Vitamin D and Fatty Acids in U.S. Infant Formulas

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Abstract

Vitamin D, a nutrient critical to normal calcium absorption and bone health, plays a significant role in preventing rickets in infants and very young children. The 1980 Infant Formula Act, and subsequent legislation, mandated fortification of all infant formulas with at least 40 IU but not more than 100 IU vitamin D/100 kcalories; manufacturers are required to assure these levels in their products. Many manufacturers have also voluntarily fortified their formulas with two fatty acids found in breast milk, docosahexanoic acid (DHA, C22:6, n-3) and arachidonic acid (ARA, C20:4, n-6). Some studies suggest these nutrients may play a role in normal mental development and several types of formula (both soy- and cow-milk-based) were represented in the sampling; 2 toddler formulas were included for vitamin D analysis because they presented similar label claims; they were separated into a 14th group for DHA/ARA analysis because the amount wasn’t declared on the label. Formulas were combined a priori into six random pairs based on location but because they were not found in each retail location, the number of samples ranged from two to six by brand. When the RTF form of the formula was not found, the powder or liquid concentrate form was selected and the data adjusted to the “as-fed” form (reconstituted).

Introduction

Fifty percent or more of infants in the U.S. have been fed infant formula by six months of age, according to the Ross Laboratories Mothers Survey (Buen et al., 2002). Vitamin D, the omega-3 (n-3) fatty acid ARA and the n-3 fatty acid DHA are nutrients determined to be important to infant development (bone, brain, and eyes, IOM, 1997). Regulations for nutrient fortifications are mandated in the Infant Formula Act of 1980 and subsequent amendments (CFR, 2003).

Vitamin D – The current recommended normal intake is 5 μg (200 IU/day) for prevention of vitamin D deficiency in healthy infants (IOM, 1997). Information on the vitamin D content of 60-100 kcal infant formulas is: 25-71 IU/100 kcal (26-73 IU/100 ml). Early research by Holick et al. (1992) found that of 10 popular infant formulas analyzed, all met or exceeded the amount on the label; 85% of formulas analyzed contained 200% of the label declaration of vitamin D. Data were later reported as a range of 23.9-43.8 IU/100 ml for standard formulas (200 manufacturers’ data, IOM, 2004).

Fatty Acids – Voluntary DHA and ARA fortification began in 2002 to support brain and eye development and health in young formula-fed infants (CFR, 2002; IOM, 2004); many brands in the U.S. are currently fortified with these fatty acids in the approved ratio (see below for approved ratio; IFC, 2008). FDA requires manufacturers to continue post-marketing surveillance of their fortified products; to date, scientific evidence of observed benefits from formula-fed infants with supplements of ARA and DHA or fortified formulas are mixed (IOM, 2002; Kolecko et al., 2008). If fortified, FDA has permitted the following levels: DHA must be 0.2% by weight of total fatty acids; the amount of ARA must be ≥ DHA (CFR, 2002).

General – This is the first USDA-generated analytical dataset for these nutrients in U.S. infant formulas.

Methods

Sampling

A nationally representative sampling frame was developed for collection of infant formulas for the USDA National Food and Nutrition Analysis Program (NFPAN, Fig. 1, Pehrsson et al., 2003). The stratified, probability proportional-to-size (PPS) design was based on a three-stage approach using 2000 Census data (U.S. Bureau of the Census): Stage 1, 48 geographically dispersed counties; Stage 2, grocery store outlets in 12 of the 48 counties; and Stage 3, 13 high consumption infant formulas. Four major manufacturer categories and seven types of formula (both soy- and cow-milk-based) were represented in the sampling; 2 toddler formulas were included for vitamin D analysis because they presented similar label claims; they were separated into a 14th group for DHA/ARA analysis because the amount wasn’t declared on the label. Formulas were combined a priori into six random pairs based on location but because they were not found in each retail location, the number of samples ranged from two to six by brand. When the RTF form of the formula was not found, the powder or liquid concentrate form was selected and the data adjusted to the “as-fed” form (reconstituted).

Vitamin D analysis

5.0 mL of sample spiked with internal standard (D3) saponified in methanolic KOH for 20 minutes at 60ºC and extracted with hexane and the n-3 fatty acid DHA and the n-3 fatty acid DHA are nutrients determined to be important to infant development (bone, brain, and eyes, IOM, 1997). Regulations for nutrient fortifications are mandated in the Infant Formula Act of 1980 and subsequent amendments (CFR, 2003).

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Fatty acid analysis

ARA and DHA were measured by a USDA-contracted lab using AAOAOJ Official Method 996.06. Fat (Total, Saturated, and Unsaturated) in foods, hydrolytic extraction gas chromatographic method, Revised 2001. In: Official Methods of Analysis of AOAC International 18th Edition (Horwitz, W, ed.).

General

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