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 kcal. This project was supported 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 allowable 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.

Vitamins and choline:
- Intake recommendations are adequate intakes (AIs) (IOM, 1998; 2000; 2001; 2006) for infants; required formulas cover ranges from official FDA regulations and for 100 kcal serving of infant formula are mandated in the Infant Formula Act (IOM) (2011) for 100 kcal serving (CFR 21, 2002). The mean analytical mineral values exceeded the current AI for all vitamin A, vitamin D, vitamin E, selenium, and vitamin B6 (FDR 21, 2002).
- A quality control committee from the Nutrient Data Laboratory (NDR) reviewed the analytical data and the quality control (QC) reference material results.
- For Ca the mean analytical mineral value exceeded the current AI for all vitamin A, vitamin D, vitamin E, selenium, and vitamin B6 (FDR 21, 2002).
- Results for the QC materials met the acceptance criteria at NDL.

Label comparisons:
- The analytical results for choline and vitamins were nearly always higher than the label claim although this differed by manufacturer as shown in Fig. 3 for vitamin A, vitamin D, and vitamin E. 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 underestimate the actual amount in the product.
- For minerals, the analytical results more closely match the label claims than the vitamin.

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References
- Reference materials from the National Institute for Standards and Technology (NIST) were included in all analyses for quality control purposes.
- Results for the QC materials met the acceptance criteria at NDL.

Figure 1. FNFAP Sampled Locations

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

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

Results
- Preliminary results (per 100 kcal) for the representative sampling and analysis of 13 U.S.-produced infant formula collected as part of the FNFAP project are shown in Figs. 2 and 3.
- 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 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 51 ± 6 mg/100 kcal (n=20).
- There was, however, a substantial difference among manufacturers.

Vitamins
- For Ca the mean analytical mineral value exceeded the current AI for all vitamin A, vitamin D, and vitamin E.

Minerals
- For Ca the mean analytical mineral value exceeded the current AI for all vitamin A, vitamin D, and vitamin E.