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Original Research Article

Selected vitamins, minerals and fatty acids in infant formulas in the United States

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ABSTRACT

Infant formulas (IF) are consumed during a short but critical growth period and are the sole source of nutrition for at least part of this time for non-breastfed infants. The 1980 Infant Formula Act (IFA) and subsequent legislation mandate fortification of all IF at specific levels of vitamins and minerals; manufacturers must assure these levels in their products. In order to determine the actual amounts of nutrients in IF and to determine how closely these conform to the IFA and labels amounts, fifteen highly consumed milk- or soy-based infant formulas were sampled nationally at 12 retail locations. These IF were analyzed, and thiamin, vitamins C, A, D, E and K, choline, calcium, iron, and arachidonic, docosohexanoic and linoleic acids values examined. Within analytical uncertainty, all IFs except linoleic acid in one formula met label claim and were within allowed ranges. These results suggest IFs provide nutrition at the level of the label or more. For some vitamins, there was substantially more present in the formula than the label amount, e.g. vitamin C, 25 ± 16 vs. 8 mg per 100 kcal (n = 20), but the variability among brands was high. These data help researchers and consumers understand the nutritional impact of formulas in the diet of infants.

1. Introduction

The primary responsibility of the Nutrient Data Laboratory (NDL), Agricultural Research Service, USDA, is to provide authoritative food composition data on foods and dietary supplements available in the United States. The USDA National Nutrient Database for Standard Reference (SR) (USDA, 2012) includes nutrient profiles for over 8000 foods, for up to 146 food components. These data are used by the Food Surveys Research Group of the USDA along with data from the National Health and Nutrition Examination Survey (CDC, 2010) to make estimates of nutrient intake for the U.S. population presented in several ways including by age.

In the past, data on infant formulas (IF) in SR have been based on label claims. The purpose of this study was to provide analytical data on IF for SR and thus to improve the accuracy of the estimates of nutrient content as well as variance indicators in this important food. Researchers and nutrition public policy makers can use these data for a more accurate assessment of the nutrient content (means and variability) of IF when evaluating the intake of very young children. This study also provides information on how well label claims conform to the actual nutrient content of the IF, and if these IF conform to specific nutrient concentrations (as minimum allowed) or ranges for a 100 kcal serving of IF mandated in the Infant Formula Act (IFA) of 1980 (CFR, 2013) and related amendments.

The National Food and Nutrient Analysis Program (NFNAP) is a research program initiated in 1997 in collaboration with the National Institutes of Health to generate a body of nutrient data with unprecedented analytical quality and which is nationally representative of the U.S. food supply (Pehrsson et al., 2003). Nutrient data presented, vitamins (A, D, E, C, K and thiamin), minerals (calcium and iron), and choline, are among many determined to be important to normal infant growth (e.g. bone, brain and visual development; (IOM, 1998, 2001, 2002, 2010). Fatty acids are also needed for development in the infant with one, linoleic acid, being required by the U.S. Food and Drug Administration (FDA) regulations (CFR, 2013). IF, therefore, must not only be in compliance with the label but should meet recommended levels. Table 1 lists recommendations for adequate intakes (AIs) for infants from the Institute of Medicine (IOM) (IOM, 2011 and IOM, 2002), required

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Table 1
Adequate intake (AI), and FDA requirements and ESPGHAN recommended amounts for select nutrients in infant formulas.

Nutrient	AI units per day	FDA required amount per 100 kcal[c]	ESPGHAN recommended amount per 100 kcal[d]
Vitamin A	400–500 μg (RAE)	75–225 μg	60–180 μg (RE[e])
Vitamin D	10 μg 400 IU	1–2.5 μg (as D3) 40–100 IU	1–2.5 μg (as D3)
Vitamin K	2–2.5 μg	4 μg	4–25 μg
Vitamin E	4–5 mg	0.315 mg (natural) 0.469 mg (synthetic) 0.7 IU	0.5–5 mg (α-TE[f])
Vitamin C	40–50 mg	8 mg	8–30 mg
Thiamin	0.2–0.3 mg	0.04 mg	0.06–0.3 mg
Choline	125–150 mg	7 mg	7–50 mg
Calcium	200–260 mg	60 mg	50–140 mg
Iron	0.27 mg[a] 6.9 mg (EAR)[b]	0.15–3.0 mg	0.3–1.3 mg[g] 0.45–2.0 mg[h]
Linoleic acid	4.4–4.6 g	0.3 g	0.3–1.2 g

[a] Iron value for ages 0–6 months.
[b] Iron value for ages 7–12 months.
[c] Single values are the minimum with no maximum mandated; ranges give the minimum and maximum (CFR, 2013).
[d] Koletzko et al. (2005).
[e] 1 μg RE (Retinol equivalent) is equal to 1 μg of retinol; RAE = Retinol activity equivalent = 1 μg retinol.
[f] 1 mg α-TE (a-tocopherol equivalent) = 1 mg D-α-tocopherol.
[g] Iron value for formula based on cows' milk protein and protein hydrolysate.
[h] Iron value for formula based on soy protein isolate.

formula concentrations/ranges from official FDA regulations in amounts per 100 kcal (CFR, 2013) and, also, recommendations from an expert panel convened by the European Society for Pediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) at the request of the Codex Committee on Nutrition and Foods for Special Dietary Uses (Koletzko et al., 2005).

Two of the vitamins in this study are thiamin and vitamin C. Thiamin, or vitamin B1, was the first of the essential B vitamins identified and is important for converting carbohydrates into energy. Vitamin C has a high reducing capacity, which helps it to act as a cofactor for several enzymes (Englard and Seifter, 1986). Within limits, excesses of these water-soluble vitamins are excreted and no maximum level is set (Table 1).

Vitamins D, K, E and A are fat-soluble. Vitamin D_3 has been incorporated into cow's milk since the early part of the 20th century for the prevention of rickets. Vitamin K, phylloquinone, is necessary for normal blood clotting and synthesis of proteins. It is also helpful for cell growth and maintains their healthy structure (IOM, 2001). Vitamin E functions as an antioxidant preventing propagation of lipid peroxidation with the α-tocopherol form being the most active (IOM, 2000). Vitamin A, as retinol in IF, is important for normal vision, gene expression and for the immune system (IOM, 2001). Maximum levels for both vitamins A and D in IF are set by the FDA (Table 1).

Choline is a nutrient essential for the production of acetylcholine, a neurotransmitter that plays a role in the proper functioning of many organs including the brain and liver (Zeisel et al., 1986). In 1998, the Institute of Medicine (IOM, 1998) set intake requirements for infants and the FDA has established fortification levels for IF (Table 1).

The two minerals in this study, calcium and iron, are essential for healthy growth in infants: iron in the body is incorporated into the red blood cells and calcium is an element essential for bone growth and other functions.

The FDA has set a minimum amount of linoleic acid for IF at 300 mg/day (CFR, 2013). Voluntary fortification with the long chain polyunsaturated fatty acids docosahexaenoic (DHA) and arachidonic (ARA) began in 2002 after the FDA recognized DHA and ARA derived from various sources as being Generally Recognized As Safe (GRAS) at the amounts and ratios specified by the formula manufacturers (FDA, 2006). These fatty acids are added to support brain development and visual acuity in young formula-fed infants (CFR, 2013; IOM, 2004); addition of these fatty acids to IF is also supported by the International Formula Council (IFC, 2010). If fortified, FDA has permitted the following levels: DHA must be 0.2–0.5% by of weight of total fatty acids; the amount of ARA must be ≥DHA (FDA, 2006).

2. Methods

2.1. Sampling

A nationally representative sampling frame shown was developed for collection of IF under the USDA National Food and Nutrient Analysis Program (NFNAP) (Pehrsson et al., 2003). The stratified, probability proportional-to-size (PPS) statistical design was based on the 2000 U.S. Census data (U.S. Bureau of the Census) (Perry et al., 2003). Fifteen high-consumption IF were obtained from grocery stores in 12 statistically selected locations in the U.S. (Fig. 1). Three major manufacturers and several types of IF (both soy- and cow milk-based) were represented in the sampling; two toddler formulas were included for analysis because they presented similar label claims but were analyzed solely for fatty acids and vitamin D, and store-brand formulas, milk and soy were obtained. IF were combined, composited, a priori into six random

Fig. 1. Sampling plan locations for procurement of infant formulas.