

Selected Vitamins and Minerals in U.S. Infant Formulas

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Abstract

The objective of this study was to analyze infant formulas in order to update values currently in the USDA National Nutrient Database for Standard Reference (SR). The 1980 Infant Formula Act and subsequent legislation mandated fortification of all infant formulas with specific levels of vitamins and minerals/100 kilocalories. Manufacturers are required to assure these levels in their products. An earlier study of the vitamin D and arachidonic and eicosapentaenoic acid values in infant formulas showed they met or exceeded label claims and fell within allowable ranges. However, sampling and analysis for other vitamins and minerals had not been conducted. Highly consumed milk- and soy-based, ready-to-feed (RTF), and reconstituted infant formulas (n = 13) were sampled nationally at 12 locations. Vitamins (n = 13) and minerals (n = 10) were analyzed by qualified laboratories using valid methods and quality control procedures. Analytical values were compared to values reported by the industry (label values) and values currently stipulated by the Infant Formula Act. Within analytical uncertainty, the data for all vitamins and minerals met label claims and were within allowed ranges for each formula analyzed. Infants must receive a complete range of nutritional needs at every stage of their growth, including vitamins and minerals. At 6 months, 57% and at 12 months, 78% of infants are dependent on infant formula and other infant foods (<http://www.cdc.gov/breastfeeding>); this new analysis indicates that vitamins and minerals listed in infant formula are present as described.

Introduction

Fifty percent or more of infants in the U.S. have consumed infant formula by six months of age according to the Ross Laboratories Mothers Survey (Ryan et al., 2002). Specific nutrient concentrations (as minimum allowed) or ranges for a 100 kcal serving of infant formula are mandated in the Infant Formula Act (IFA) of 1980 (21 CFR 107, 2002) and related amendments. Select vitamins (A, C, D, K, and thiamin), minerals (calcium and iron), and choline are among many nutrients determined to be important to infant development (e.g., bone, brain and visual development; IOM, 1998; 2000; 2001; 2011).

- Vitamins and choline:
- Intake recommendations are adequate intakes (AIs) (IOM, 1998; 2000; 2001; 2011) for infants; required formula concentrations/ranges are from official FDA regulations and for 100 kcal serving (CFR, 2002).
 - Vitamin A – current AI is 400-500 µg/day; formulas required to contain 250-750 IU/100 kcal.
 - Vitamin D – current AI is 10 µg (400 IU)/day; formulas required to contain 40-100 IU/100 kcal as vitamin D₃.
 - Vitamin K – current AI is 2-2.5 mcg/day; formulas required to contain 4 mcg/100 kcal.
 - Vitamin C – current AI is 40-50 mg/day; formulas required to contain 8 mg/100 kcal.
 - Thiamin – current AI is 0.2-0.3 mg/day; formulas required to contain 0.04 mg/100 kcal.
 - Choline – current AI is 125 (0-6 months)-150 mg (7-12 months)/day; formulas required to contain 7 mg/100 kcal.

- Minerals:
- Calcium – current AI is 200 mg/day; formulas required to contain 60 mg/100 kcal.
 - Iron – current recommendation is 0.27 (AI, 0-6 months) – 11 mg (RDA; 7-12 months)/day; formulas required to contain 0.15 mg/100 kcal.

Infant formulas, therefore, must not only be in compliance with the label but should meet recommended levels. This study will examine these comparisons.

Acknowledgement

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Methods

Sampling

- A nationally representative sampling frame was developed for collection of infant formulas under the USDA National Food and Nutrient Analysis Program (NFNAP).
- Samples were obtained at 12 statistically selected locations in the US from retail stores (Fig. 1)
- Four major manufacturers and several types of formula (both soy- and cow milk-based) were represented in the sampling.
- Formula types included:
 - Regular formula
 - Lactose-free formula
 - Formula for neonates (premature infants)
 - Hypoallergenic formula
 - Formula for toddlers
- When the ready-to-feed (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).

Sample Preparation

- All samples were shipped to the Food Analysis Laboratory Control Center (FALCC) at Virginia Tech.
- Composites were homogenized and subsamples were dispensed into 1-oz. jars, sealed under nitrogen, and stored frozen at ≤ -60°C until analyzed.

Nutrient Analysis

- Samples were analyzed by laboratories that had been prequalified for capability in making specific nutrient measurements using valid methods.
- Reference materials from the National Institute for Standards and Technology (NIST) were included in all analyses for quality control purposes.

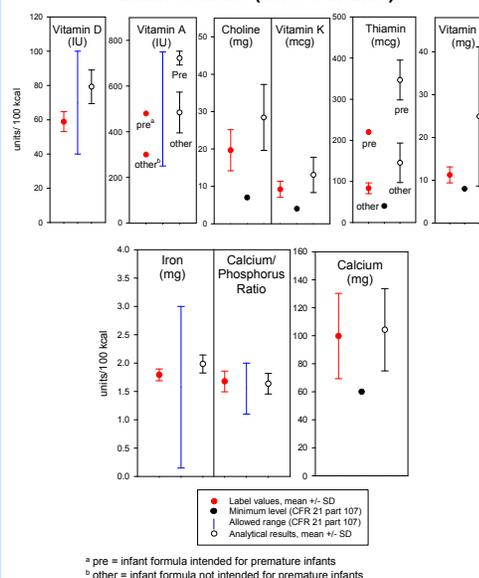
Quality Control

- NIST SRM 1846 Infant Formula was used as the reference material for all nutrients except vitamin A. For vitamin A, NIST SRM 2383 Baby Food was used.
- A quality control committee from the Nutrient Data Laboratory (NDL) reviewed the analytical data and the quality control (QC) reference material results.
- Results for the QC materials met the acceptance criteria at NDL.



Figure 1. NFNAP Sampled Locations

Figure 2. Comparison of label value to CFR 21 part 107 regulations and to the analytical results for infant formula (across brands)



Results

Preliminary results (per 100kcal) for the representative sampling and analysis of 13 U.S.-produced infant formulas collected as part of the NFNAP project are shown in Figs. 2 and 3.

Requirement comparisons

- Vitamins and choline**
- Nearly all of the vitamin and choline results exceeded the FDA minimum nutrient requirement, and in some cases, the results were substantially higher (Fig. 2). Since the shelf life of many formulas is 2-3 years, this may be done to ensure that the levels do not drop below this minimum from deterioration over time.
 - The one formula analyzed for premature infants (four samples) had thiamin and vitamin A amounts much higher than for the other formulas, in keeping with the higher label claim. The analytical vitamin A results for this formula fell at the top of the FDA code requirements range and the thiamin greatly exceeded the required minimum.
 - On average, across all brands of formula, the vitamin C was more than three times the minimum required amount or 25 ± 16 versus 8mg /100kcal (n=20). There was, however, a substantial difference among manufacturers.

Minerals

- For Ca the mean analytical mineral value exceeded the minimum value; for Fe and Ca/P ratio, the means fell within the required range (Fig. 2).
- All formulas were fortified with iron and the results for all products were very close in value.
- The calcium values averaged almost twice (104.3 > 60mg/100kcal) the required minimum level from fortification regulations.

Label comparisons

- The analytical results for choline and vitamins were nearly always higher than label claim although this differed by manufacturer as shown in Fig. 3 for vitamins A and C, and thiamin. This was especially true for vitamin C from manufacturer A.
- The analytical results for minerals agreed well with the label claims. Unlike vitamins, additional amounts of minerals would not need to be added to offset deterioration (loss) over time.

Conclusions

- Nearly all analytical results for the nutrients reported here met or exceeded the minimum nutrient content for infant formula or fell within range as given in the Code of Federal Regulations.
- For choline and vitamins, the label claim may understate the actual amount in the product.
- For minerals, the analytical results more closely match the label claims than for the vitamins.

References

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Figure 3. Analytical results as % of label amount for selected nutrients by manufacturer

