

IBFAN urges Codex delegates to support the prohibition on nutrition and health claims for foods for infants and young children

Why Nutrition and Health Claims for Foods for Infants and Young Children should be not be permitted

The Scope of the **Draft Guidelines for the Use of Nutrition and Health Claims** at Step 8 for adoption by the Commission includes provision 1.4 which reads:

Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Code standards or national legislation. (our emphasis)

This critical provision is indispensable in order to support optimal infant feeding practices and to ensure the health and well being of infants and young children. Moreover, the prohibition of claims for these foods brings the standard into conformity with the recommendations of the World Health Organization designed to protect the best possible infant and young child feeding practices.

The World Health Organization recommends that parents exclusively breastfeed their children for the first six months of life. Locally available, nutritious complementary foods can be introduced at six months with continued breastfeeding to two years and beyond (WHA Resolution 54.2).

As well the Convention on the Rights of the Child, the most ratified UN convention to date, obliges *State Parties to recognize the right of the child to the enjoyment of the highest attainable standard of health*. This right is exercised through the protection and support of breastfeeding.

1. Nutrition and health claims are not necessary for infant foods

Nutrition and health claims are intended to persuade parents to purchase infant formulas and infant foods on the basis of claims of enhanced nutrition and health benefits associated with the products. However these so-called enhanced benefits are not made in comparison with infants who are optimally fed according to the recommendations of the World Health Organization, but to some other inferior form of infant feeding, such as whole cow's milk or other formulations and the early introduction of complementary foods. Nutrition content and purpose information may be beneficial in some limited cases where these products are medically indicated, for example, when infants diagnosed with PKU or galactosemia need specialized formulas. However for the majority of parents, breastfeeding must be protected as the normal means to feed infants. Commercial complementary foods are an unnecessary expense and inferior in nutritional composition (except for fortified ingredients) in comparison to home prepared foods. Specialized formulas should only be used when medically prescribed and information about their composition and use should be scientific and factual, not promotional. Thus, there is no place for commercial

intervention in the vital process of supporting parents to feed their infants according to WHO recommendations.

2. Nutrition and health claims for infant formulas are by nature misleading

The scope of **Draft Guidelines for Use of Nutrition and Health Claims** requires claims to be “truthful” and “non-misleading”. For infant formulas, any statement to claim nutritional superiority or equivalency or health benefits is non-truthful. Current scientific evidence confirms increased mortality rates and increased rates for illnesses such as infectious diseases, chronic diseases, autoimmune diseases and less than optimal development and growth such as lower cognitive and visual development and increased risk for obesity. To be truthful to parents, these products should be labelled instead with warnings about increased health risks rather than misleading them to think there are health benefits.

3. The scientific evidence used to justify nutrition and health claims is not independent

When investigating the evidence to determine the truthfulness of claims, INFACT Canada found that:

- authors of “scientific” articles were frequently paid by the manufacturer of the product to do the research,
- authors were employees of the manufacturer,
- the articles did not study the specific brand product for which the claims were made,
- the scientific evidence was not published in peer review journals,
- the “evidence” was available in abstract format only. As well,
- frequently the claims were in contradiction with generally accepted scientific evidence.

4. Nutrition and health claims are comparisons that give the impression they are like breastmilk

Certain products claim that they are “higher” in a certain ingredient or effect, “improved” through compositional tinkering, “superior” to another product, “closer to” the real thing or “easier to” etc. In the case of infant foods the implication and impression that these superlatives make is that the product is as good as or perhaps even better than breastmilk. When a label claims the product to be “easier to digest” the comparison is not completed and the impression left is that the product is as good as breastmilk. When the advertisement accompanying the label reads, “proven to result in higher early mental development scores”, the impression is made that using this formula will result in smarter babies. When the comparison is not made to the norm, which is the breastfed baby, but to an inferior product such other formulas, the effect is misleading.

5. Nutrition and health claims are marketing tools.

Nutrition and health claims are intended to create a perceived advantage over competing products - especially breastmilk. Infant formula promotions using nutrition and health claims are aimed at the breastfeeding mother. Surveys and analysis of the impact of formula marketing have noted that the breastfeeding mother is the primary target. In countries where marketing restrictions for the industry are lax, there is massive abuse of the use of claims that have no scientific substantiation. In effect, claims glamourize a product that results in over 1.5 million deaths annually because

infants were not breastfed. Many millions more are malnourished and ill because they are fed breastmilk substitutes.

6. Nutrition and health claims are a contravention of the International Code of Marketing of Breastmilk Substitutes

Article 9 of the International Code (WHA 39.22) requires manufacturers and distributors to label as follows:

Neither the container nor the label should have pictures of infants, nor should they have other pictures or text which may idealise the use of infant formula. They may, however, have graphics for easy identification of the product as a breastmilk substitute and for illustrating methods of preparation. The terms "humanised", "maternalised" or similar terms should not be used.

Additionally WHA Resolution 54.2 preamble also reminds Member States to be:

*...conscious of the need for the Code Alimentarius Commission to take the International Code and subsequent relevant Health Assembly Resolutions into consideration in dealing with **health claims** in the development of food standards and guidelines. (our emphasis)*

7. Nutrition and health claims are in conflict with national nutrition policies

The scope of the guidelines for nutrition and health claims requires the claims to be consistent with national nutrition and health policies and where possible to support such policies. It should be noted that without exception, national policies on infant and young child feeding support the goal of breastfeeding as the normal means to feed infants and recognize the health and developmental risks when infants are not breastfed. In over 70 countries policies have been implemented to support the important WHA 54.2 Resolution of exclusive breastfeeding for first six months of life. Nutrition and health claims for infant formulas would interfere with these critical nutrition policies designed to alleviate malnutrition and reduce infant mortality worldwide.

Examples of how nutrition and health claims are used worldwide

[Graphics and text of examples from various countries will be placed here]

Appendix

Risks of formula feeding

A brief annotated bibliography

Increased risk of asthma

A study of 2184 children done by the Hospital for Sick Children in Toronto determined that the risk of asthma and wheezing was approximately 50 per cent higher when infants were formula fed compared to infants who were breastfed for nine months or longer.

Dell S, To T. Breastfeeding and Asthma in Young Children. Arch Pediatr Adolesc Med 155: 1261-1265, 2001

Researchers in West Australia studied 2602 children to determine the development of asthma and wheeze at six years of age. Not breastfeeding increased the risk of asthma and wheeze by 40 per cent compared to infants who were exclusively breastfed for four months. The authors recommend exclusive breastfeeding for at least four months to reduce the risk of asthma.

Oddy WH, Peat JK, de Klerk NH. Maternal asthma, infant feeding, and the risk for asthma in childhood. J. Allergy Clin Immunol. 110: 65-67, 2002

Increased risk of allergy

Children in Finland who had been breastfed the longest had the lowest incidence of atopy, eczema, food allergy and respiratory allergy. At 17 years of age, the incidence of respiratory allergy for those who had little breastfeeding was 65 per cent and for those who were breastfed the longest 42 per cent.

Saarinen UM, Kajosarri M. Breastfeeding as a prophylactic against atopic disease: Prospective follow-up study until 17 years old. Lancet 346: 1065-1069, 1995

A longitudinal prospective study of 1246 healthy infants in Arizona, USA, aimed to determine the relationship between breastfeeding and recurrent wheeze. The results showed that non-atopic children at the age of six years, who had not been breastfed, were three times more likely to have recurrent wheezing.

Wright AL, Holberg CJ, Taussig LM, Martinez FD. Relationship of infant feeding to recurrent wheezing at age 6 years. Arch Pediatr Adolesc Med 149: 758-763, 1995

Reduced cognitive development

A total of 3880 Australian children were followed from birth to determine breastfeeding patterns and later cognitive development. Those breastfed for six months or more had an 8.2 point higher for females and a 5.8 point higher for males in vocabulary tests over those who had never been breastfed.

Quinn PJ, O'Callagan M, Williams GM, Najman JM, Anderson MJ, Bo W. The effect of breastfeeding on child development at 5 years: a cohort study. J Paediatr Child Health 37: 465-469, 2001

To determine the impact of exclusive breastfeeding on cognitive development for infants born small for gestational age, this US based study evaluated 220 infants, using the Bayley Scale of Infant Development at 13 months and the Wechsler Preschool and Primary Scales of Intelligence at five years. The researchers concluded that exclusively breastfed (without supplements) small for gestational age infants had a significant advantage in cognitive development without compromising growth.

Rao MR, Hediger ML, Levine RJ, Naficy AB, Vik T. Effect of breastfeeding on cognitive development of infants born small for gestational age. Arch Pediatr Adolesc 156: 651-655, 2002

The benefits of breastfeeding have long term potential on a person's life through its influence on childhood cognitive and educational development concludes this UK study. Regression analysis was used to determine that breastfeeding was significantly and positively associated with educational levels obtained by age 26 as well as cognitive abilities at age 53 years.

Richards M, Hardy R, Wadsworth ME. Long-term effects of breast-feeding in a national cohort: educational attainment and midlife cognition function. Publ Health Nutr 5: 631-635, 2002

Increased risk of acute respiratory disease

Brazilian children not breastfed were 16.7 times more likely to be diagnosed with pneumonia than children who had received breastmilk only as infants.

Cesar JA, Victora CG, Barros FC, et al. Impact of breastfeeding on admission for pneumonia during postneonatal period in Brazil: Nested case-controlled study. BMJ 318: 1316-1320, 1999

To determine the modifiable risk factors for acute lower respiratory infection in young children, this Indian hospital based study compared 201 cases to 311 controls. Lack of breastfeeding was one of the key modifiable risk factors for lower respiratory infection in children under five years of age.

Broor S, Pandey RM, Ghosh M, Maitreyi RS, Lodha R, Singhal T, Kabra SK. Risk factors for severe acute lower respiratory tract infection in under-five children. Indian Pediatr 38: 1361-1369, 2001

Increased risk for infection from contaminated formula

Case report from a recent US based outbreak of *Enterobacter sakazakii* in a neonatal intensive care unit documents the death of a 20 day old infant who developed fever, tachycardia, decreased vascular perfusions and seizures at 11 days. The infant died at day 20. *E. sakazakii* cultures were identified from the spinal fluid and traced to contaminated powdered infant formula used in the NICU.

Weir E, Powdered infant formula and fatal infection with Enterobacter sakazakii. CMAJ 166, 2002

A Belgian based outbreak of necrotizing enterocolitis (NEC) is traced back to infant formula contaminated with *Enterobacter sakazakii*. A total of 12 infants developed NEC during the outbreak and two infants (twin brothers) died.

Van Acker J, de Smet F, Muyltermans G, Bougatef A, Naessens A, Lauwers S. Outbreak of necrotizing enterocolitis associated with Enterobacter sakazakii in powdered infant formulas. J Clin Microbiol 39: 293-297, 2001

Increased risk of childhood cancers

The UK Childhood Cancer Study analyzed 3500 childhood cancer cases and the relationship to breastfeeding. Results showed a small reduction for leukemia and for all cancers combined when infants had “ever been breastfed”.

*UK Childhood Cancer Investigators. Breastfeeding and Childhood Cancer. *Br J Cancer* 85: 1685-1694, 2001*

A case controlled study, in the United Arab Emirates looked at 117 cases of acute lymphocytic leukemia and 117 controls. They found that the breastfeeding duration of those with leukemia was significantly shorter than the breastfeeding duration of the controls. They concluded that breastfeeding duration of six months or longer may protect against childhood acute leukaemia and lymphomas.

*Bener A, Denic S, Galadari S. Longer breast-feeding and protection against childhood leukaemia and lymphomas. *Eur J Cancer* 37: 234-238, 2001*

Increased risk of chronic diseases

A review of infant feeding practices and childhood chronic diseases shows increased risk for Type I diabetes, celiac disease, some childhood cancers, and inflammatory bowel disease associated with artificial infant feeding.

*Davis MK Breastfeeding and chronic diseases in childhood and adolescence. *Pediatr Clin North Amer* 48: 125-141, 2001*

Celiac disease may be triggered by an autoimmune response when an infant is exposed to a food containing gluten proteins. In order to investigate the impact of breastfeeding on this response, Ivarsson and her team of researchers looked at the breastfeeding patterns of 627 children with celiac disease and at 1254 healthy children to determine the effect of breastfeeding during the time of introduction of gluten containing foods on the outcome of the development of celiac disease.

An astounding 40 per cent risk reduction was reported for the development of celiac disease in children at two years of age or younger for those who were breastfed when dietary gluten was introduced. And the effect was even more pronounced in infants who continued to be breastfed after dietary gluten was introduced, the authors noted.

*Ivarsson, A. et al. Breast-Feeding May Protect Against Celiac Disease *Am J Clin Nutr* 75:914-21, 2002*

Increased risk of diabetes

To determine the link between cow's milk consumption (cow's milk based infant formula) and the development of antibody response to cow's milk protein, Italian researchers measured the antibody response of 16 breastfed and 12 cow's milk fed infants under four months of age. Cow's milk fed infants had elevated levels of beta-casein antibodies when compared to breastfed infants. They concluded that breastfeeding for the first four months prevented the production of antibodies and could have a preventive effect on the development of Type 1 diabetes.

Monetini L, Cavallo MG, Stefanini L, Ferrazzoli F, Bizzarri C, Marietti G, Curro V, Cervoni M, Pozzilli P, IMDIAB Group. Bovine beta-casein antibodies in breast-and bottle-fed infants: their relevance in Type 1 diabetes. *Hormone Metab Res* 34: 455-459, 2002

In this case-controlled study of 46 native Canadian Type II diabetes patients were matched with 92 controls. Pre and postnatal risk factors were compared. Breastfeeding was found to reduce the risk of Type II diabetes.

Young TK, Martens PJ, Taback SP, Sellers EA, Dean HJ, Cheang M, Flett B. Type 2 diabetes mellitus in children: prenatal and early infancy risk factors among native Canadians. *Arch Pediatr Adolesc Med* 156: 651-655, 2002

Increased risk of cardiovascular disease

This UK study looked at the cholesterol levels of 1500 - 13 to 16 year olds and determined that breastfeeding may have long term benefits for cardiovascular disease by reducing the total cholesterol and the low-density lipid cholesterol. The research suggests that early exposure to breastmilk may program fat metabolism in later life, resulting in lower blood cholesterol levels and therefore a lower risk of cardiovascular disease.

Owen GC, Whipcup PH, Odoki JA, Cook DG. Infant feeding and blood cholesterol: a study in adolescents and systematic review. *Pediatrics* 110: 597-608, 2002

To confirm links between infant nutrition and health risks in later life, British researchers measured blood pressure at 13 to 16 years of age of 216 children who had been born prematurely. For those who had received preterm infant formula or routine infant formula, blood pressure was higher than for those who had received breastmilk during infancy. The authors concluded that for children born prematurely, breastfeeding lowers blood pressure in later life and that this conclusion can be extended to term infants as well.

Singhal A, Cole TJ, Lucas A. Early nutrition in preterm infants and later blood pressure: two cohorts after randomized trials. *The Lancet* 357: 413-419, 2001

Increased risk of obesity

To determine the impact of infant feeding on childhood obesity, this large Scottish study looked at body-mass index of 32,200 children aged 39 to 42 months. After elimination of confounding factors, socioeconomic status, birthweight and sex, the prevalence of obesity was significantly higher in the formula fed children; leading to the conclusion that formula feeding is associated with an increase in childhood obesity risk.

Armstrong, J. et al. Breastfeeding and lowering the risk of childhood obesity. *Lancet* 359:2003-04, 2002

German researchers collected height and weight data of 9375 school children to determine the impact of early childhood feeding on the development of obesity. The prevalence of obesity was found to be 4.5 per cent – nearly 40 per cent higher - in those who had never been breastfed compared to 2.8 per cent for those who had been exclusively breastfed.

Von Kries R. Breastfeeding and obesity: cross sectional study. BMJ 319: 147-150, 1999

Increased risk of gastrointestinal infections

A comparison between infants who received primarily breastmilk during the first 12 months of life to infants who were exclusively formula-fed or who were breastfed for three months or less found that diarrheal disease was twice as high for the formula-fed infants then for those who were breastfed.

Dewey KG, Heinig MJ, Nommsen-Rivers LA. Differences in morbidity between breast-fed and formula-fed infants. J Pediatr 126: 696-702, 1995

Breastfeeding promotion in Belarus significantly reduced the incidence of gastrointestinal infections by 40 per cent.

Kramer MS, Chalmers B, Hodnett ED, et al. Promotion of Breastfeeding Intervention Trial (PROBIT): A randomized trial in the Republic of Belarus. JAMA 285: 413-420, 2001

Increased risk of mortality

Compared with exclusive breastfeeding, children who were partially breastfed had a 4.2 times increased risk of death due to diarrheal disease. No breastfeeding was associated with a 14.2 times increased risk for death due to diarrheal disease in Brazilian children.

Victora CG, Smith PG, Patrick J, et al. Infant feeding and deaths due to diarrhea: A case-controlled study. Amer J Epidemiol 129: 1032-1041, 1989

Infants in Bangladesh who were partially breastfed or not breastfed had a risk of acute respiratory infection death 2.4 times greater than exclusively breastfed infants. If children were predominantly breastfed the risk of death due to acute respiratory infection was similar to that of exclusively breastfed children.

Arifeen S, Black RE, Atbeknab G, Baqui A, Caulfield L, Becker S, Exclusive breastfeeding reduces acute respiratory infection and diarrhea deaths among infants in Dhaka slums. Pediatrics 108: e67, 2001

The authors of this review discuss the impact of breastfeeding on child spacing and estimate that exclusive breastfeeding can lead to decreased mortality of 20 per cent when infants are spaced at least two years apart.

Thapa S, Short RV, Potts M. Breast feeding, birth spacing and their effect on child survival. Nature 335: 679-682, 1988

Increased risk of otitis media and ear infections

The number of episodes of acute otitis media increased significantly with decreased duration of and exclusivity of breastfeeding. US Infants who were exclusively breastfed for four months or more had a 50 per cent reduction of episodes compared to infants who were not breastfed. A 40 per cent reduction of episodes was reported for breastfeeding infants who were supplemented before four months of age.

Duncan B, Ey J, Holberg CJ, Wright AL, Martines F, Taussig LM. Exclusive breastfeeding for at least 4 months protects against otitis media. Pediatrics 91: 867-872, 1993

Between six and 12 months of age the incidence of first episodes of otitis media increased from 25 per cent to 51 per cent in infants exclusively breastfed. In infants that were exclusively formula fed the incidence rose from 54 per cent to 76 per cent during the second half of the first year. The authors concluded that breastfeeding even for a short period (three months) would significantly reduce the episodes of otitis media during infancy.

Duffy LC, Faden H, Wasielewski R, Wolf J, Krystofik D. Exclusive breastfeeding protects against bacterial colonization and day care exposure to otitis media. Pediatrics 100: E7, 1997

Increased risk of side effects of environmental contaminants

A Dutch study showed that at six years of age, cognitive development is affected by prenatal exposure to PCBs and dioxins. An adverse effect of prenatal exposure on neurological outcome was also demonstrated in the formula fed group but not in the breastfed group. Despite higher PCB exposures from breast milk, the study found at 18 months, 42 months of age, and at six years of age a beneficial effect of breast feeding on the quality of movements, in terms of fluency, and in cognitive development tests.

The data that gives evidence that prenatal exposure to PCBs do have subtle negative effects on neurological and cognitive development of the child up to school age. The study also gives evidence that breastfeeding counteracts the adverse developmental effects of PCBs and dioxins.

Boersma ER, Lanting CI. Environmental exposure to polychlorinated biphenyls (PCBs) and dioxins. Consequences for longterm neurological and cognitive development of the child. Adv Exp Med Biol 478:271-87, 2000

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