are also typically lower in calcium than cows’ milk.


Political declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases September 2011 43 (i) Promote, protect and support breastfeeding, including exclusive breastfeeding for about six months from birth, as appropriate, as breastfeeding reduces susceptibility to infections and the risk of undernutrition, promotes infant and young children’s growth and development and helps to reduce the risk of developing conditions such as obesity and non-communicable diseases later in life, and, in this regard, strengthen the implementation of the international code of marketing of breast milk substitutes and subsequent relevant World Health Assembly resolutions;


9 FAO WHO. Enterobacter sakazakii (Cronobacter spp.) in powdered follow-up formulae. MEETING REPORT, Oct.08
The CCNFSDU has not yet reached consensus on whether to proceed with a revision.

Only two options are proposed: to retain the existing standard or to proceed with a review. The Appendix jumps to the proposals for a “limited review” or a “full review,” assuming that the committee will proceed with a review of some sort. No option is given to declare the Standard obsolete, or to provide the simple solution that existing products could be accommodated in the infant formula standard, simply stating that all formulas for older babies and young children must meet the compositional and marketing requirements for infant formula.

2 BACKGROUND

The Background paper notes the increasing consumption of follow-up formulas in particular across Asia, noting increasing markets and consumption of infant formula, “it is developing countries within the Asian region that have some of the highest reported levels of consumption of follow-up formula and growing up milk products”. The rationale for the revision assumes the need to have a harmonized Codex Standard in order to facilitate trade. No concern is expressed regarding the need to protect health or support national nutrition policies, nor is there any acknowledgement that these products undermine and replace breastfeeding and can impact negatively on the health, growth and development of children. Increase in consumption is seen purely as a market advantage.

3. RATIONALE FOR ASPECTS TO BE COVERED

The age range for follow-up formula and the starting age for follow-up formula and growing up milks

While the Background paper refers to the fact that the majority of countries use 6 months as the appropriate ‘starting age’ for FUF, it also refers to the 2009 EFSA Scientific Opinion that 4-6 months may be ‘safe.’

The EFSA opinion is illogical and contradictory. If "full breast feeding for up to 6 months provides greater protection than partial breast feeding or shorter breast feeding against the risk of infectious morbidity" it is illogical to state that "the introduction of complementary food...between the age of 4 and 6 months is safe and does not pose a risk for adverse health effects..." If foods are started 4-6 months, breastfeeding cannot be full or exclusive for 6 months so babies are put at unnecessary risk of increased morbidity. A nationally representative study in the USA in 2006 documented that children who received only breastmilk for the first 6 months as recommended had fewer chest and ear infections than those breastfed for shorter periods, supporting the current recommendations in the USA that infants receive only breast milk for the first 6 months of life.

Impact on public health recommendations: EFSA has failed to consider the issue of developmental readiness, or the wider issue of how public health recommendations are interpreted. Before the UK adopted the WHO 6 month recommendation, the 5-yearly UK Infant Feeding Surveys shows that most babies were given solids far too early, before 4 months.(6) The message to start solids from 6 months led to a postponement until the 4-5 months, an important behavioural shift in public health terms. The proportion of mothers introducing solid foods by 4 months fell from 85% in 2000 to 51% in 2005. The proportion introducing by 3 months halved in that five years, from about 23% to 10%. (6) If the EFSA opinion is used to inform policy one can expect a reversal of this positive trend.

Over-emphasis on Coeliac Disease. The studies used by EFSA regarding the age of introduction of gluten use at risk populations, but give no convincing argument for introducing solids to breastfed babies between 4-6 months rather than after six months. A much more important factor in reducing the incidence of Coeliac Disease seems to be the continuation of breastfeeding alongside the introduction of gluten.


The Background Report also highlights that the WHO Expert consultation the WHO recommendation for exclusive breastfeeding for the first six months “can lead to iron deficiency in susceptible infants” and that “available data are insufficient to exclude several micronutrient deficiencies in some infants.”

It has to be remembered that the WHO recommendation, like Codex Standards are global – not individual. So it is inappropriate and irrelevant to refer to individual nutritional problems.\(^\text{12}\)

The conclusion given that the lack of harmonization in age ranges applied internationally could create a barrier to trade indicates that the rationale for this section is a commercial one, rather than a concern to help Member States take appropriate action to protect child health. Codex needs to send a strong message to Member States that consumer protection is paramount in this area.

3.3 Labelling

3.3.1 Health Claims

The background paper acknowledges that health claims are a “contentious issue” citing a web-based journal that is part-funded by a DHA manufacturer. The paper gives an uncritical report on the controversial EU Decision to allow a health claim linking consumption of DHA in formulas and baby food with improved vision. No mention is made of the widespread concern about this claim, and the majority vote in the European Parliament to block it, or the fact that there was no evidence to support this claim in follow-on formulas.\(^\text{15}\)

In April 2011 WHO wrote to Glenis Willmot, the MEP leading the Parliamentary debate, saying: “WHO does not have a recommendation about the addition of docosahexaenoic acid (DHA) to formula milk….to date no solid evidence exists to be able to say that adding DHA to infant formula will have important clinical benefits. Were WHO to give such a recommendation, it would have to follow a strict guideline development process based on grading of all available evidence collected through systematic reviews by expert panels free from conflict of interest.”

The European Food Safety Authority (EFSA), which evaluated the evidence for this particular health claim, is not required to look at independently-funded research\(^\text{7}\) and the EFSA opinions on which the claim is based, state that EFSA could not have reached its conclusion on the DHA claim “without considering the studies claimed by the applicant as proprietary.”\(^\text{6}\)

In a letter to the European Commission 2009, EFSA also stated that there is no sound evidence to support the claim for follow-on formulas or baby foods: “The evidence, however, does not establish that starting DHA supplementation at 4-6 months in infants who had received a control (DHA-free)

\(^\text{12}\) The Caroline Walker Trust Report, Infant Milks in the UK. 2011 “increasing the iron content of follow-on formula beyond that typically found in first formula has only a limited effect on increasing the net amount of iron absorbed…”There is also some evidence that excessive iron intakes may result in a reduced uptake of other trace metals including copper and oxidation of lipids, due to the pro-oxidant effects of excess iron (Aggett et al, 2002b).

\(^\text{15}\) Baby milk claim approved - despite majority of MEPs against - 2011-04-06 http://www.eurolabour.org.uk/Baby_milk_claim_approved_-_despite_majority_of_MEPs_against European Parliament votes to block DHA health claim - but not by a large enough majority to guarantee action by the Commission http://info.babymilkaction.org/pressrelease/pressrelease06apr11

Although true for breastmilk, there is no consistent peer-reviewed independent evidence of a causal relationship between DHA-fortified formulas and better visual acuity in term babies. The 2007 Cochrane Library concluded: “This review found that feeding term infants with milk formula enriched with LCPUFA had no proven benefit regarding vision, cognition or physical growth.” Simmer K, Patole S, Rao SC. Longchain polyunsaturated fatty acid supplementation in infants born at term. Cochrane Database of Systematic Reviews 2008, issue 1. Art. No.: CD000376. DOI: 10.1002/14651858.CD000376.pub2 www2.cochrane.org/reviews/en/ab000376.html

Researcher Dr. Mijna Hadders-Algra, Professor of Developmental Neurology, is conducting a long-term follow-up study of children who were either breastfed or fed on DHA (with AHA) or no-DHA supplemented formula. She warned MEPs that the DHA claim is not supported by the body of scientific research and that there is evidence of minor long-term negative impacts. She explained: “Breastmilk contains DHA, but this does not imply if we supply infants with DHA in an artificial dosage that this will promote health or development. What we learned from our studies is that it is the balance between fatty acids which plays a prominent role. Supplying one, may have a negative impact on other fatty acids with net negative effect. Breastmilk most likely contains the adequate balances, suggesting that nature knows how to handle this.”
formula in the first months of life would have an effect on the visual development of those children... There are no data from specific randomised control trials supporting a benefit of DHA supplementation starting at 6 months of life in infants fed a DHA-free formula in the first 6 months of life....”

In 2007 the UK Scientific Advisory Committee on Nutrition said: “We find the case for labelling infant formula or follow on formula with health or nutrition claims entirely unsupportable. If an ingredient is unequivocally beneficial as demonstrated by independent review of scientific data it would be unethical to withhold it for commercial reasons. Rather it should be made a required ingredient of infant formula in order to reduce existing risks associated with artificial feeding.”

IBFAN supports this position and is opposed to all nutrition and health claims for foods for infants and young children. The marketing of FUMs and GUMs increases the chances of parents being mislead by health and nutrition claims, since the compositional requirements for these products allow manufacturers to add optional ingredients, which increases the use of claims.

3.3.2 The International Code:

The Background paper refers only briefly to the WHA Resolution 39.28 [1986] which states that “the practice being introduced in some countries of providing infants with specially formulated milks (so called ‘follow-up milks’) is not necessary”. This important Resolution should be the over-arching principle that should guide policy in this area.

There no mention of the WHA 63:23(4) which calls on Member States “to end inappropriate promotion of food for infants and young children, and to ensure that nutrition and health claims shall not be permitted for foods for infants and young children, except where specifically provided for in relevant Codex Alimentarius standards or national legislation”

Instead of highlighting the above, the background paper selectively quotes from a document that has no official status or reference number. It appeared for a while on the WHO website and is quoted extensively by the baby food industry to support the misleading notion that follow-on milks do not fall within the scope of the International Code. The Report fails to mention that the paper has been removed from the WHO website. It is irrelevant to the discussion in hand and misleading to quote from it in this context.

As UNICEF explained in its statement to the European Parliament Development and Co-operation Committee in November 2000.14

“The Code applies to ALL BREASTMILK SUBSTITUTE and related products, which include feeding bottles and teats. The Code is not limited to basic infant formula intended for healthy babies born after nine months of gestation and with adequate weight and length for age as many companies would argue. The Code covers special formulae such as those for premature infants, hypoallergenic formulae, lactose free formulae and follow-on formulae (ref 4). It also covers waters, juices, teas, and foods if marketed or in any other way represented as a partial or total replacement for breastmilk. These two principles, universality and the scope including all breastmilk substitutes, cannot be over emphasised given the tendency of the infant feeding industry to attempt to limit the application of the Code.”

14 http://www.babymilkaction.org/press/press23nov00unicef.html

The definition of ‘breastmilk substitute’ in the International Code refers to “any food being marketed or otherwise represented as a partial or total replacement for breast milk, whether or not suitable for that purpose.” The scope attempts to cover all foods targeted at infants and young children and covers far more than infant formula: “The Code applies to the marketing, and practices related thereto, of the following products: breastmilk substitutes, including infant formula; other milk products, foods and beverages, including bottle-fed complementary foods, when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breast-milk; feeding bottles and teats. It also applies to their quality and availability, and to information concerning their use.”
Historical note: In 1985 the Consumer Committee of the EU Parliament questioned the scientific basis for including compositional requirements for follow-on milks in the proposed Directives saying: “The need of follow-up milks is extremely dubious (page 14) and there is no need whatsoever for a new specially manufactured product.”

The European baby food industry (IDACE) and the Commission ignored these concerns and used a draft Codex standard and the opinion of industry-funded scientists (who in those days did not have to declare their interests) to legitimise these unnecessary products saying: “No scientific references are given to support these statements. In the opinion of the paediatric experts of the SCF a standard is necessary. There are many papers which support this scientific opinion..... it should also be noted that FAO/WHO is also developing a Codex standard for follow-up foods.”

4 Options for the Committee to consider.

Only two options are given, A or B. IBFAN proposes two other options:

1. The CODEX STAN 156-1987 is obsolete.

2. A reference is placed in the Infant Formula Standard CODEX STAN 72 – 1981 that the marketing and compositional requirements of milks for older babies meet the requirements for infant formulas.