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EDF HEALTH

Lead in food: A hidden health threat

FDA and industry can and must do better **June 15, 2017**

EDF's analysis of 11 years of FDA data found:
- *Lead was detected in 20% of baby food samples compared to 14% for other foods.*
- *Eight types of baby foods had detectable lead in more than 40% of samples.*
- *Baby food versions of apple and grape juices and carrots had more samples with detectable lead than the regular versions.*

EDF also found that more than 1 million children consume more lead than FDA's limit. Eliminating lead in food would save society more than $27 billion annually in total lifetime earnings from saved IQ points.

Food is a meaningful – and surprising – source of young children's exposure to lead

No safe level of lead in blood has been identified. In children, even very low blood lead levels can cause behavioral problems and lower IQ. Protecting children's ability to learn and thrive demands that we find effective ways to reduce exposures to lead from all sources. Environmental Defense Fund (EDF) analyzed 11 years of data from the Food and Drug Administration (FDA) and found that food, and baby food in particular, is a meaningful – and surprising – source of lead. If it were eliminated completely, we estimate the societal benefits at more than $27 billion annually. In this report, EDF presents the major findings of our analysis and recommendations for how to take steps towards reducing children's exposure to lead in food.

EDF evaluated data collected and assayed by FDA from 2003 to 2013 as part of the agency's Total Diet Study (TDS). Since the 1970s, the TDS has tracked metals, pesticides, and nutrients in food. Overall, 20% of 2,164 baby food samples and 14% of the other 10,064 food samples had detectable levels of lead. At least one sample in 52 of the 57 types of baby food analyzed by FDA had detectable levels of lead in it.

Lead was most commonly found in the following baby food types:

- Fruit juices: Grape (89% of 44 samples), mixed fruit (67% of 111 samples), apple (55% of 44 samples), and pear (45% of 44 samples)
- Root vegetables: Sweet potatoes (86% of 44 samples) and carrots (43% of 44 samples)
- Cookies: Arrowroot cookies (64% of 44 samples) and teething biscuits (47% of 43 samples)

The report also shows that samples of the baby food versions of apple and grape juices and carrots had detectable lead more often than their regular versions.

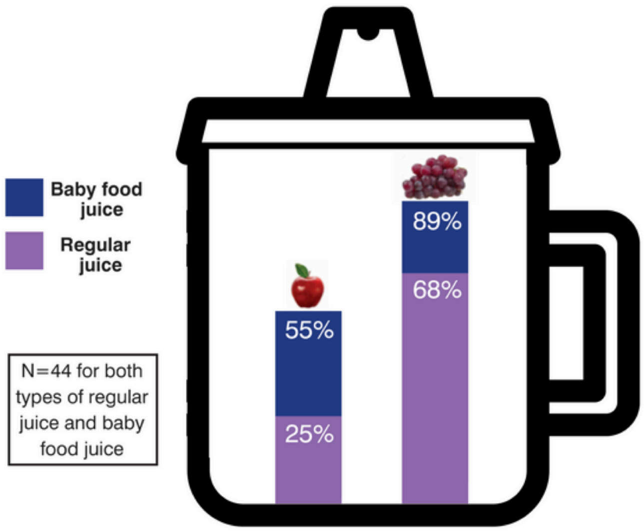
More than 1 million young children over FDA's limit

FDA set a maximum daily intake level of 6 micrograms of lead a day (µg/day) in 1993 based on its review of the science. Earlier this year, the Environmental Protection Agency (EPA) estimated that over 5% of children between ages 2 and 6 years—more than 1 million children—exceed the 6 µg/day of lead in their diet. The FDA has yet to update its decades-old daily exposure limit.
For fruit juices, however, FDA relies on international limits for the amount of lead allowed in juices. For apple juice, the limit is set at 30 parts per billion (ppb) and 50 ppb for grape juice; these

levels are based on ensuring 95% of juice produced globally can achieve them. By comparison, the limit for bottled water is 5 ppb.

In May 2017, the agency said it is reevaluating the juice limits.

Percentage of samples with detectable lead based on 2003-2013 FDA Total Diet Study data



Both FDA and food manufacturers can and must do better to reduce lead in food, especially baby food

EDF recommends that FDA:

- Ensure lead is not added to any food contact material where it is reasonably expected to get into food;
- Make clear that the international standards for fruit juice are inadequate;
- Update its limits and food safety guidance to reflect current scientific understanding of lead risks that better protect children; and
- Encourage manufacturers to reduce lead levels in food and take enforcement action when limits are exceeded.

Manufacturers need not wait for FDA to act. EDF recommends companies:

- Set a goal of less than 1 ppb of lead in baby food and other foods marketed to young children;
- Continue to prioritize lead contaminant minimization when sourcing ingredients;
- Test more frequently during processing to identify additional sources of lead, and take appropriate corrective actions; and
- Publicly commit to consumers to drive down lead levels through health-protective limits and robust product stewardship.

In the meantime, parents should consult with their child's pediatrician to learn about all the ways to reduce lead exposure. They should also check with their favorite brands to ask whether the company:

- Regularly tests its products for lead; and
- Ensures that, especially for baby food, there is less than 1 ppb of lead in the food and juices they sell.

Healthy eating requires safe, nutritious food. Lead has no place in a child's diet.

Introduction

No safe level of lead in blood has been identified. In children, even very low blood lead levels can cause behavioral problems and lower IQ.[1] When lead is ingested, some gets into the blood[2] and poses a risk of harm to a child's developing brain, contributing to learning and behavioral problems and lower IQ.[3] As the American Academy of Pediatrics stated in 2016, "The key to preventing lead toxicity in children is to reduce or eliminate persistent sources of lead exposure in their environment."[4]

Most discussion about lead exposure has involved paint, drinking water, and contaminated soil or dust where young children live, play, and learn. When children have unusually high levels of lead in their blood, these are the most likely sources.[5]

One poorly understood and often overlooked source of lead is contaminated food. A January 2017 draft report[6] from EPA provided useful insight on how much lead young children may be exposed to from their diet (Table 1).

Table 1. EPA's estimated dietary exposures to lead in micrograms per day (µg/day)

Age of child	Mean	Top 5%
0-6 months	0.27	2.71
0-1 years	0.65	3.88
1-2 years	2.00	5.83
2-3 years	2.85	7.23
3-4 years	2.98	7.26
4-5 years	3.00	7.25
5-6 years	3.31	7.86
6-7 years	3.29	7.55

Derived from Exhibit 10 in EPA's draft "Proposed Modeling Approaches for a Health Based Benchmark for Lead in Drinking Water," 2017. Mean is geometric mean. Top 5% is the 95th percentile.

To provide context for the potential significance of these levels, FDA's Provisional Tolerable Total Dietary Intake level (PTTDI) (also known as the maximum daily intake level) of lead for young children is 6 µg/day.[7] FDA uses this level, set in 1993, to assess the risk of lead in food and to support enforcement actions, rulemaking, and guidance development.[8] With more than 20 million children aged 2 to 6 years in the U.S., we estimate that more than 1 million (5% of 20 million) of those children consume more lead than the PTTDI (6 µg/day).

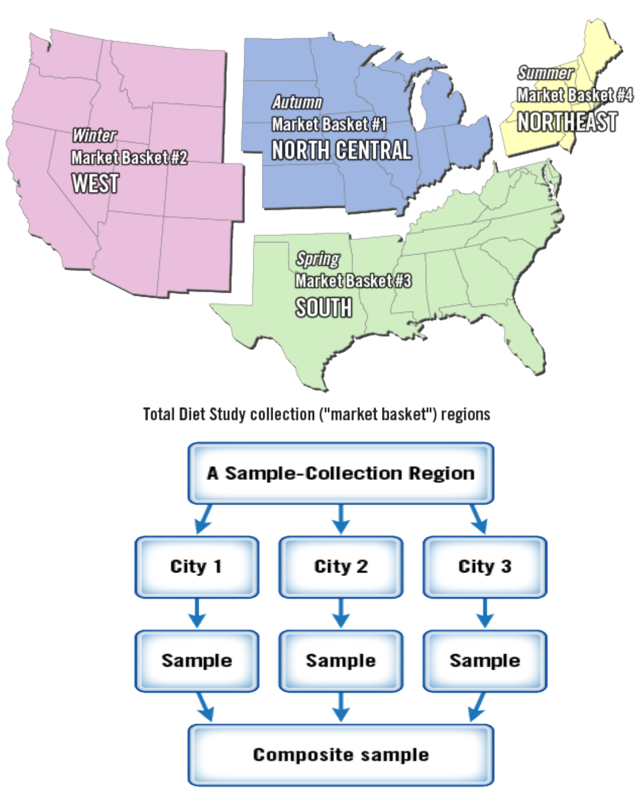
EDF also estimates that if lead in food were eliminated, millions of children would live healthier lives, and the total societal economic benefit would exceed $27 billion a year in increased lifetime earnings resulting from the impact of lead on children's IQ. See Appendix 1 for calculations.

What is FDA's Total Diet Study?

EDF's analysis relies on FDA's Total Diet Study (TDS)[9] results from 2003 to 2013. For more than 40 years, FDA has conducted the TDS to monitor levels of approximately 800 pesticides, metals, and other contaminants, as well as nutrients, in food. Each year, the agency buys, prepares, and analyzes as many as 280 types of foods and beverages from three different cities in each of the four regions of the country (Figure 1).

About one of every five food types are foods that the agency staff designate as baby foods based on their labeling. If staff who buy the food have an option, FDA directs them to select national brands over a local or house brand.[10] About every decade, FDA revises the food types sampled to reflect changing eating patterns. Such an update has not occurred since 2003.[11]

Figure 1. Total Diet Study regions and sampling method[12]



For each type of food, the samples bought within each of the four regions are blended together to form a composite sample and then assayed (Figure 1). For each composite sample, FDA provides details including the year and region represented, the concentration of the contaminant or nutrient found, and the limit of detection (LOD).

The LOD is the lowest level at which FDA could say with confidence that a chemical, such as lead, was present. The LOD for lead in the TDS varies from 4 ppb for most beverages, including fruit juices, to 20 ppb, for some solid foods like butter, candy, and potato chips. The highest LOD for baby foods is 10 ppb for cereals and crackers. In contrast the Limit of Quantification (LOQ) is the level at which FDA was confident that the measurement was accurate. The LOQ is always greater than the LOD.

What did EDF do?

EDF evaluated more than 12,000 publicly available test results from 11 years of FDA's TDS.[13] The combined data are available on our website.[14]

While we evaluated all types of food collected by FDA, we focused on 57 types of baby food because infants are most vulnerable to lead.[15] We divided baby food into eight categories: root vegetables; non-root vegetables; fruits including juices; cereal; infant formula; prepared meals; crackers and cookies; and desserts. See Appendix 2 for the list of baby foods included in each category.

We specifically focused on fruit juice because it is more likely than other food types to have soluble instead of particulate lead due to its lower pH.[16] Soluble lead is a greater concern because it is more easily absorbed into the body when ingested than particulate lead.[17]

Our analysis focused on detectable levels of lead (at or above the LOD) for two reasons: 1) even low levels of lead in the blood increases the risk of harm to children's brain development; and 2) most of the composite samples had amounts of lead that were below the LOQ and, therefore, could not be reliably quantified. In addition, the number of composite sample results of most food types was small (44 or less) and most were below the LOQ. Therefore, we opted not to calculate average concentrations and focused on what we could say with confidence – whether lead was detected by FDA or not. We do report the amount of lead in a specific food type if the level was above the LOQ.

FDA reported to us that in 2014 it upgraded its analytical method to lower the amount of lead that can be detected and quantified. However, new data are not publicly available as of June 2017.

What did EDF find in FDA's TDS?

Overall, 20% of the 2,164 baby food composite samples and 14% of the other 10,064 food composite samples had detectable levels of lead. Complete results (44 composite samples per food type for the 4 regions for 11 years) for 262 of 286 food types including 37 of 57 baby foods are available from the TDS. For the remaining food types, there are less than 44 results because the agency could not find the type of food or there were problems in the collection, preparation, or analysis of the composite sample.

Fifty-two of the 57 types of baby foods had at least one composite sample with detectable levels of lead. In Figure 2, we plotted the eight baby food categories based on the percent of composite samples with detectable levels of lead versus those with non-detectable levels.

The root vegetables category had the highest rate of lead detection, with lead found in 65% of the composite samples. The crackers and cookies category was next with 47% followed by fruits, including juices, with 29%. The cereals category had the lowest percent lead detection with 4%. However, in some categories with comparably low rates of detection, there were composite samples with particularly high levels of lead. For example, two prepared baby food meals, a turkey rice dish and a vegetable beef dish, had concentrations of 34 ppb and 64 ppb of lead respectively, and one dry rice cereal had a concentration of 40 ppb. The LOQ was 30 ppb for the two meals and 40 ppb for the rice cereal.

Due to the high rate of detectable lead in baby food root vegetables, crackers and cookies, and fruit juices, we analyzed each of these categories in more depth (Figure 3). Sweet potatoes had a higher rate of detection than carrots, and had a maximum concentration of 34 ppb of lead in one composite sample. Specialty crackers and cookies marketed for teething babies, including arrowroot cookies and teething biscuits, had surprisingly high rates of lead detection – 64% and 47% respectively – in the composite samples tested.

Figure 2. Percentage of baby food composite samples with detectable lead in eight categories based on 2003-2013 FDA Total Diet Study data

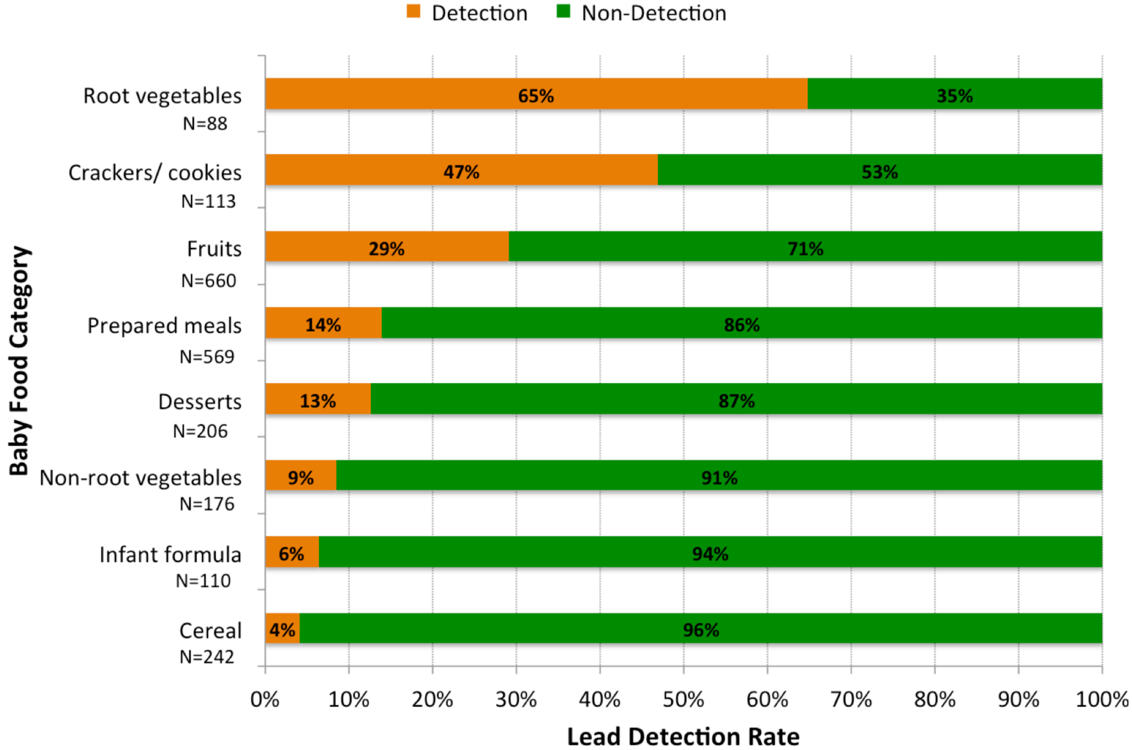
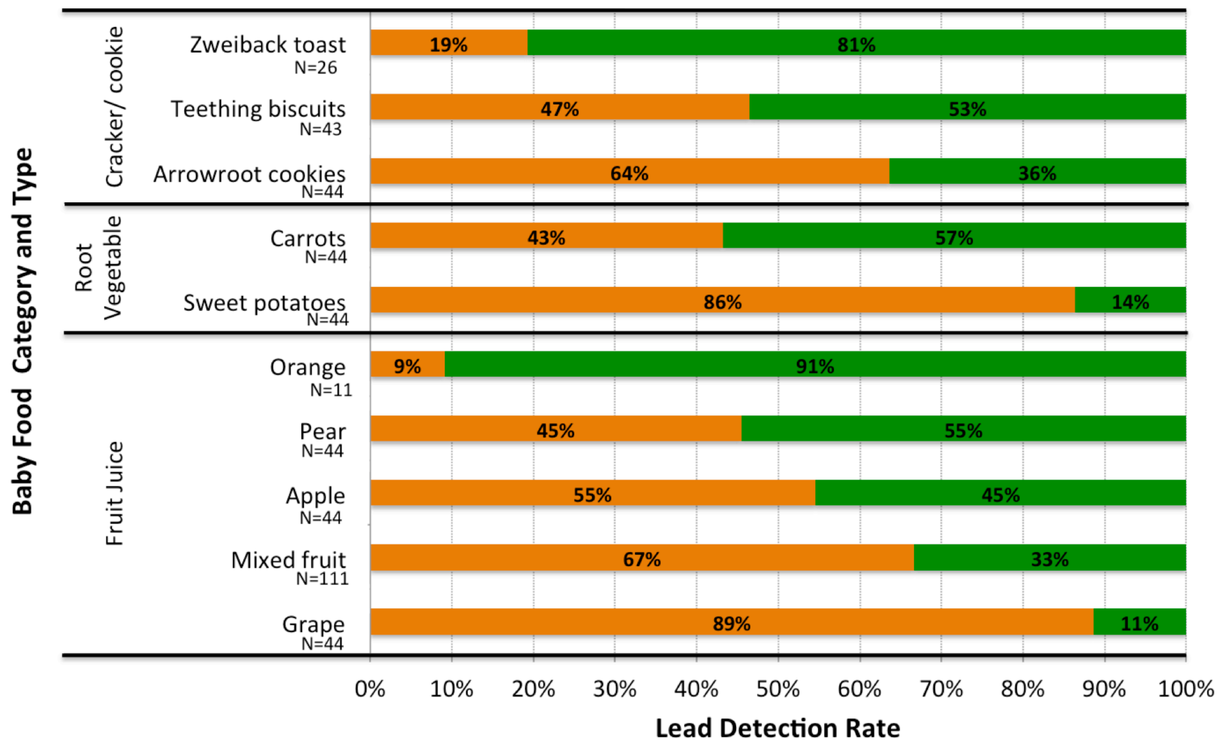


Figure 3. Percentage of composite samples of selected baby foods with detectable lead based on 2003-2013 FDA Total Diet Study data



Of the baby food fruit juices, grape juice had the highest rate of lead detection, followed by mixed fruit juices – including apple-banana, apple-cherry, apple-grape, and mixed fruit – and then apple and pear juices. Orange juice had the lowest rate. One apple juice composite sample had the highest concentration of lead of the baby food fruit juices at 29 ppb, followed by mixed and grape juice composite samples with 23 and 20 ppb, respectively. For juices, the LOD was 4 ppb, and the LOQ was 20 ppb.

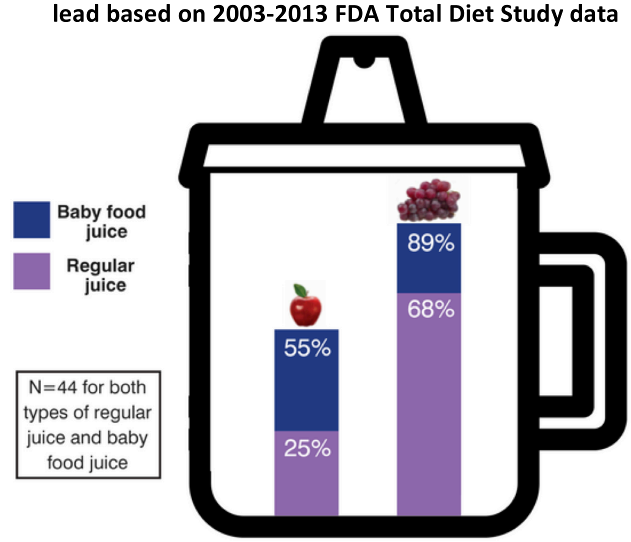
We also compared the lead detection rates for the three types of baby food fruit juices –apple, grape and orange – for which there were composite samples of the raw fruit sold in stores and fruit juice not specifically marketed to babies (regular fruit juice). For apple and grape, baby food fruit juice consistently had higher lead detection rates than regular fruit juice (Figure 4).[18] We did not see higher detection rates for baby food orange juice compared to regular. The same pattern was true for carrots with lead detected in 44% of baby food carrots but only 14% of regular carrots.

Although apple and grape processed juices had higher lead detection rates than the corresponding raw fruits analyzed in the TDS, we cannot make a direct comparison due to different LODs.

These findings raise important questions that need further investigation:

- Are foods marketed for infants and babies more likely to have lead contamination when compared with similar products not marketed to infants and babies?
- If there is a significant difference, what are the contributing factors? These might include the source of the crop, growing conditions, varieties, food and juice processing and preparation.

Figure 4. Percentage of composite samples with detectable lead based on 2003-2013 FDA Total Diet Study data



How much lead has FDA determined is tolerable to eat?

In 1993, FDA established a Provisional Tolerable Total Dietary Intake level (PTTDI) for lead of 6 µg/day for young children.[19] It relied on the Level of Concern set by the Centers for Disease Control and Prevention (CDC) two years earlier. At the time, the FDA stated that the PTTDI was provisional; it "may be reduced if additional research shows even lower blood [lead] levels cause adverse health effects."[20]

In May 2017, FDA affirmed that it continues to use the PTTDI as the maximum daily intake level for lead exposure but also indicated it is reevaluating its standard.[21] Such a reevaluation is long overdue and urgently needed since the level does not reflect the scientific discoveries of the past 25 years, which show that no safe level of lead in the blood of children has been identified.[22]

FDA's continued use of the 1993 PTTDI stands in stark contrast to recent scientific conclusions made by other federal agencies as well as an international scientific advisory committee on food additives safety. Specifically:

- In 2008, EPA lowered its air quality standards for lead and acknowledged that blood lead levels below CDC's Level of Concern were expected to "cause a greater incremental increase in adverse neurocognitive effects" in children than at higher levels.[23]
- In 2011, the Joint Food Agricultural Organization/ World Health Organization Expert Committee on Food Additives (JECFA), an international scientific body for food additive and contaminant safety, withdrew its Provisional Tolerable Weekly Intake level that it set in the 1980s concluding "that it was not possible to establish a new PTWI that would be considered health protective."[24]
- In 2012, the National Toxicology Program (NTP), a part of the National Institutes of Health, conducted a comprehensive review and concluded that blood lead levels less than 5 µg/dL had sufficient evidence of "decreased academic achievement, IQ, and specific cognitive measures; increased incidence of attention-related behaviors and problem behaviors."[25] These blood lead levels are half of those upon which FDA based its PTTDI.
- In 2012, CDC concluded that no safe level of lead in children's blood has been identified.[26] It replaced its Level of Concern with a reference level set at 5 µg/dL to represent the levels in the 97.5th percentile of children.[27] CDC is expected to further reduce the level to 3.5 µg/dL in 2017.[28]

"Because the dose-response analyses do not provide any indication of a threshold for the key effects of lead, the Committee concluded that it was not possible to establish a new PTWI [Provisional Tolerable Weekly Intake] that would be considered to be health protective."

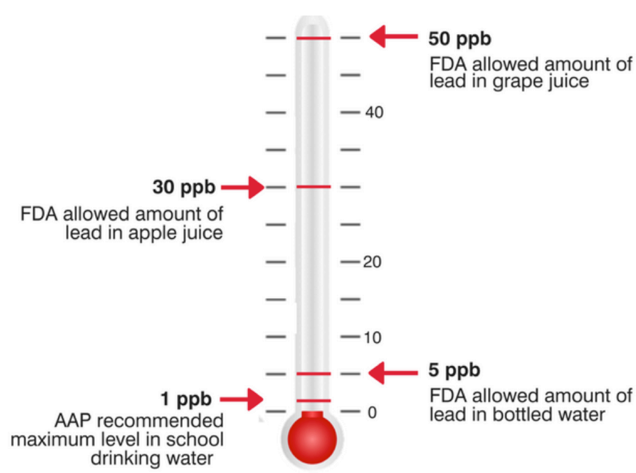
Joint Food Agricultural Organization/ World Health Organization Expert Committee on Food Additives (JECFA) in 2011

Does FDA have standards for lead contamination in specific foods?

FDA has set limits for lead in a few foods:[29]

- Bottled water (5 ppb);
- Juices from berries and other small fruits, including grapes, and passion fruits (50 ppb);
- Other fruit juices and nectars including apple (30 ppb);
- Candy likely to be consumed by small children (100 ppb);[30] and
- Dried fruits, including raisins (100 ppb).[31]

Figure 5. Limits on lead allowed in juices and water



Only the bottled water limit is established in regulations.[32] For the rest, FDA sets the limits in guidance or other actions. The bottled water limit was set at 5 ppb because it was the lowest amount FDA could reliably measure in 1995, and only 4% of the water tested exceeded the limit.[33] For comparison, the American Academy of Pediatrics (AAP) recommends lead in drinking water at schools be less than 1 ppb (Figure 5).[34]

For fruit juices, FDA uses international food standards set by the Codex Alimentarius Commission (Codex), an organization representing 188 countries and the European Union.[35] For years, the Codex standard for fruit juice – 50 ppb – was based on a provisional dietary intake level set by JECFA in the late 1980s. In 2011, when JECFA withdrew its provisional level because it concluded it could not identify a health protective weekly tolerance level for lead in food, Codex began the long process of negotiating lower standards.[36]

In 2015, Codex lowered its standard for ready-to-drink fruit juices and nectars (including apple and excluding juices exclusively from berries, and other small fruits and passion fruits) from 50 ppb to 30 ppb. For other fruit juices, including grape, 50 ppb is still the standard while negotiations to lower it remain ongoing.[37] The U.S. led the working group developing the recommendations.

The problem is that the Codex approach is designed to set a level "as low as reasonably achievable."[38] For lead, the revised standard was designed to ensure that about 95% of fruit juices would achieve it.[39] It was not based on the health risks to children, infants, and pregnant women.

While the Codex standard may facilitate trade, we believe it is inadequate to protect children's health. We are greatly concerned that, like FDA, industry may rely on the Codex standards to set their internal "safe" amounts of lead in fruit juice.

Are there additional FDA studies on lead in food?

EDF identified one recent special study that FDA conducted outside of the TDS. In September 2016, FDA reported its lead and cadmium results for 407 samples of infant and toddler food collected as part of its evaluation of arsenic in foods (Table 2).[40] We do not know when and where the products were purchased or what brands are represented. EDF submitted a Freedom of Information Act (FOIA) request on March 16, 2017, with Earthjustice and others, seeking to obtain that information.

From its analysis, the agency stated that "Overall, these data indicate levels of lead and cadmium in infant/toddler foods, on average, are relatively low and are not likely to cause a human health concern."[41] We disagree with that assessment.

Table 2. Results of FDA's special study of heavy metals in infant and toddler foods

Food type	# Samples (all/ organic)	Percent detectable lead	Maximum lead detected
Cereal – Infant/ toddler with rice as only grain	76/33	100%	82 ppb
Cereal – Infant/ toddler with rice and other grains	6/0	100%	8 ppb
Quinoa	30/20	97%	98 ppb
Teething biscuits	27/11	93%	131 ppb
Stage 2 toddler foods with rice	35/13	63%	NA
Cereal – Infant/ toddler without rice	30/4	57%	NA
Juice – Grape	30/5	47%	41 ppb
Cereal – Oat ring	30/2	37%	NA
Juice boxes and pouches with grape or apple	40/8	28%	17 ppb
Raisins	23/7	26%	151 ppb
Toddler puffs	31/7	23%	91 ppb
Peanut butter	29/8	10%	45 ppb
Grapes	10/2	10%	NA
Apples	10/5	0%	NA
Total	407/125	34%	151 ppb

Derived from FDA's "Combination Metals Testing" study posted online in Sept. 2016. NA means FDA reported that the maximum level was below the limit of quantification.

Is lead avoidable in food?

FDA's data, both from the TDS and special studies, showed that the percent of detectable lead levels in food samples varied greatly. Even for the food types with the highest percentages – baby food sweet potatoes and grape juice – some of the samples had no detectable lead. Among baby food fruit juices, orange juice had the lowest rate. Because each of FDA's TDS results are for a composite of three samples from different cities and the agency does not provide brand information, we do not know whether the results with no detectable levels were due to chance or a vigilant manufacturer with strong standards.

When FDA responds to our March 16, 2017 FOIA request, we anticipate having detailed information, including brand and lot number, on more than 400 samples collected by FDA's special study of heavy metals in infant and toddler foods discussed earlier. Until then, the only available data on lead by brand is a study by Consumer Reports in 2012 that looked at arsenic and lead levels in apple and grape juice products.[42] The 88 juice samples were collected in August and September 2011 from around New York City. Thus, the information is limited given the time period in which it was collected and the small region, though in a large market.

With these caveats, we averaged the results by unique combination of juice type, brand, packaging type, and packaging size. The study showed 4 of 28 apple juice products and 3 of 3 grape juice products had lead levels greater than the bottled water standard of 5 ppb.[43] The good news is that 8 apple juice products had levels below 1 ppb, the limit recommended by AAP for drinking water in schools. The two organic apple juice products had levels between 2 and 4 ppb.

Over 75% of the 28 apple juice products had levels below the 4 ppb limit of detection in FDA's TDS. This means the lead in those juices would be undetectable by the agency, which highlights the importance of its ongoing efforts to upgrade its analytical methods.

We looked for changes in the detection rates for all fruit juices and baby food fruit juices in the TDS data available for the two years after the Consumer Reports study was published, 2012 and 2013. Detectable rates of lead in apple and grape juice, especially baby food, appeared to be somewhat lower in 2013 compared to the earlier years, but there were too few composite samples to draw conclusions.

The variability in lead levels across products, including those labeled organic, from both the Consumer Reports study and FDA's special study of heavy metals in infant and toddler foods, suggests that there are important opportunities to reduce lead in food, including baby food. Such opportunities may include more frequent testing of ingredients and final products for lead, managing the supply chain to favor ingredients with lower levels of lead, and controlling potential sources of lead that may enter the product during processing.

Where is the lead coming from?

We were not able to identify any study evaluating the relative contribution of various sources of the lead in food. FDA appears to attribute the lead in food to contamination of soil.[44] More research on sources of lead in food is needed.

Potential sources of lead in the food supply chain are described in Figure 6 and include:

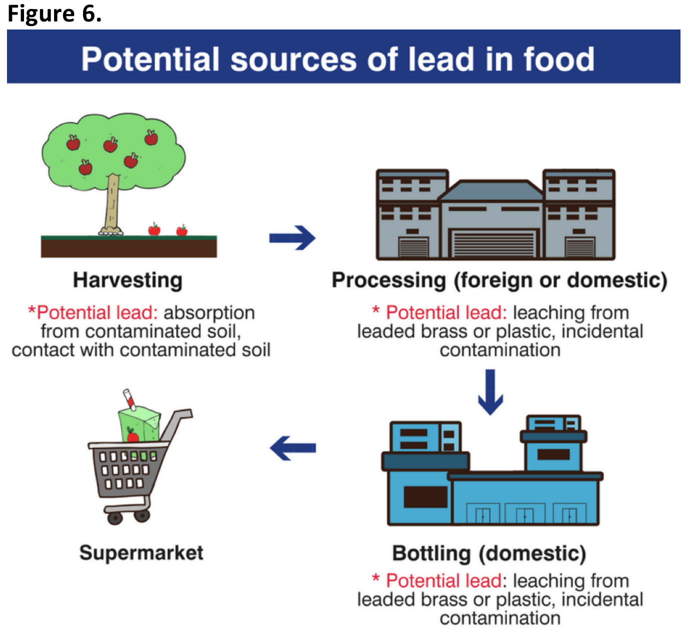
Absorption from contaminated soil into the roots, stem, leaves, and fruit – with some evidence that the fruit may have the lowest levels.[45] Although lead can be naturally present in soil, such background levels would likely be small compared with the amount of contamination from decades of use of lead arsenate pesticides, air deposition from burning leaded gasoline and other industrial operations. Once absorbed by the crop, the lead would likely be difficult to remove.

Contact with contaminated soil in the field. For example, windblown soil may get into a head of lettuce, or an apple being harvested could fall onto the ground.[46] This lead may be removed with washing, but once in juice, the lead would likely be difficult to remove.

Contamination during processing. Potential sources of lead include leaching from brass, bronze, plastic, or coated food handling equipment that contains lead. Since 1997, the National Sanitation Foundation (NSF) has a voluntary standard for commercial food equipment that prohibits lead as an intentional ingredient in any surface material intended to be in direct contact with food.[47] Coatings may have lead as an impurity at levels up to 0.6%. Brass or bronze components in contact with tea, coffee, or water may contain as much as 0.25% lead. Until 2014, the allowable lead level for brass and bronze was 8%.[48]

Incidental contamination of food or food contact materials during processing such as lead from deteriorated paint in the building or air deposition from lead used in aviation fuel for small airplanes.

Figure 6.



Are programs in place in food production to minimize chemical hazards like lead?

Yes. Since 2002, under the Hazard Analysis and Critical Control Point (HACCP) Plan Rule, juice facilities must identify chemical hazards, such as lead, if it is reasonably foreseeable that it could get into food either as a contaminant or from its intentional addition to materials such as brass or plastic used in food handling equipment.[49] A company must also develop and implement preventive controls to assure chemical hazards, like lead, are prevented or minimized, and the food is not adulterated.

In its 2004 HACCP guidance for the juice industry, FDA recommended that companies establish controls to ensure lead levels do not exceed 50 ppb, based on the Codex Alimentarius standard at the time.[50] In 2015, Codex lowered the standard to 30 ppb for fruit juices (including apple) other than juices from berries and other small fruits, including grapes, and passion fruits.[51]

In the FDA Food Safety Modernization Act of 2011 (FSMA), Congress directed FDA to extend the HACCP approach to most other types of food facilities.[52] These facilities have been required since September 17, 2016 to develop and implement a Food Safety Plan similar to the HACCP plan.[53] See Appendix 3 for details.

The HACCP and Food Safety Plans are not publicly available, but they must be available to FDA on request or during an inspection. We are unaware of FDA inspectors specifically asking fruit juice companies about their plans to prevent and minimize lead contamination.

What is the solution to avoiding lead?

FDA and food manufacturers can and must address lead in food. Fruit juices and baby food should be the top priority because of the well-established scientific understanding that even very low blood lead levels can impair brain development and behavior in children.

As we look to better understand how lead is traveling through the food supply chain, EDF has identified actions for FDA, the food industry, and parents to reduce lead contamination in food.

EDF recommends that FDA take the following actions:

- Ensure lead is not added to any food contact material where it is reasonably expected to get into food;
- Make clear that the international standards for fruit juice are inadequate;
- Update its limits and food safety guidance to reflect current scientific understanding of lead risks that better protect children; and
- Encourage manufacturers to reduce lead levels in food and take enforcement action when limits are exceeded.

Manufacturers need not wait for FDA to act. EDF recommends companies:

- Set a goal of less than 1 ppb of lead in baby food and other foods marketed to young children;
- Continue to prioritize lead contaminant minimization when sourcing ingredients;
- Test more frequently during processing to identify additional sources of lead, and take appropriate corrective actions; and
- Publicly commit to consumers to drive down lead levels through health-protective limits and robust product stewardship.

In the meantime, parents should consult with their pediatrician to learn about how to reduce lead exposure. They should also check with their favorite brands and ask whether the company:

- Regularly tests their products for lead; and
- Ensures that, especially for baby food, there is less than 1 ppb of lead in the food and juices they sell.

Healthy eating requires safe, nutritious food. We can and must do more to reduce and eliminate lead in our food supply.

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Resources

This report relies on the most recently available public scientific data from the FDA, EPA, JECFA, CDC, and Consumer Reports regarding lead in food. As such, the information in this report is historical, not current, and may not be as applicable to food produced and sold today. EDF did not perform a statistical analysis on the data.

Appendix 1: Estimated cost to society in lost earnings from lead in food

EDF calculated the estimated benefit to society if lead were eliminated from food. Using a five step analysis described below, we estimated the benefit to be at least $27 billion annually (summarized in Figure 7).

Step 1: Mean consumption of lead from food at 2.91 µg/day. EDF calculated the average of the geometric means for children between 1 and 7 years using the geometric mean for each age from Section 5.9 and Exhibit 10 of EPA's 2017 report. The geometric mean is more appropriate than the median or the arithmetic mean because the data are not normally distributed and skewed low. EPA's dietary intake calculation is based on CDC's National Health and Nutrition Examination Survey (NHANES) data from 2005-2012 and FDA's Total Diet Study data from 2007-2013. EPA used a model developed by Xue et al. in 2010[54] to estimate levels below the limit of detection.

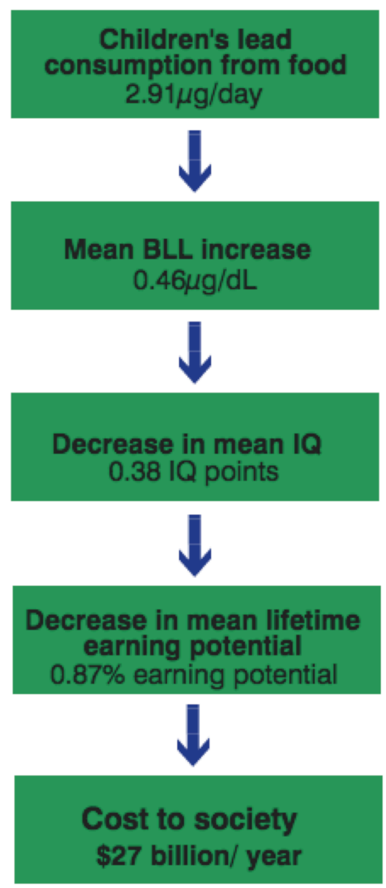
Step 2: Lead in food increases young children's mean blood lead levels by 0.46 µg/dL. EDF used a ratio of 1 µg/day of dietary lead intake to 0.16 µg/dL of blood lead level (BLL) to estimate that 2.9 µg/day of dietary lead intake would result in a BLL of 0.46 µg/dL. We used the same ratio FDA used in developing its 1993 provisional total tolerable intake level.[55] This estimate was based on a 1983 study of 17 infants age 112 to 195 days.[56] The ratio was also used by the European Food Safety Authority (EFSA) in 2010.[57] In 2011, the Joint Expert Committee for Food Additives (JECFA) reviewed the literature and reported that the ratio could be as low as 0.05 for children.[58] We chose the estimate used by FDA and EFSA and supported by JECFA. For context, CDC reported that the mean BLL for children 1 to 5 years old was 0.86 µg/dL based on NHANES data from 2011 to 2014.[59]

Step 3: Lead in food decreases mean IQ points by 0.38 for young children. EDF used a ratio of 0.83 IQ points lost per 1 µg/dL in BLL below 5 µg/dL to calculate 0.38 IQ points lost due to BLL increase of 0.46 µg/dL. This ratio is drawn from a benchmark dose analysis by EFSA where the 1% extra risk is a 1-point change in IQ.[60] EFSA chose 12 micrograms of blood lead per liter of blood (µg B-Pb/L) from the lower confidence interval of the piecewise linear model for concurrent blood lead (blood lead measured at approximately the same time as IQ, generally between the ages of 5-7 years). We converted the units of the 12 µg B-Pb/L estimate to 1.2 µg /dL and used the EFSA-accepted relationship of 1.2 µg/dL to a 1 IQ point loss. Four studies[61] of IQ in young children with blood lead levels in the <5 µg/dL showed an IQ decrease of 0.19 to 2.53 points per 1 µg/dL increase in blood lead.

Step 4: Lead in food would decrease mean lifetime earnings potential by 0.87%. EDF relied on a ratio of 2.27% decrease in lifetime earnings for 1 IQ point decrease to calculate 0.87% decrease in earnings for 0.38 IQ point decrease. This ratio was drawn from an analysis by Altarum Institute of three studies[62] evaluating the 1979 and 1997 cohorts in the National Longitudinal Survey of Youth. The studies reported ratios of 1.43, 2.56 and 2.82%. Altarum used the mean of the three estimates. The study with the lowest ratio was published by the National Bureau of Economic Research in 2016, and, therefore, resulted in a more conservative estimate. Unlike the other two studies, it was not peer-reviewed and did not include indirect impacts of the IQ, such as number of years of education and participation in the workplace. We included it because it was a credible source.

Step 5: Removing all lead in food would increase lifetime earnings of children by $27 billion annually. Using an estimated lifetime earnings potential of $800,000[63] (at a 3% discount rate) and 4 million children per year gaining 0.87% in earnings, we calculated a societal savings of $27 billion by reducing mean dietary consumption of lead for the cohort from 2.91 µg/day to zero.

Figure 7. Estimated cost to society in lost earnings from lead in food



Appendix 2: Categories of baby food used by EDF to evaluate food designated by FDA as baby food in its Total Diet Study

Category	Baby Food Name in FDA's Total Diet Study
Cereal	BF, cereal, barley, dry, prepared with water (2 types) BF, cereal, oatmeal, dry, prepared with water BF, cereal, oatmeal with fruit, prepared with water BF, cereal, rice, dry, prepared with water BF, cereal, rice w/apples, dry, prep w/ water
Cracker/ cookie	BF, arrowroot cookies BF, teething biscuits BF, zweiback toast
Dessert	BF, banana dessert BF, custard/pudding BF, Dutch apple/apple cobbler BF, fruit dessert/pudding BF, fruit yogurt dessert BF, peach cobbler/dessert
Fruit	BF. apples with berries BF, apples with fruit other than berries BF, applesauce BF, apricots with mixed fruit BF, bananas BF, bananas and pineapple BF, juice, apple BF, juice, apple-banana BF, juice, apple-cherry BF, juice, apple-grape BF, juice, grape BF, juice, pear BF, juice, mixed fruit BF, juice, orange BF, peaches BF, pears BF, pears and pineapple BF, plums/prunes with apples or pears
Infant formula	BF, Infant formula, milk-based, iron fortified, RTF BF, Infant formula, milk-based, low iron, RTF BF, Infant formula, soy-based, RTF
Non-root vegetable	BF, green beans BF, mixed vegetables BF, peas BF, squash
Prepared meal	BF, beef and broth/gravy BF, beef and noodles/beef stroganoff BF, chicken and broth/gravy BF, chicken noodle dinner BF, chicken with rice BF, lamb and broth/gravy BF, macaroni and cheese BF, macaroni, tomato and beef BF, turkey and broth/gravy BF, turkey and rice BF, veal and broth/ gravy BF, vegetables and beef BF, vegetables and chicken BF, vegetables and ham BF, vegetables and turkey
Root vegetable	BF, carrots BF, sweet potatoes

For more information, see FDA's study design for the Total Diet Study at https://www.fda.gov/Food/FoodScienceResearch/TotalDietStudy/ucm184232.htm.

Appendix 3: How a Food Safety Plan should eliminate lead as a chemical hazard

Elements of a Food Safety Plan

A written Food Safety Plan[64] is an essential part of hazardous analysis and risk-based preventive controls at 21 CFR Part 117 pursuant to the FDA Food Safety Modernization Act of 2011. The plan must include:

- Preventive controls to ensure hazards are significantly minimized or prevented and food will not be adulterated;
- Risk-based supply chain program to protect raw materials and ingredients from hazards;
- Plan for recalls should they be necessary;
- Procedures to monitor preventive controls to assure they are consistently performed;
- Corrective action procedures if preventive controls are not properly implemented; and
- Verification procedures to validate that:
    - Preventive controls are adequate and effective,
    - Other procedures are being followed, and
    - The plan is reevaluated at least once every three years.

What a Food Safety Plan would say for lead

To comply with the regulations and mitigate risk, the food manufacturers/processors are required to identify chemical hazards in their written Food Safety Plan if it is reasonably foreseeable that the chemical could get into food.

A Food Safety Plan for lead as a chemical hazard would evaluate the risk by assessing (1) the severity of the illness or injury if the hazard were to occur, and (2) the probability that the hazard will occur in the absence of preventive controls. The plan must also develop and implement preventive controls to assure lead levels are significantly minimized or prevented and the food is not adulterated.

The company must also identify how the preventive controls would be monitored to spot implementation problems, explain how a recall would be conducted if lead were found to exceed the maximum amount identified in the plan or is present as an unapproved food additive, and describe what corrective action would be taken to prevent future recalls.

Finally, the food manufacturer/processor must reanalyze its Food Safety Plan at least every three years or more often if there is a significant change, an unanticipated food safety problem occurs, or the preventive controls or the plan are ineffective.

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