Standards for infant formula milk

Commercial interests may be the strongest driver of what goes into formula milk

The quality of infant feeding is of paramount importance for growth, development, and long term health well into adulthood.[1] Breast feeding is recognised as the ideal form of infant feeding, providing multiple benefits for child health.[2] Thus breast feeding should be actively promoted, protected, and supported. Infants who cannot be fed at the breast, who should not receive breast milk, or for whom breast milk is not available need infant formula milks of high quality.[3]

The Codex Alimentarius Commission, part of both the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization, develops standards, guidelines, and related texts on food to protect consumers' health and to ensure fair trade practices globally. Most of the world's population lives in the more than 160 countries that are members of the Codex Alimentarius. Its standard on infant formula was adopted in 1981, based on scientific knowledge of the 1970s,[4] and it is currently being revised.

At the end of November 2005 the Codex Committee on Nutrition and Foods for Special Dietary Uses met in Bonn, Germany, and discussed among other issues revision of the standard on infant formula. The meeting was attended by government delegations of some 71 member states of the committee, along with observers of 32 international non-governmental organisations, mostly umbrella organisations for food manufacturers and other groups with commercial interests in infant formula.

Infant formula must be the sole source of nutrients for several months during a critical phase of growth

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and development, and thus it must meet very high quality standards. After several years of work on the draft standard for infant formula, the committee had requested from an international group of experts a science based review on the compositional requirements for infant formula to facilitate the process of taking decisions in this area.[5] Two issues arising at the meeting in Bonn showed, however, that scientific and medical arguments may be unduly influenced by commercial considerations.

Three recent scientific reviews on the compositional requirements of infant formula by expert groups reporting to the Food and Drug Administration (FDA) in the United States, the European Commission, and the Codex Alimentarius Commission all agreed that the determination of infant formula protein should be based on total nitrogen content multiplied by a conversion factor of 6.25.[5–7] This nitrogen conversion factor is also used in the new WHO/FAO report on human protein requirements (currently in preparation) for calculating both safe levels of protein intake in infants and human milk protein content, as well as in the Codex guidelines on nutrition labelling.[8]

In Bonn, however, the International Dairy Federation demanded that the proportion of protein in formula derived from cows' milk should be determined with a conversion factor of 6.38—as conventionally used for whole cows' milk and based on data published in 1883[9] —even though modern infant formulas contain modified cows' milk protein fractions for which this factor is not appropriate.[5–7] Moreover, a conversion factor for nitrogen in cows' milk that is higher than that used for human milk proteins would suggest that cows' milk has a greater biological value, which clearly is not the case.

Even though no scientific arguments were put forward to justify the federation's request, it got support from several Codex member states with strong dairy industries. Meanwhile, an internal newsletter of the German dairy industry association, the Milchindustrieverband (www.vdm-deutschland.de), suggested that the application of a nitrogen conversion factor of 6.25 instead of 6.38 for all dairy products would lead to a loss of some €80m (£55m; $96m) for the dairy industry in Europe alone

Another controversial issue was the approach to setting maximum values for nutrients. Maximum values have been proposed for most nutrients in infant formula by all the recent expert consultations in order to provide safe and nutritionally adequate infant formula products meeting the normal nutritional requirements of babies.[5–7] The guiding principle is that infant formulas should contain components only in such amounts that serve a nutritional purpose, provide another benefit, or are necessary for technological reasons. The inclusion of unnecessary components, or unnecessary amounts of components, may put a burden on metabolic and other physiological functions of the infant and will reduce the margin of safety.[5]

These maximum values should be based on available scientific data on infants' requirements and the absence of adverse effects. For example, maximum values for vitamin A were based on scientific risk assessment that took into account the upper safe levels of intake established for infants and young children.[5–7] For some water soluble vitamins acceptable daily intakes for infants and young children have not been established. If these vitamins are supplied in amounts that cannot be used or stored by the body they must be excreted, and excessive intakes will reduce the margin of safety. This is particularly the case under conditions of stress such as during fever or diarrhoea or especially during weight loss. Therefore, the scientific expert report to Codex recommended that contents of water soluble vitamins in infant formulas generally should not exceed five times the minimum level unless there are data to justify other decisions.[5]

Contrary to this strong scientific advice, delegations to the Codex committee from some member states requested that maximum values should be established only for levels of nutrients with documented adverse effects in infants, while in all other cases only interim upper values should be established which would not be binding for manufacturers. Moreover, the US delegation requested that both maximum values and guidance values should not be lower than values used for formulas already on the market, even if such levels have not been subjected to systematic evaluation of their biological effects and safety. The underlying concept that levels of exposure determine safety is unknown in science, be it in toxicology, pharmacology, or nutrition. None the less, the committee has agreed to collect, before its next session in 2006, data on observed high nutrient levels in infant formula in different countries.

The worldwide medical community might question the basis of the decisions of Codex Alimentarius on the global guidelines for infant formula standards and might rise to reject such commercial pressures. Doctors should choose and recommend only those infant formulas with compositions based on current scientific knowledge and on the nutritional requirements of infants.

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