Food and Nutrition Sciences, 2023, 14, 791-811
https://www.scirp.org/journal/fns
ISSN Online: 2157-9458
ISSN Print: 2157-944X

Trends of Laboratory-Detected Heavy Metals in Children: Solutions for Heavy Metal Contamination in Infant Food Products

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How to cite this paper: Khan, M. (2023) Trends of Laboratory-Detected Heavy Metals in Children: Solutions for Heavy Metal Contamination in Infant Food Products. *Food and Nutrition Sciences*, **14**, 791-811.
https://doi.org/10.4236/fns.2023.149051

Received: August 10, 2023
Accepted: September 15, 2023
Published: September 18, 2023

Abstract

In 2019, an investigation by the U.S. House of Representatives revealed major infant food conglomerates had products with high levels of arsenic, lead, cadmium, and mercury, posing concerns for infants' vulnerability to the neurotoxic effects of these metals. Trends of laboratory-detected heavy metals were analyzed in children aged zero to five from 1999-2020, providing insights on heavy metal contamination in infant food products. Utilizing National Health and Nutrition Examination Survey (NHANES) data, mean heavy metal levels in children were calculated, considering gender, race, and income-to-poverty ratio as proxies for assessing associations with increasing heavy metal rates in infant food. Findings indicated an overall decrease in mean concentrations over time, though remaining elevated. Black children exhibited higher lead levels than the overall average, while the Asian subgroup displayed higher levels of total blood mercury and cadmium levels. Lack of internal standards in regulatory bodies, particularly the FDA, exacerbates the issue, with no legally enforceable guidelines or strict maximum levels for heavy metals in infant foods. Urgent FDA interventions are needed, addressing contamination at the sources of raw materials, implementing transparent and extensive product testing, and comprehensive manufacturer labeling to inform consumers about elevated heavy metal levels in infant products.

Keywords

Infant Nutrition, Infant Food Products, Laboratory-Detected Heavy Metals, Environmental Contaminants, Consumer Safety

1. Introduction

There is a lack of federal oversight in the infant and pediatric food industry, which has consequently resulted in companies exploiting consumer trust and supplying products on the market tainted with heavy metals. This is a critical public health issue, as parents and caregivers confide in these companies to be providing nutritious foods for their children.

In 2019, the U.S. House of Representatives Subcommittee on Economic and Consumer Policy conducted an investigation and tested baby food products from major infant food conglomerates, Nurture (Happy Baby), Hain (Earth's Best Organic), Beechnut, and Gerber. The investigation revealed that their products contained detectable high levels of arsenic, lead, cadmium, and mercury [1]. Dangerously, these companies had set high internal standards for allowable heavy metal limits in their products, and regularly exceeded them. Notably, Nurture continued to sell its products to consumers despite testing indicating a high toxic metal content. Walmart (Parent's Choice), Sprout Organic Foods, and Campbell refused to cooperate with the investigation, raising further concerns about their products. While heavy metal exposure ultimately can affect all demographics and populations, infants are the most vulnerable due to their smaller body masses and developing metabolism, making them more susceptible to the neurotoxic effects of these contaminants. The lack of internal standards within regulatory bodies, specifically the United States Food and Drug Administration (FDA), further compounds these concerns and underscores the urgency of addressing the issue.

1.1. Understanding the Toxic Effects of the Presence of Heavy Metals in Children

In the scientific community, the term heavy metals has many connotations and implications. However, within the scope of this study, the FDA classifies heavy metals as toxic elements occurring naturally in the environment or existing at elevated concentrations due to historical industrial activities and anthropogenic pollution [2]. Arsenic, lead, mercury, and cadmium are specifically prioritized due to their potential to cause harm during the critical period of cognitive development, spanning from prenatal stages to early childhood.

According to the Department of Health and Human Services' Agency for Toxic Substances and Disease Registry's (ATSDR) Substance Priority List, arsenic has been designated as the number one hazardous substance present in the environment, posing a potential threat and substantial risk to human health [3]. Inorganic arsenic exposure is associated with health risks that impact several anatomical systems, including the gastrointestinal, renal, pulmonary, hematological, and hepatic systems, while also exerting significant effects on cognitive development and central nervous system activities [4]. Specifically, findings assert that a 0.4 reduction in the intelligence quotient (IQ) of children ranging from zero to fifteen is present for every 50% increase of arsenic levels [4].

Lead is next on ATSDR's Substance Priority List and is a potent neurotoxin particularly harmful to children under six years of age, since their bodies absorb more lead per pound than adults as their nervous systems are still developing

[3]. Increased lead levels in children are correlated with behavioral issues, delayed puberty, stunted cognitive development, as well as incompetent postnatal growth [5]. Longitudinal impacts of lead were visualized in a follow-up study, in which adults who experienced previous developmental obstruction linked to past lead exposure, exhibited persistent cognitive deficits [6].

Mercury is third on the ATSDR's list for substances that pose potential human risk [3]. Mercury exposure during embryo development and early infancy has also been correlated with later incidences of autism spectrum disorders (ASD), as well as attention-deficit hyperactivity disorder [7]. Dose-response studies have cited how prenatal exposure to methylmercury is associated with adverse childhood neurologic outcomes, with a 0.18 decrease in IQ points per million increase in maternal hair mercury [8].

Cadmium is classified as a Group 1 substance carcinogenic to humans [9]. Its toxic effects are primarily connected to its bioaccumulation in the body over time especially in the kidneys, liver, and bones, since it has a long-biological half-life [10]. Elevated cadmium exposure during pregnancy and in early infancy has been linked inversely to cognitive development. In one study, children with blood cord cadmium concentrations higher than the median limit, had notably lower full scale and performance IQ [11]. Additionally, there have been associations between levels of cadmium during gestation and incidences of ASD and attention-deficit/hyperactivity disorder (ADHD) [12].

Selenium is also on the ATSDR's list for substances in the environment that pose potential human risk [3]. While selenium is an essential trace element, excess consumption through contaminated food sources can have adverse effects on health leading to selenosis. Selenosis is characterized by gastrointestinal disturbances, hair loss, brittle nails, and neurological abnormalities [13].

1.2. Origins of Heavy Metal Contamination in Infant Food Products

Heavy metals are naturally occurring elements present on Earth that can infiltrate the environment through natural processes, such as volcanic eruptions, weathering, and erosion, as well as anthropogenic activities, including point source pollution, industrial operations, agricultural practices, technological applications, and mining [14]. Precipitation can facilitate the transportation of pollutants originating from industrial facilities, carrying them into bodies of water. Subsequently, these pollutants can migrate through groundwater pathways, contaminating soil and agricultural crops. Though certain heavy metals can naturally occur in the soil, as plants grow, specific species exhibit a remarkable ability to uptake heavy metals from their environment, accumulating heavy metals within their root systems and leaves [15].

The utilization of contaminated crops as raw materials in the infant food production has resulted in growing concerns, particularly surrounding grains, especially rice. Arsenic has been identified to accumulate more readily in rice compared to other crops, prompting caregivers to limit the consumption of rice cereal by children. Dimethylarsinic acid (DMA) and monomethylarsonic acid (MMA), organic forms of arsenic, are classified as "possibly carcinogenic to humans [16]". One study revealed that in rice cereal available in the United States, 37% consisted of organic forms (MMA and DMA) and 63% inorganic form (As_i) [17].

1.3. Regulatory Thresholds Governing Heavy Metal Limits by the FDA in the Infant Food Products

1.3.1. Closer to Zero

Closer to Zero is an initiative undertaken by the FDA aimed at minimizing and mitigating childhood exposures to contaminants in food. It emphasizes the need to reduce the levels of harmful substances, including heavy metals, in infant and toddler food products [18]. Their process includes evaluating the science, monitoring and addressing the presence of heavy metals (As, Pb, Cd, and Hg), proposing draft action levels, consulting with stakeholders to share best practices, and ultimately finalizing action levels for contaminants.

However, while the FDA provides draft action guidance documents, these papers "do not establish legally enforceable responsibilities", but instead reflect the "current thinking on a topic and should be viewed only as recommendations [18]". The subsequent section presents recommendations based on the FDA's guidance documents, acknowledging that these are not finalized or legally binding action levels.

1.3.2. Arsenic (Inorganic)

In August 2020, the FDA provided the infant food industry with a final guidance level pertaining to inorganic arsenic content in all variants of infant rice cereals, setting a limit of 100 micrograms per kilogram (μg/kg) or 100 parts per billion (ppb) [19]. In June 2023, the FDA also established a guidance level of 10 ppb of inorganic arsenic in apple juice to manufacturers [20].

1.3.3. Lead

In April 2022, the FDA issued guidance specifying action levels for lead in fruit juices, establishing a threshold of 50 ppb [21]. In January 2023, the FDA further released guidance for the infant food industry, outlining recommended action levels for lead in processed food products intended for infants and young children. A maximum permissible level of 10 ppb was set for lead in various categories, including fruits, vegetables, mixtures, yogurts, custards/puddings, and single-ingredient meats. Single ingredient root vegetables and dry infant cereals were allotted a limit of 20 ppb of lead [22].

1.3.4. Mercury

The FDA has yet to issue specific guidance regarding limits for mercury in infant food products. FDA had initially stated their intention to propose guidance in January 2023 as part of their Closer to Zero timeline, yet no guidelines have been provided [18].

1.3.5. Cadmium

Currently, the FDA has not released guidance regarding limits for cadmium in infant food products. According to their Closer to Zero Timeline, the FDA plans to propose draft action levels for cadmium in infant foods in the year 2024 [18].

1.3.6. Selenium

At present, no guidance levels have been issued by the FDA regarding allowable levels of selenium in infant food products.

1.4. Objective

The objective of this longitudinal study is to investigate overall trends of mean levels of laboratory tested heavy metals, including arsenic, lead, mercury, cadmium, and selenium, in children aged zero to five from the years 1999-2020, while assessing current figures and FDA guidance regarding heavy metal contamination in infant food products.

2. Methods

2.1. Data Source

The National Health and Nutrition Examination Survey (NHANES) is a program of the National Center of Health Statistics (NCHS), which is a part of the Centers for Disease Control and Prevention (CDC) within the U.S Department of Health and Human Services [23]. NHANES is a nationally representative survey that collects data on the health and nutritional status of the U.S. population through random sampling strategies [23]. All quantitative data, population statistics, and statistical analyses were obtained and studied from datasets from NHANES.

From the Laboratory Data available on the NHANES database, the years researched were 1999-2000, 2001-2002, 2003-2004, 2005-2006, 2007-2008, 2009-2010, 2011-2012, 2013-2014, 2015-2016, and 2017-March 2020 [24]. To supplement the laboratory data, information regarding demographics of the sampled population was also extracted from the Demographic Data available in NHANES [24]. The NHANES program suspended partial field operations as a result of the coronavirus disease 2019 pandemic and data collection was not completed for the NHANES 2019-2020 cycle. Therefore, "data collected from 2019 to March 2020 were combined with data from the NHANES 2017-2018 cycle to form a nationally representative sample of NHANES 2017-March 2020 pre-pandemic data" [23].

2.2. Population of Interest

The study population of concern of this study is limited to children ages zero to five years.

2.3. Outcomes of Interest

In order to identify the elements for evaluation in children, a selection process was employed that involved considering common metals and metalloids analyzed by laboratories. The list was further refined by identifying specific hazards that children may be vulnerable to in infant food products, including reproductive and developmental risks, carcinogenic potential, and mutagenicity. The resulting identified elements were lead, mercury, cadmium, and selenium, whose data was pulled from the Laboratory Data. Several studies, referenced in the introduction, have identified the elements and emphasized the need to assess their risks to infants and young children, considering both their relevance in the infant food industry [4]-[13].

Levels of these metals came from whole blood samples extracted from children tested. No samples derived from urine are utilized for this study. Blood sample data was the preferred medium due to a greater accuracy record and was more readily available in NHANES in regard to the specific metal concentrations being measured in children. Additionally, no data for blood arsenic levels in children zero to five were available in the database even though adverse attributes of this metal were discussed extensively in this paper. No data from 2001-2010 were available for blood selenium levels in children zero to five. Furtherly, no data was available for blood lead levels in the year 2017-2020 as the sample size was zero. It is also important to note that the laboratory data files included various variables for mercury. However, in this study, all data for mercury levels researched were pulled from the variable "Total Mercury", as it is more holistic.

All levels of heavy metals were derived from blood samples of children in the units μg/dL for lead, as well as μg/L for total mercury, cadmium, and predominantly for selenium. One exception is that from the data available for 1999-2000, selenium was measured in the units ng/mL for which it was converted to μg/L.

2.4. Demographics of Interest

The gender variable was studied under the variable name in the demographic file to assess if mean values of certain gender, categorized into males and females, fostered higher levels on average of lead, mercury, cadmium. The race/ethnicity variable was also analyzed for the purpose of identifying differences in mean heavy metals among various races and to see if this factor made a difference in the high average metal concentrations in children. The specific sub-race categories for the years, 2011-2012, 2013-2014, 2015-2016, 2017-March 2020, included Mexican American, Other Hispanic, Non-Hispanic White, Non-Hispanic Black, Non-Hispanic Asian, and Other Race—Including Multi Racial, under the variable name RIDRETH3 in the demographic file. However, for the years 1999-2000, 2001-2002, 2003-2004, 2005-2006, 2007-2008, and 2009-2010 the specific sub-race categories included Mexican American, Other Hispanic, Non-Hispanic White, Non-Hispanic Black, and Other Race—Including Multi Racial, excluding Non-Hispanic Asian, under the variable name RIDRETH1. This is as a result of the file variable being recoded. Lastly, the ratio of family income to poverty variable was examined. In the demographic file in NHANES, this variable was initially categorized in two groups separated into a range of values from 0 to 4.98 and all values above 5.00 under the file name. However, in this analysis, data under this variable was recategorized to at or below the poverty line with values at or below 1.00 or above poverty line, from values above 1.00. This is because generally the ratio of 1.00 means that the level of income is at the poverty level [25]. The income test was conducted as it could determine if economic stress may have resulted in parents/caregivers giving their children more commercial or store-bought infant food products rather than homemade sources of nutrition accessible, which are often accessible to those with a higher ratio of family income to poverty.

2.5. Data Analysis Approach

This study conducted a descriptive analysis to evaluate trends in the data extracted from available NHANES data. Once a final pool of data was generated according to the age group of interest, means of individual levels of the heavy metals (Hg, Pb, Cd, and Se) in the blood samples were identified from the Laboratory Dataset. This same process was used for each set of the aforementioned years that this study focuses on: 1999-2020. After calculating mean levels of each heavy metal in the overall population of interest, additional stratified analysis by gender, race, and ratio of family income to poverty occurred using the demographic variables from the Demographic Data. R-Studio version 4.3.0 was used to calculate mean levels of each heavy metal [26].

3. Results

3.1. Sampled Respondents

From 1999-2020, there has been a general decrease in sample sizes in NHANES of respondents across all demographics and categories (**Table 1**). Examining the distribution of respondents across the ratio of family income to poverty subgroups, it is apparent that there is a higher representation of children ages zero to five above the poverty line compared to those at or below it. Among the racial demographics, sample sizes were largest for White children. The sample sizes for males and females were relatively equal to each other and remained consistent over the years. To emphasize, the years 2017-2020, contained combined datasets which justifies the uptick in samples across the demographics.

3.2. Mean Lead Levels

Table 2 presents a comprehensive overview of the mean lead levels among children aged 0 - 5, stratified by gender, race, and ratio of family income to poverty. A longitudinal analysis of trends, through calculations of average metal levels in children by demographic, spanning from 1999 to 2016 reveals a notable decrease in the overall mean lead levels (3.120 μg/dL - 1.083 μg/dL). This trend was consistent across gender, race, and ratio of family income to poverty (**Figures 1-3**). **Figure 1** depicts a consistent downward trend in mean lead levels

Table 1. Sampled respondents of children ages 0 - 5 from demographics over time (1999-2020).

Year	Sampled Respondents										
	Overall	Males	Females	Asian	Black	Mexican American	Other	Other Hispanic	White	At or Below Poverty Line	Above Poverty Line
1999-2000	1013	542	471	0	247	382	58	66	260	335	547
2001-2002	1282	645	637	0	365	350	69	79	419	496	716
2003-2004	1197	594	603	0	369	344	69	56	359	496	648
2005-2006	1354	677	677	0	358	463	75	70	388	466	805
2007-2008	1175	640	535	0	252	314	69	143	397	402	689
2009-2010	1244	642	602	0	216	355	94	141	438	476	668
2011-2012	1135	561	574	132	345	237	66	146	209	561	574
2013-2014	1131	598	533	98	273	239	92	124	305	598	533
2015-2016	1144	591	553	85	262	228	97	129	343	591	553
2017-2020	1574	812	762	113	428	201	148	147	537	501	887

Table 2. Mean lead levels by gender, race, and ratio of family income to poverty in children ages 0 - 5.

Year	Mean Lead Levels										
	Overall	Males	Females	Asian	Black	Mexican American	Other	Other Hispanic	White	At or Below Poverty Line	Above Poverty Line
1999-2000	3.120	3.200	3.020	-	4.099	2.954	2.822	2.386	2.780	3.756	2.628
2001-2002	2.547	2.658	2.430	-	3.438	2.000	2.771	2.733	2.134	3.272	1.990
2003-2004	2.650	2.664	2.640	-	3.763	2.107	2.550	2.159	2.117	3.217	2.158
2005-2006	2.064	2.018	2.109	-	2.823	1.665	2.189	2.640	1.738	2.432	0.177
2007-2008	2.028	2.010	2.048	-	2.588	1.738	2.318	1.684	1.962	2.349	1.796
2009-2010	1.614	1.590	1.640	-	2.043	1.403	1.602	1.453	1.633	0.182	1.409
2011-2012	1.330	1.440	1.217	0.924	1.626	1.092	1.110	1.036	1.591	1.441	1.217
2013-2014	1.109	1.095	1.124	1.106	1.437	0.911	1.383	1.175	0.896	1.095	1.124
2015-2016	1.083	1.131	1.029	1.115	1.277	0.886	0.934	0.905	1.185	1.131	1.029
2017-2020	-	-	-	-	-	-	-	-	-	-	-

a. Dashes (-) indicate the absence of metal data for the specified years within the given category.

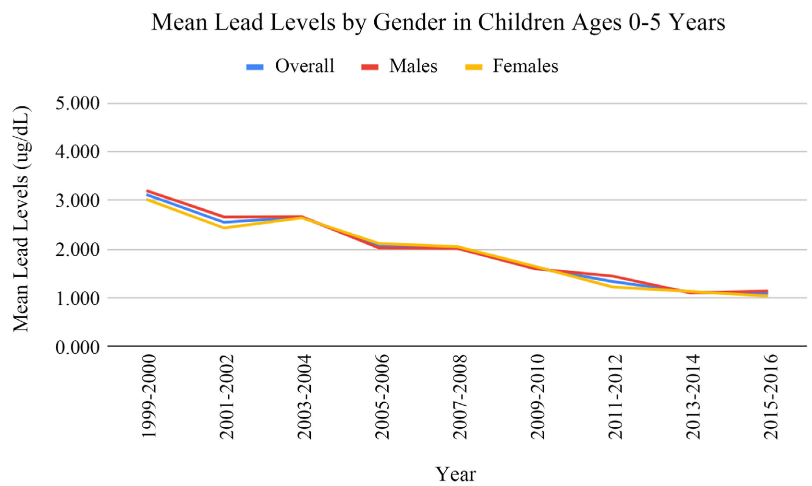

Figure 1. Mean lead levels by gender.

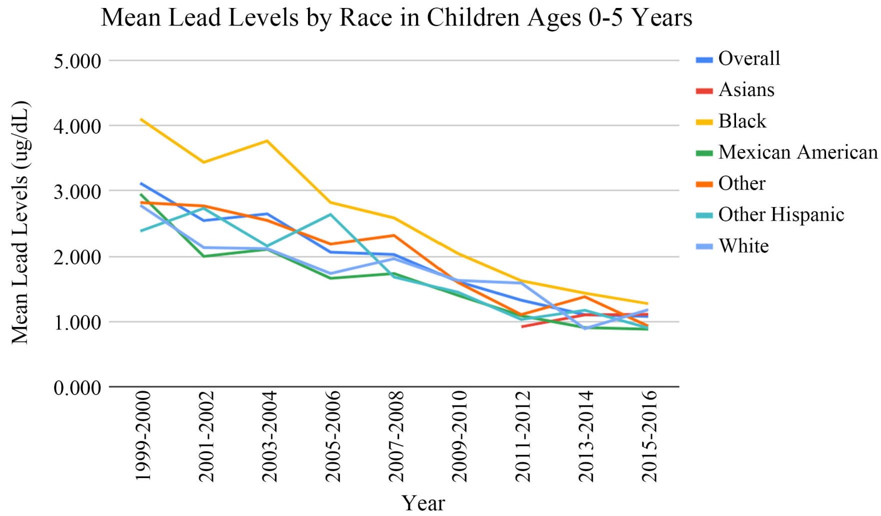

Figure 2. Mean lead levels by race.

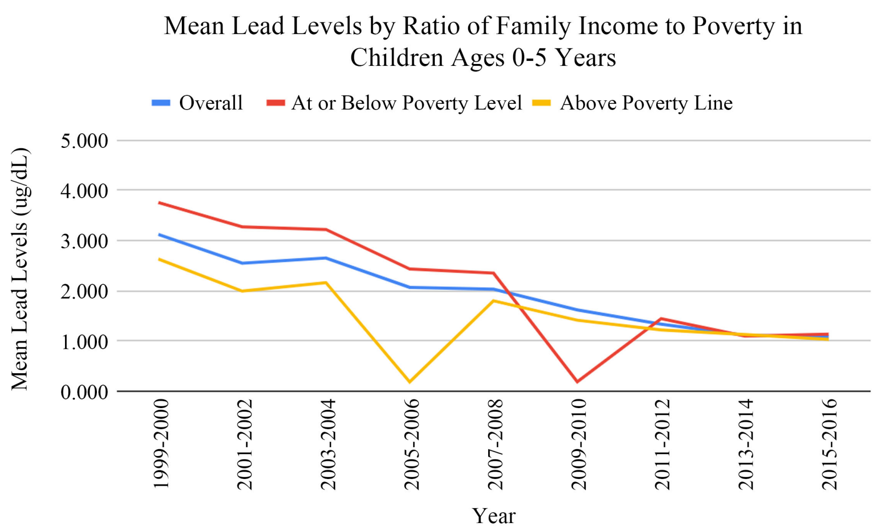

Figure 3. Mean lead levels by ratio of family income to poverty.

for both males and females. Notably, the Black demographic consistently exhibits lead levels above the overall average, whereas Mexican Americans consistently display lead levels below the overall trend line. Mean lead levels in children belonging to the "Other" race category exhibit occasional spikes but do at a noticeable rate. The White demographic has also experienced a spike in lead levels recently. However, it is worth noting that the trend for "Other Hispanic" notably increased during 2005-2006, which eventually stabilized and remained relatively constant thereafter. Based on the data available, the Asian demographic remained below the overall mean lead level, but levels have been increasing as of 2015-2016. Nevertheless, when considering the broader time frame, all races demonstrate a general decline in average lead levels (**Figure 2**). For children at or below the poverty line, mean lead levels are consistently above the overall average, with a significant decrease from 2009-2010, while those above the poverty line have levels below the overall average, with a significant decrease from 2005-2006. It is noted that trend lines for those at or below poverty line and above poverty line have been leveling off and matching the overall mean lead levels (Figure 3).

3.3. Mean Mercury Levels

Table 3 provides a comprehensive overview of mean mercury levels among children aged 0 - 5, categorized by gender, race, and the ratio of family income to poverty. A longitudinal analysis reveals a notable decrease in the overall mean mercury levels over time (0.759 μg/L - 0.359 μg/L). Figure 4 illustrates that females generally exhibit higher mercury levels, though there have been decreases in 2011-2012 and more recently. Males, on the other hand, have consistently displayed levels below the overall mean, although occasional spikes have been observed, while females have mean levels above the overall average (Figure 4). Among different racial demographics, the Asian population has consistently demonstrated the highest mercury levels, followed by individuals identifying as "Other" and Black. In contrast, White children have consistently exhibited mercury levels below the overall mean, along with the Mexican American demographic (Figure 5). Examining the impact of socioeconomic factors, between 1999 and 2004, children from both categories—those at or below the poverty line and those above it—experienced fairly consistent decreasing trends in overall mean mercury levels. However, both subcategories have since encountered spikes above and below the overall average, though they continue to show decreasing trends in recent years (Figure 6).

Table 3. Mean mercury levels by gender, race, and ratio of family income to poverty in children ages 0 - 5.

Year	Mean Mercury Levels										
	Overall	Males	Females	Asian	Black	Mexican American	Other	Other Hispanic	White	At or Below Poverty Line	Above Poverty Line
1999-2000	0.759	0.724	0.800	-	0.937	0.718	0.711	0.940	0.605	0.712	0.780
2001-2002	0.569	0.530	0.600	-	0.689	0.436	0.845	0.544	0.547	0.581	0.565
2003-2004	0.512	0.490	0.530	-	0.504	0.499	0.657	0.442	0.518	0.501	0.523
2005-2006	0.509	0.456	0.561	-	0.571	0.492	0.676	0.580	0.427	0.542	0.485
2007-2008	0.460	0.394	0.539	-	0.473	0.402	1.407	0.505	0.336	0.431	0.464
2009-2010	0.483	0.425	0.545	-	0.608	0.526	0.519	0.402	0.392	0.452	0.512
2011-2012	0.451	0.459	0.442	0.922	0.502	0.328	0.440	0.469	0.260	0.459	0.442
2013-2014	0.460	0.430	0.495	1.136	0.433	0.376	0.452	0.381	0.367	0.429	0.495
2015-2016	0.445	0.466	0.420	1.464	0.424	0.397	0.359	0.529	0.313	0.466	0.420
2017-2020	0.359	0.361	0.356	0.629	0.370	0.320	0.402	0.388	0.293	0.322	0.368

a. Dashes (-) indicate the absence of metal data for the specified years within the given category.

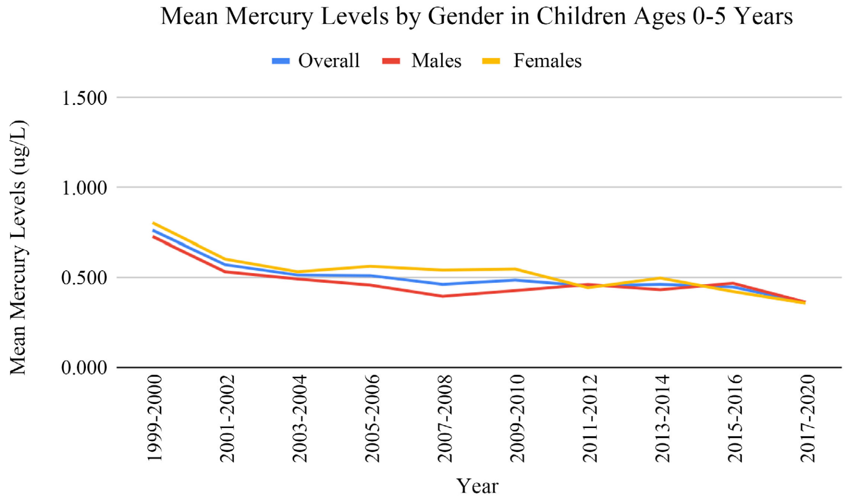

Figure 4. Mean mercury levels by gender.

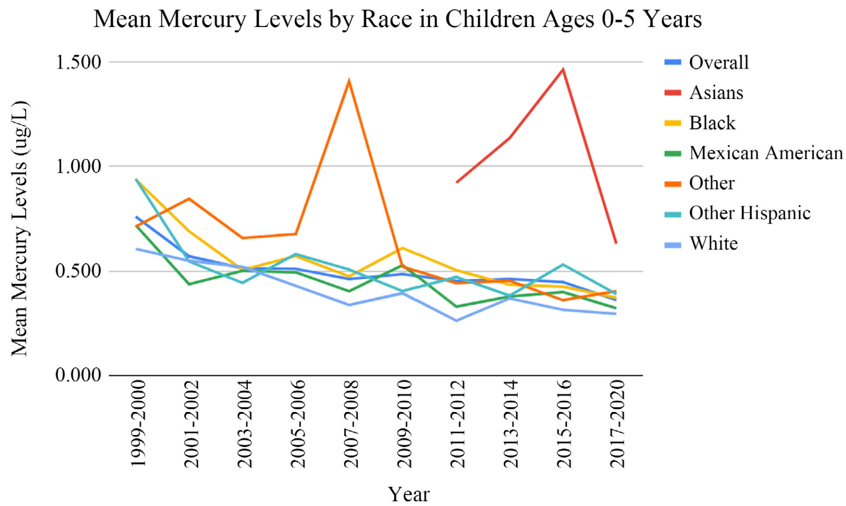

Figure 5. Mean mercury levels by race.

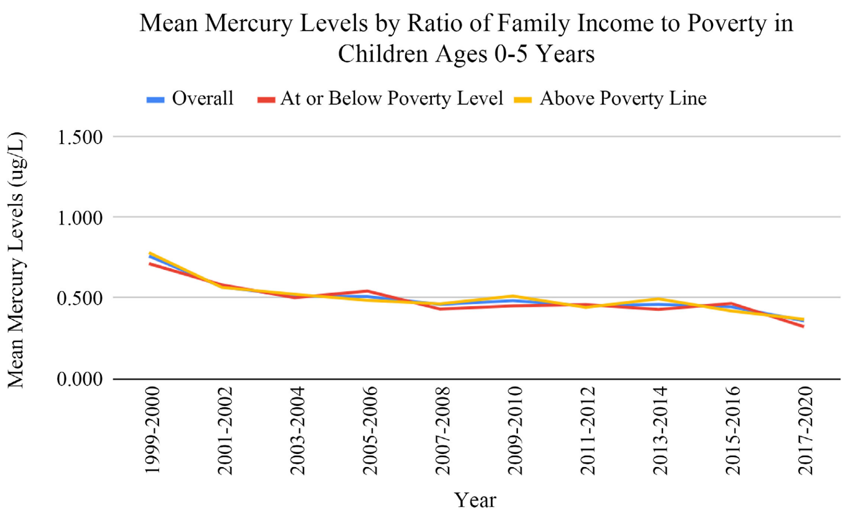

Figure 6. Mean mercury levels by ratio of family income to poverty.

3.4. Mean Cadmium Levels

Table 4 provides a comprehensive overview of mean cadmium (Cd) levels among children aged 0 - 5, categorized by gender, race, and the ratio of family income to poverty. A longitudinal analysis spanning from 1999 to 2020 reveals a notable decreasing trend in the overall mean cadmium levels (0.265 μg/L - 0.093 μg/L). Figure 7 illustrates that males and females consistently exhibit similar mean cadmium levels, aligning with the overall cadmium levels. There is a consistent downward trend observed for both genders, with occasional spikes and a recent increase. When analyzing cadmium levels by race, trends have been decreasing with occasional spikes (Figure 8). However, the other race category has shown an increase in mean cadmium levels in recent times. Asian children, particularly, have had cadmium levels higher than other races and the overall average. Mean cadmium levels by ratio of family income to poverty demonstrate an overall decrease (Figure 9).

Table 4. Mean cadmium levels by gender, race, and ratio of family income to poverty in children ages 0 - 5.

Year	Mean Cadmium Levels										
	Overall	Males	Females	Asian	Black	Mexican American	Other	Other Hispanic	White	At or Below Poverty Line	Above Poverty Line
1999-2000	0.265	0.263	0.267	-	0.255	0.283	0.098	0.227	0.261	0.266	0.263
2001-2002	0.212	0.213	0.211	-	0.211	0.212	0.219	0.205	0.214	0.212	0.213
2003-2004	0.133	0.135	0.130	-	0.152	0.120	0.120	0.132	0.127	0.142	0.126
2005-2006	0.154	0.154	0.155	-	0.162	0.150	0.154	0.149	0.153	0.155	0.154
2007-2008	0.153	0.153	0.153	-	0.157	0.149	0.170	0.149	0.152	0.154	0.152
2009-2010	0.149	0.149	0.149	-	0.159	0.147	0.150	0.147	0.146	0.149	0.149
2011-2012	0.130	0.131	0.129	0.165	0.128	0.129	0.130	0.125	0.120	0.131	0.129
2013-2014	0.086	0.088	0.085	0.113	0.083	0.085	0.097	0.082	0.081	0.088	0.085
2015-2016	0.091	0.090	0.090	0.121	0.093	0.094	0.082	0.089	0.084	0.090	0.091
2017-2020	0.093	0.093	0.094	0.118	0.090	0.092	0.110	0.081	0.091	0.089	0.096

a. Dashes (-) indicate the absence of metal data for the specified years within the given category.

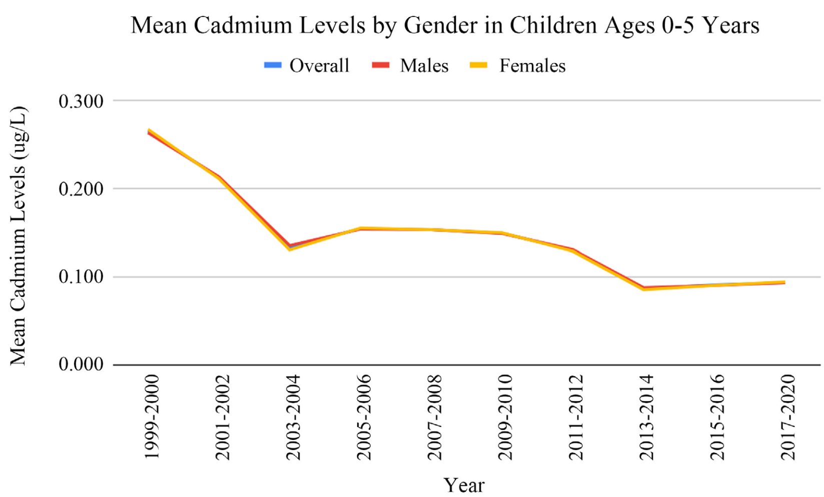

Figure 7. Mean cadmium levels by gender.

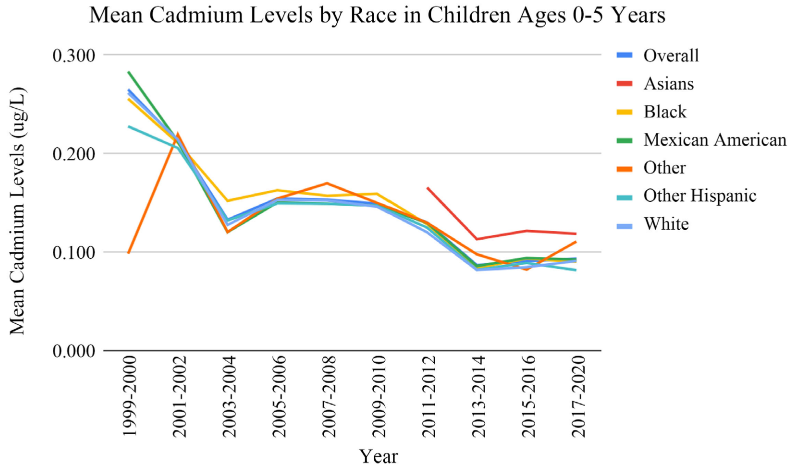

Figure 8. Mean cadmium levels by race.

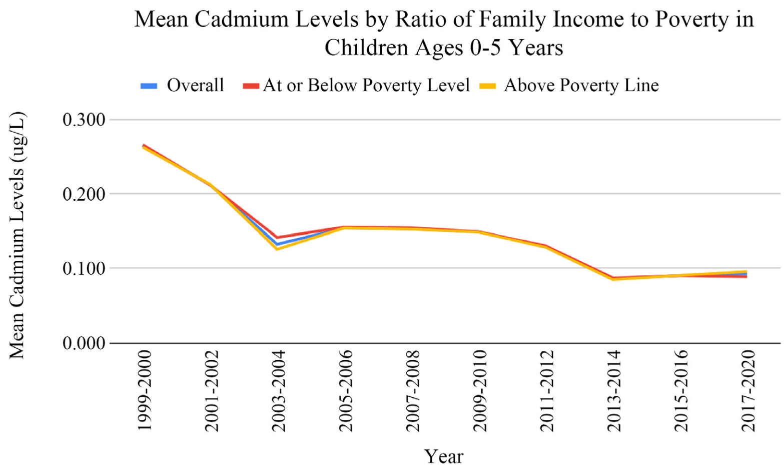

Figure 9. Mean cadmium levels by ratio of family income to poverty.

3.5. Mean Selenium Levels

Table 5 provides a comprehensive overview of mean selenium (Se) levels among children aged 0 - 5, categorized by gender, race, and the ratio of family income to poverty. A longitudinal analysis spanning from 1999-2000 to 2011-2020 reveals that the overall mean selenium levels have remained consistent throughout the years, with a decrease in 2017-2020 (108.020 μg/L - 160.895 μg/L). Change in mean selenium levels over time was similar for males and females, suggesting no significant gender differences (Figure 10). In terms of race, selenium levels for each distinct demographic have also been consistent. The Other Hispanic and Asian demographics consistently demonstrate selenium levels below the overall average. In contrast, White children exhibit higher selenium levels compared to other races and the overall mean levels (Figure 11). Children from both socioeconomic categories, at or below the poverty line and above it, exhibit similar selenium concentrations to each other and in comparison to the overall average levels, suggesting that ratio of family income to poverty does not impact selenium levels in children (Figure 12).

Table 5. Mean selenium levels by gender, race, and ratio of family income to poverty in children ages 0 - 5.

Year	Mean Selenium Levels										
	Overall	Males	Females	Asian	Black	Mexican American	Other	Other Hispanic	White	At or Below Poverty Line	Above Poverty Line
1999-2000	108.020	108.630	107.280	-	105.260	108.702	120.270	104.450	109.530	106.653	109.160
2001-2002	-	-	-	-	-	-	-	-	-	-	-
2003-2004	-	-	-	-	-	-	-	-	-	-	-
2005-2006	-	-	-	-	-	-	-	-	-	-	-
2007-2008	-	-	-	-	-	-	-	-	-	-	-
2009-2010	-	-	-	-	-	-	-	-	-	-	-
2011-2012	166.159	166.655	165.630	165.003	165.247	167.174	166.373	163.683	169.216	166.655	165.630
2013-2014	167.800	166.940	168.753	163.870	168.795	164.888	170.219	166.737	170.290	166.940	168.753
2015-2016	166.400	164.593	168.394	164.016	167.415	167.870	164.672	162.894	166.802	164.593	168.394
2017-2020	160.895	161.055	160.717	158.395	160.841	163.167	163.353	156.031	161.080	161.839	160.778

a. Dashes (-) indicate the absence of metal data for the specified years within the given category.

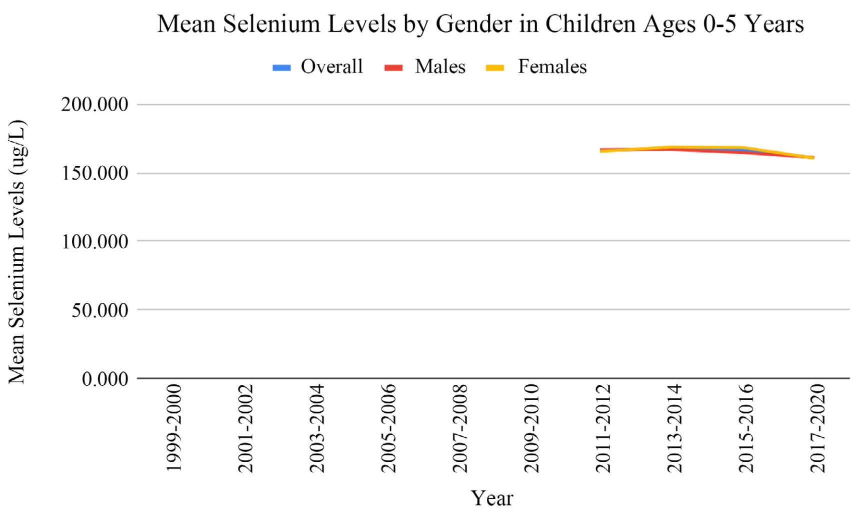

Figure 10. Mean selenium levels by gender.

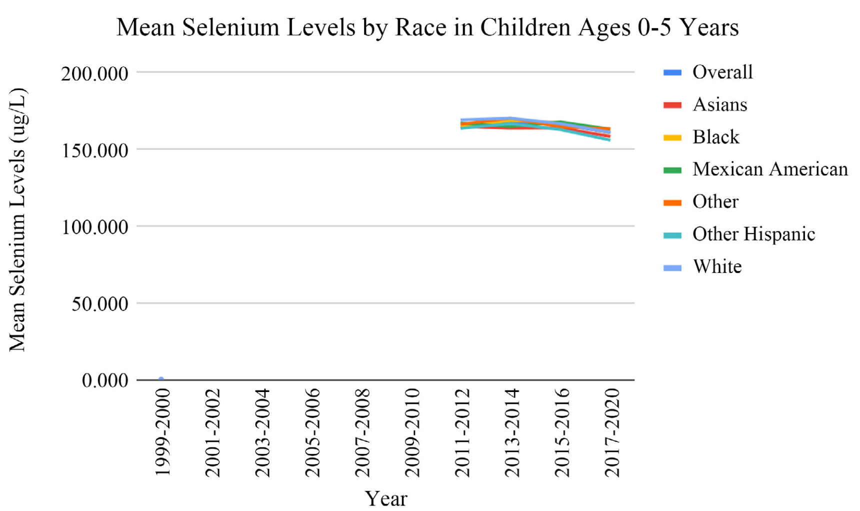

Figure 11. Mean selenium levels by race.

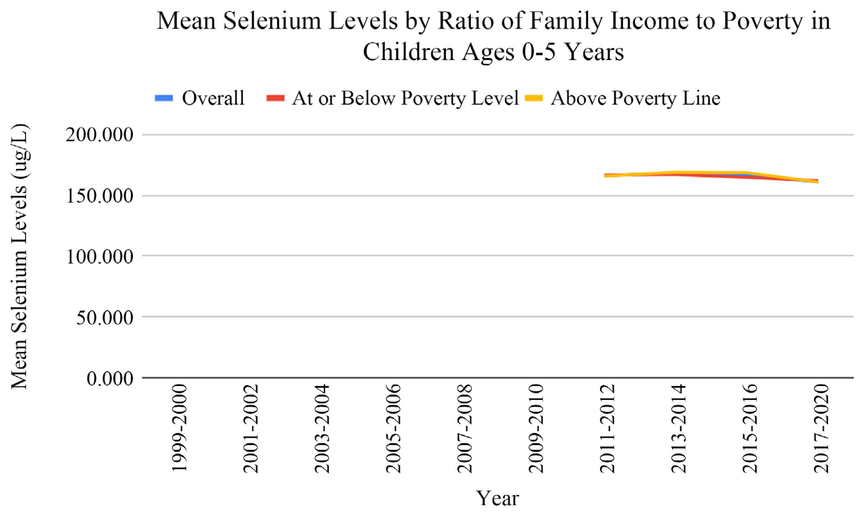

Figure 12. Mean selenium levels by ratio of family income to poverty.

4. Discussion

While there has been a decrease in mean levels of lead (Pb), mercury (Hg), cadmium (Cd), and selenium (Se) in children from 1999 to the present day, it is important to note that heavy metals should be absent in children entirely. Currently, there are no safe levels of As, Pb, Hg, Cd, and Se in children, as all elevated levels are of concern since heavy metals are highly toxic elements that provide no added physiological benefits. However, the Centers for Disease Control (CDC) uses a blood lead reference value (BLRV) of 3.5 μg/dL to identify children with higher levels than the average and the United States Environmental Protection Agency (EPA) has set a blood mercury level of <5.8 μg/L as a threshold for no health effects [27] [28]. Additionally, according to the CDC the 95% confidence limit for blood cadmium levels is 0.4 μg/L [29].

One notable trend highlighted that children aged 0 - 5 belonging to the Black demographic tended to exhibit higher lead levels compared to the overall average, whereas those of the Asian subgroup displayed higher levels of total blood mercury and cadmium. Mean cadmium levels were consistent across gender and socioeconomic categories, with slight variations observed across different racial and ethnic groups. Mean selenium levels have demonstrated consistency across all tested demographics.

4.1. Limitations and Strengths

This study is subject to certain limitations, including the inability to directly attribute the observed changes in overall mean levels of heavy metals in children's bloodstream to the increase of toxic elements in infant food products. Various factors can contribute to the presence of heavy metals in the bloodstream, such as environmental exposures, water sources, air pollution, and other dietary sources beyond infant food alone. Additionally, individual variations in metabolism, genetics, and lifestyle factors may influence the levels of heavy metals in the body. While the data suggests associations between heavy metal levels and certain demographics, caution should be exercised in drawing direct relationships between infant food products heavy metal levels in children. Further research is necessary to assess the contribution of different sources and factors to the levels of heavy metals in children's bloodstream. The absence of available data on arsenic levels in the bloodstream of children aged 0 - 5 hinders an analysis of arsenic exposure in young children. Existing arsenic data in NHANES primarily focuses on children aged six and above, limiting the ability to draw conclusions regarding mean levels. This data gap highlights the need for future data collection of arsenic by NHANES to accommodate the youngest age brackets.

Strengths of this study include the utilization of a representative sample with survey responses from a diverse range of demographics which increases the generalizability of the findings. Further, while infant food products primarily target children aged six months to three years of age, this study extended the age range to include infants and children from zero years to the age of five. Through a broader age group, the study provides a more comprehensive overview of heavy metal exposures in children and allows for the observation of potential lasting mean levels impacts and effects of heavy metals beyond the toddler age and into the school-aged years.

While some decrease in heavy metal concentrations over time has been observed, the current levels are still high. It is imperative for regulatory bodies, such as the FDA to intervene and develop stringent strategies to combat this issue. Similarly, vigilance must be warranted by infant food companies and manufacturers to take proactive steps to decrease heavy metals in their products.

4.2. Proposed Levels of FDA Intervention

1) Preventing Contamination at the Sources of Raw Materials Used in Products

2) Transparency with Consumers on Levels of Heavy Metals in Infant Foods through Extensive Product Testing and Comprehensive Manufacturer Labeling

4.2.1. Concerns over Source Contamination and Prevention

Thorough testing and screening of raw materials before the manufacturing and milling processes of fine infant powder foods is a crucial preliminary step. This is imperative as the sources of the ingredients used in these products can be a potential contamination point for heavy metals. This precautionary measure is significant for products containing rice, flour, and grain, which are ingredients proven to be susceptible to heavy metal contamination from environmental exposures [17].

Parents and caregivers must be vigilant and avoid infant food products that contain rice, such as rice cereals, snacks, food pouches, purees, and similar items. Rice has been recognized as a notable source of increased heavy metal content and accumulation, especially arsenic, which poses potential health effects. Opting for alternative food options that are known to have lower levels if not any heavy metals can minimize risk.

Manufacturers must consider substituting the raw materials in infant foods that are known to have heavy metal contamination, specifically rice and grains, along with ingredients that contain rice, for alternatives that have lower levels of heavy metals. Sourcing raw materials for products from regions with stricter regulations and practices regarding heavy metal contamination can also reduce levels significantly. Manufacturers can enhance their quality control measures by requesting reports from suppliers on the content and profiles of heavy metals levels in their ingredients to assure that the ingredients meet the necessary safety standards for infant consumption. Prioritizing such rigorous testing can ensure a comprehensive understanding of the ingredients before incorporating them into their products.

Another solution is that the FDA contacts these infant food manufactures and conglomerates to remove products from the market entirely that consistently contain ingredients and raw materials testing high for heavy metals.

4.2.2. Mandatory Rigorous Testing Enforced by the FDA

The FDA should implement periodic testing intervals of heavy metals in infant food products to ensure ongoing safety and quality. Regular testing can be conducted in monthly or quarterly intervals to consistently monitor and evaluate risks to ensure that infant food products mass produced by conglomerates are not contaminated. Periodic testing can enable the FDA to assess the compliance of manufacturers and promptly identify contamination issues.

The FDA should also encourage open data sharing with the public regarding the levels of heavy metals present in infant food products from various companies. Providing this information fosters transparency and enables caregivers to make informed choices.

Surprise testing of products could also hold manufacturers accountable and ensure abidance with safety regulations. Through the FDA conducting unannounced tests on products, they can assess at random the ongoing quality control practices of infant food companies and conglomerates. This approach not only helps identify any potential shortcomings but also motivates manufacturers to maintain constant vigilance in their own self-assessment and quality assurance processes.

Aside from the FDA performing rigorous testing of infant products on the market, manufacturers themselves must be mandated by regulatory bodies, such as the FDA, to increase their own product testing and assess heavy metal levels in their finished products. Manufacturers must be regularly testing throughout the entire production process from assessing levels in their raw materials, vitamin mixes, flavorings, and additives up until the product is completed and ready to be transported to markets for sale. This approach is similar to FDA's regulations on the product testing of cosmetics, which requires manufacturers to do toxicological testing to "determine the safety of each ingredient and the finished product” [30].

4.2.3. Lack of FDA Maximum Levels for Heavy Metals in Infant Foods

The FDA must establish stricter maximum levels of As, Pb, Hg, Cd, and Se in infant food products to prevent toxicity and mitigate developmental issues in children. While the FDA’s has been issuing draft guidances to the general public on plausible maximum levels in regards to arsenic and lead through their Closer to Zero initiative, recommendations alone are simply not sufficient [18]. The FDA must issue legally binding limits and compliance orders to hold infant food manufacturers accountable for ensuring heavy metal contents in their products are within safe thresholds. Furtherly, the levels proposed in the draft guidances are still far too high and lack adequate protection as abundant amounts of research have consistently indicated that even low levels of toxic elements in developing infants and children can have detrimental neurological impacts [4]-[13]. In summary, the FDA and subsequent regulatory bodies, are not setting quantified standards or limits of the amount of heavy metals acceptable in infant food products.

4.2.4. Manufacturer Labeling of Heavy Metal Warnings on Products

Infant food manufacturers should consider enhancing current food labels to provide detailed information about the presence of heavy metals including, As, Pb, Hg, and Cd. This can be achieved by applying warning signs or labels on the packaging. This additional layer of consumer transparency can allow caregivers to make more informed decisions about the products they introduce to their children and be aware of potential heavy metal exposure.

5. Conclusion

While the study found that heavy metals have generally been decreasing in children overall and across various demographics overtime, it is still imperative for regulatory bodies, such as the FDA to intervene and develop stringent strategies to combat the issue of heavy metal contaminants in infant food products. This may be done through preventing contamination of raw materials used in products, setting maximum allowable limits of heavy metals in infant food products, comprehensive manufacturer labeling, and mandatory rigorous product testing by manufacturers and regulatory bodies.

Acknowledgements

I would like to thank the Polygence Research Academy for their support, including their mentors and reviewers, Shaina Desai, Desiree Chu, and Makenna Lenover.

Funding

This research received no external funding.

Data Availability

Publicly available datasets were analyzed in this study. This data can be found here: https://wwwn.cdc.gov/nchs/nhanes/Default.aspx.

Conflicts of Interest

The author declares no conflicts of interest regarding the publication of this paper.

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