



# Lead and cadmium contamination in a large sample of United States infant formulas and baby foods

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## HIGHLIGHTS

- Data is limited on heavy metal levels in food for babies, a sensitive population.
- We examined lead and cadmium in baby food in relation to regulatory limits.
- 0/91 infant formulas exceeded FDA lead guidelines in 31 oz, 22% exceeded Prop 65.
- 23% infant formulas exceeded Prop 65 cadmium guidelines, 14% exceeded WHO PTMI.
- 3% food exceeded FDA lead consumption limit in 300 cal, 34% exceeded Prop 65.

## GRAPHICAL ABSTRACT



### Of the 471 baby food samples tested

- For Lead**
- 1% exceeded FDA lead guidelines in two servings (26% exceeded CA Prop 65 limits)
  - 3% in 300 calories (34% exceeded CA Prop 65 limits)
- For cadmium**
- 6% exceeded CA Prop 65 guidelines in two servings
  - 8% in 300 calories



### Of 91 infant formula samples tested

- 0 exceed FDA lead consumption guidelines in 31oz
- 22% exceeded CA Prop 65 lead guidelines
- 23% exceeded CA Prop 65 cadmium guidelines
- 14% exceeded the World Health Organization tolerable cadmium intake levels for a 4-month baby

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## ABSTRACT

Data is limited on lead and cadmium contamination in baby food, a population uniquely susceptible to the toxic effects of heavy metals. The goal of this study was to examine lead and cadmium concentrations in a large convenience sample of US baby foods. We identified the number of baby food product samples that exceeded US FDA and California Proposition 65 limits for daily lead consumption across a range of servings/calories, and the number of samples that exceeded World Health Organization and California Proposition 65 limits for daily cadmium consumption across a range of servings/calories. In total, 564 baby foods were tested across infant and toddler formula, cereals, meals, juices/drinks, jars, pouches, snacks, and electrolyte water. ICP-MS analysis of lead and cadmium was completed using a modified version of EPA method 6020A. Samples were analyzed using kinetic energy distribution mode. Lead was detected in 37% of samples (median = non-detect, 75% = 5.6, maximum = 183.6  $\mu\text{g}/\text{kg}$ ), and cadmium in 57% (25% = non-detect, median = 2.8, 75% = 9.5, maximum = 103.90  $\mu\text{g}/\text{kg}$ ). Of 91 infant formula samples, none exceeded FDA lead consumption guidelines in 31 oz, but 22% exceeded the Proposition 65 lead guidelines, 23% exceeded the Proposition 65 cadmium guidelines, and 14% exceeded the WHO tolerable cadmium intake levels for a four-month-old baby. In the solid baby food samples, 1% exceeded FDA lead guidelines in two servings (26% exceeded CA Proposition 65 limits), 3% in 300 cal (34% exceeded CA Proposition 65 limits). For cadmium, 6% exceeded Proposition 65 guidelines in two servings, 8% in 300 cal. There was no association between whether the product was certified organic and its heavy metal concentration. Products containing rice were higher in both lead and cadmium concentrations. Further research is needed to understand the long-term health effects of this chronic daily low level heavy metal exposure in babies.

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## 1. Introduction

Lead is a potent neurotoxin and reproductive toxin with permanent irreversible effects, and the brains of infants and children are particularly susceptible to its deleterious effects (Bellinger, 2008; Téllez-Rojo et al., 2006). It is well-established that there is no safe lead exposure level (Joint FOA/WHO Expert Committee on Food Additives, 2011). Although the removal of lead from house paint and gasoline has reduced the occurrence of very high lead poisoning, low-level lead exposure remains ubiquitous, and diet is a relevant source (US Food and Drug Administration, 2018a, 2018b). Contaminated food is also an exposure source for cadmium, a heavy metal that is a neurotoxin, renal toxin, and reproductive toxin (Noonan et al., 2002; Rigon et al., 2008). In fact, the most recent total diet study (TDS) in France underscored the health concern based on the lead and cadmium exposure in the typical diet of a large portion of children under age three and the importance of reducing this exposure for public health (Jean et al., 2018; Sirot et al., 2018). However, there is limited information about the presence of these metals among a broad array of commercially-available baby foods in the United States.

In consideration of the reproductive toxicity of lead and cadmium, the California Office of Environmental Health Hazard Assessment (2018) set a maximum allowable oral dose level of 0.5  $\mu\text{g}/\text{day}$  for lead and 4.1  $\mu\text{g}/\text{day}$  for cadmium (i.e. Proposition 65). The latter maximum allowable daily dose level for cadmium is stricter than the provisional tolerable monthly intake (PTMI) of 25  $\mu\text{g}/\text{kg}$  body weight established by the World Health Organization (WHO, 2013). The WHO determined that it is not possible to establish a provisional tolerable intake level of lead that would be health protective. The Proposition 65 maximum dose level for lead is also substantially lower than that set by the US Food and Drug Administration (FDA) in 1993 of 6  $\mu\text{g}/\text{day}$  (US FDA, 2017). The US FDA limit was based on the CDC's blood lead "level of concern" that at the time was 10  $\mu\text{g}/\text{dL}$ . FDA guidelines also include limits of 100 PPB for candy and certain dried fruits and 50 PPB for fruit juice. These limits reflect the fact that lead is unavoidable in many otherwise healthy foods due to the natural occurrence of lead in soil, and therefore realistically achievable limits must be balanced against the known dangers of lead exposure. Since the guidelines were established, a growing body of literature has shown deleterious cognitive effects even at much lower and commonly-observed exposure levels (Bellinger, 2008; Téllez-Rojo et al., 2006), underscoring the need for further evaluation. Since then the EPA air quality standard was reduced to reflect the latest findings, and the CDC has reduced their blood lead "level of concern" to 5  $\mu\text{g}/\text{dL}$  (US FDA, 2017). Despite these important advancements, there has been no change in the FDA guidelines, and the 1993 FDA provisional maximum daily lead intake level of 6  $\mu\text{g}/\text{day}$  remains. Existing survey data on lead levels in US food samples suggest that lead contamination in the US food supply is generally low in relation to FDA limits, typically well below 100 PPB (US Food and Drug Administration, 2018a, 2018b).

The current study examines the levels of lead and cadmium contamination in a large convenience sample of US baby foods in relation to the maximum allowable dose levels set according to California's Proposition 65 for lead and cadmium, as well as WHO PTMI for cadmium and the FDA standard for lead. Our goal is to describe the levels of lead and cadmium contamination in the baby food sample, identify the types of foods that have higher levels of lead and cadmium, and identify ingredients associated with elevated lead and cadmium. Our hypothesis is that a varied diet is needed for babies and toddlers to avoid exceeding the maximum limits of lead and cadmium consumption set by California Proposition 65.

## 2. Materials and methods

### 2.1. Sample purchasing

564 baby foods were purchased from Denver, Colorado area conventional and natural/organic supermarkets, online retailers, and direct-to-

consumer sources. Fifty-two week US national sales data compiled Nielson Holdings, a leading global data, measurement, and information company, was used to identify the top selling infant formulas and baby foods according to mainstream retail sales. The convenience sample was expanded to also include top sellers within the natural/organic retail channel and brands promoted online as direct to consumer. These products were purchased with the intent of modeling the consumer shopping experience and were chosen from popular brands across a range of price points. Baby foods were divided into seven categories: infant formula ( $N = 91$ ), cereals ( $N = 30$ ), kids' meals ( $N = 23$ ), toddler formula ( $N = 22$ ), juices/drinks ( $N = 30$ ), jars/first meals ( $N = 107$ ), pouches ( $N = 140$ ), snacks ( $N = 107$ ), and electrolyte solutions ( $N = 14$ ). No prescription or medical foods were included in this dataset. A minimum of 300 g per sample was purchased to ensure adequate material for testing. When multiple samples were purchased, the sample lots were recorded to control for this variable. Original sample packaging was retained, and the list of ingredients along with other nutritional information was recorded.

### 2.2. List of reagents

Tracemetal Grade  $\text{HNO}_3$ , and concentrated HCl were purchased from Fischer Scientific (Hampton, NH). Tracemetal grade methanol was purchased from Honeywell (Morris Plains, NJ). HPLC grade water was purchased from Rocky Mountain Reagents (Golden, CO). Multi-element standard (10  $\mu\text{g}/\text{mL}$ ), mercury standard (10  $\mu\text{g}/\text{mL}$ ) and gold standard (1000  $\mu\text{g}/\text{mL}$ ) were purchased from Inorganic Ventures (Christiansburg, VA).

### 2.3. Heavy metals analysis by ICP/MS

Infant formulas and baby foods can be heterogenous. Prior to analysis, all infant formulas and baby food samples were homogenized using a mortar and pestle and mixed until the food achieved a uniform texture. The sample preparation process follows a modified version of EPA method 3015A. Approximately 0.25 g of this homogenized sample was digested using an acid solution of 2 mL  $\text{HNO}_3$  + 0.5 mL HCl + 7.6 mL HPLC water in a microwave digester (Mars6 One Touch microwave, CEM). The digest protocol utilized a 10 min ramp to 170 °C followed by a 10 min hold and 50 min cool down. Following digestion, the samples were then transferred to 50 mL vials and were diluted with HPLC water to ~20 mL for analysis.

Diluted sample was combined with internal standards prior to assay. Heavy metals analysis was carried out by ICP-MS (NexION 350x IPC Mass Spectrometer with PerkinElmer ESI: 2DX Auto-sampler and Polyscience: Whisper Cool cooler) using a modified version of EPA method 6020A. Samples were analyzed using kinetic energy distribution (KED) mode, which uses energized He to collide with potentially interfering molecules. This step reduces interference and produces a stronger, cleaner signal. To counteract this, 2% Tracemetal grade Methanol was added to all standards prior to analysis. ICP-MS data were processed using Syngistix Software (PerkinElmer).

For this study the quantification limits (LoQ's) were 2PPB for cadmium and 4PPB for lead. For quality control purposes, our minimum acceptable  $R^2$  value for the calibration curve for each run for both metals was 0.998, the maximum acceptable RSD for matrix spike duplicates was 20%, the maximum acceptable variability for the low-level and mid-level calibration verification was 30% and 10%, respectively. For these metals, our maximum measure of uncertainty for cadmium and lead were  $\pm 2.36\%$  and 2.39%, respectively. The MDL for this method was based on acid solution and was not matrix-corrected – method accuracy for each matrix was determined using matrix spike and matrix spike duplicates.

### 2.4. Data analysis

The distributions of lead and cadmium in  $\mu\text{g}/\text{kg}$  were examined in the full sample of infant formula and baby food items, and by the type

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