Baby Foods With Toxic Metals Stay on US Market While FDA Dithers

Photo Illustration: Jonathan Hurtarte/Bloomberg Law; Photographer: Gary Harki

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Walk into any grocery store in America, and you'll find shelves full of baby foods that contain heavy metals in amounts known to lower IQ, slow development, and create other serious health problems.

The problem is pervasive. All but one of 33 baby food products recently purchased by Bloomberg Law and tested by an accredited laboratory were found to contain at least two of three heavy metals: lead, arsenic, and cadmium.

The Food and Drug Administration has known about these dangers for decades. So have Congress and manufacturers.

Yet the FDA's oversight has been piecemeal, leaving children vulnerable to harmful exposure, according to critics. It's set limits for metals content in a few types of foods but not most, and when it has addressed the issue, it's done it in the form of guidance—which doesn't carry the full force of regulation and makes enforcement optional.

The agency, which has come under fire for a wide range of failures in regulating food safety, has no plans to set enforceable limits for most heavy metals in most baby foods until at least 2024. And a bill in Congress that would have bypassed the FDA process and imposed limits died in committee.

Families aren't protected by the current system, said Maida Galvez, a pediatrician and professor in the Department of Environmental Medicine and Public Health at Mount Sinai and the founding director of the New York State Children's Environmental Health Center.

"That they may be feeding their children foods and drinks that have heavy metals in them without their

knowledge is fundamentally flawed," she said. "We know a lot and we know enough to act."

As Congress scrutinized heavy metals in baby food in 2021, the FDA started a new program called Closer to Zero. So far, it's only issued guidelines around juices. In that instance it set a level for lead that protects 90% of children but leaves the 10% of kids who drink the most juice still exposed to higher levels, which advocates have criticized.

Troubling Test Results

Still, the creation of Closer to Zero reflects how persistent the contamination continues to be, as shown by Bloomberg Law's testing.

The foods tested were purchased from Amazon.com, online food providers, and Washington, D.C.-area grocery stores and analyzed by an accredited laboratory that asked not to be named because it works closely with the food industry. Some of the highest toxin levels were in products containing rice, which is often found in the first solid foods parents give to their infants.

Heavy Metals in Baby Food

Bloomberg Law tested 33 baby food products for arsenic, cadmium, and lead. The results prov
heavy metal contents of baby foods. They were purchased in July 2022 and tested in August a
shaded blue indicate a metal level above the amount in parts per billion (ppb) that would be all
baby food safety bill.

Search by brand

Brand	Product	Arsenic (ppb)	Inorganic Arsenic (ppb)	Cadmium (ppb)	Lead (ppb)	Store and Location	Why We Tested
Beech-Nut	Fruities - Banana, Apple, Strawberry	1.30	Not tested	0.70	0.90	Amazon Fresh delivery to Washington	Apple products high in lead con

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Levels preceded by the less-than sign < indicate that the food contains an amount of the metal smaller than the listed number, manufacturer responses can be found here, graphic by Gary Harki.

Bloomberg Law's test results are troubling and in line with what others have found, said Scott Faber, senior vice president of government affairs at Environmental Working Group, an advocacy group that specializes in the research of agriculture and pollutants with a focus on corporate accountability.

Faber, who used to work in the food industry, said manufacturers are quick to respond to the FDA's direction—when it's given. "The problem is the FDA is extraordinarily slow to set limits," he said. "The FDA has for a generation failed to treat heavy metals in baby food as a priority."

Susan Mayne, director of the FDA's Center for Food Safety and Applied Nutrition, said the agency is moving "as fast as the speed of science" on the issue.

"It's that balancing of being as aggressive as we can to protect public health without having unintended consequences on the availability of these important nutritious foods for our infants," Mayne said.

Bloomberg Law tested products from nine companies. Plum Organics, Sprout, and Walmart released statements asserting their commitment to complying with the FDA and stating that the safety of their products is a top priority. Earth's Best Organic, Beech-Nut, and Happy Baby Organics didn't respond to repeated requests for comment. Gerber, along with Yumi and Little Spoon, which sell their products online, said they take steps to eliminate heavy metals from their products.

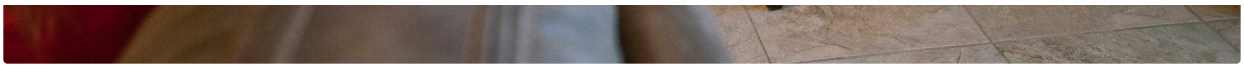
Lead, Arsenic

In the human body, heavy metals are imposters.

A growing baby's body treats lead like calcium, an element vital to neurological and bone development. When ingested, lead takes calcium's place in the brain, disrupting the communication between neurons and ultimately killing growing children's brain cells.

The difficulty in reducing heavy metals levels in baby foods stems largely from the fact the toxins are in the foods before they're processed. Some occur naturally, and industrial pollutants and pesticides break down and seep into soil and groundwater.

Inorganic arsenic, which has a different makeup from organic arsenic, is among the greatest concerns in baby foods. A 2019 review of 14 studies on inorganic arsenic published in Chemical Research in Toxicology found consistent evidence supporting a link between early exposure to the heavy metal and a diagnosis of autism spectrum disorder.



Noah Cantabrana, who was diagnosed with autism as a toddler, plays the piano at his family's California home. His family is suing baby food companies for allegedly exposing him to heavy metals.

Photographer: Alisha Jucevic/Bloomberg

It's a particularly stubborn hazard in rice, which absorbs the metal naturally while growing in water. A 2016 study published by The Journal of the American Medical Association examined the diets of more than 750 babies. It estimated 80% of the babies ate rice by their first birthday and found that eating rice products contributed to infants' exposure to arsenic.

This is why heavy metals aren't found just in foods from major manufacturers such as Gerber and Beech-Nut: A new study from Healthy Babies Bright Futures, an organization dedicated to raising awareness of children's exposure to toxic substances, found that home-prepared foods contain heavy metals in levels about the same as what's found in store-bought products.

The FDA's use of the name "Closer to Zero" for its new baby food program is in part an acknowledgment that "getting to zero is challenging given that they occur in our environment," Mayne said.

The FDA's predecessor started investigating lead in coffee, gelatin, and foils shortly after its creation in 1906. In the 1930s, the agency started trying to reduce the lead in food, focusing on lead-based pesticides on fruits and vegetables.

Baby food has been a part of the FDA's Total Dietary Study, which tests foods for chemicals, metals, and other substances, since 1974.

Thanks to the FDA, the Environmental Protection Agency and other federal agencies, Americans' exposure to lead has decreased at least 93.6% since the 1970s. Still, a 2017 study using FDA Total Diet Study data found that food and water are a major source of exposure for kids between the ages of 1 and 6.

For arsenic, the story is much the same. Rice cereal accounts for 55% of infants' and toddlers' exposure, according to a 2016 study published in the International Journal of Environmental Research and Public Health.

Autism Court Case

Noah Cantabrana was by all appearances a typical baby, hitting all his developmental milestones in his first year. Then his mother, Melissa Cantabrana, started to notice changes.

"Everything was a meltdown," she said in an interview.

Noah was diagnosed with autism at 2 years and 9 months old. His psychologist advised the Cantabranas to start therapy to help with behavioral and communication issues. Searching for answers, Melissa Cantabrana started reading about links between heavy metals and developmental disorders. She became convinced Noah's autism was tied to the copious amounts of baby food pouches and various rice-based snacks and cereal he ate, especially rice puffs.

"We had those in every flavor, every category, and he walked around eating those all day long," she said.

Melissa and Noah Cantabrana bake together at their home.

Photographer: Alisha Jucevic/Bloomberg

The family is suing Gerber, Earth's Best Organic, Sprout, Plum, Beech-Nut, Happy Baby, and Walmart for allegedly exposing Noah to heavy metals. They are represented by Baum Hedlund, including attorney Pedram Esfandiary. He was a key part of the trial team that won a $2 billion verdict against Monsanto, maker of Roundup weed killer.

The Cantabranas' suit was cleared for trial in May 2022 after a California judge said their scientific evidence that the metals can cause neurodevelopmental disorders was sound enough to allow a jury to hear the case. The trial is set to start in May 2023.

While the Cantabranas' suit is the only autism lawsuit the firm has currently filed, Baum Hedlund has about 2,700 clients who say baby foods are responsible for their children's autism or attention-deficit/hyperactivity disorder, Esfandiary said. He said he believes the manufacturers need to be taken to court to force change.

In court filings, the companies denied their products contained harmful levels of heavy metals and disputed any link between their foods and Noah's condition. They said autism is a genetic disorder that develops before birth or shortly afterward.

"I really want justice for my son, for my family," Melissa Cantabrana said. "I want them to pull the baby foods off the shelves."

Avoiding Recall

In 2019, Healthy Babies Bright Futures released a report detailing high levels of lead, arsenic, cadmium, and mercury in baby foods. It tested 168 baby foods and found at least one of the four substances in 95% of the products.

That prompted the House Oversight and Reform Subcommittee on Economic and Consumer Policy,

then led by Rep. Raja Krishnamoorthi (D-Ill.), to investigate. It published reports in February and September of 2021 that examined testing data from baby food manufacturers.

It found high levels of inorganic arsenic in rice cereals and other rice products, including some higher than 100 parts per billion (ppb), the current FDA limit for such products. The reports also recorded high levels of lead, cadmium, and mercury.

It also found that the industry's testing was flawed. Often companies tested just a few samples a year or only tested ingredients, which can give lower results than the finished products. Many companies say they've improved their testing methods since.

In May 2021, the state of Alaska reported its own testing results, which were funded through an FDA program and cited in the September 2021 House report. The state tested infant rice cereal and found high levels of inorganic arsenic in Gerber and Beech-Nut brands.

Eight of the samples were higher than 100 ppb. Beech-Nut recalled some of the products and has since stopped manufacturing infant rice cereal. The company didn't respond to repeated voicemails, emails, and calls to company officials.

Gerber test samples had a higher average level of inorganic arsenic than Beech-Nut's. Two samples were higher than 100 ppb but the company didn't issue a recall and continued to sell the cereals, according to the report.

The FDA had the authority to force Gerber to recall but didn't because FDA officials knew the company would fight it, said a source with knowledge of the House investigation. The agency believed Gerber could come back with additional test results and would argue that the Alaska testing came from a stray high sample, the source said.

A spokesperson for Gerber said the FDA made the company aware of the initial test results, but when the agency retested that sample, it was unable to confirm the high level and told the company no action was needed

Mayne declined to comment on the Alaska testing or any company-specific issues, including the agency's decision not to issue a recall. She said infant rice cereal is a unique situation because it is the largest contributor to inorganic arsenic in infants. The agency set the guidance at 100 ppb in August 2020.

"We identified that as a priority based upon risk and based upon that particular exposure and started working with the industry moving towards establishing action levels," she said. "And through a multi-year process, we have demonstrated reductions in inorganic arsenic in infant rice cereal."

'Putting Out Fires'

In April 2022, the FDA issued its first – and so far only – proposed guidelines under Closer to Zero.

It proposed reducing the amount of lead allowed in apple juice to 10 ppb from the 50 ppb guidance adopted in 2004. The level for other juices would be set at 20 ppb, four times the amount allowed in bottled water.

The guidelines, called draft action levels, give the industry time to comment and aren't enforceable before becoming finalized. Even finalized action levels don't carry the weight of regulations, which go through a separate process and commit the FDA to enforcement.

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> Scott Faber, Environmental Working Group

Once finalized, action levels are essentially limits set by the FDA above which it has discretion to issue enforcement actions, including requiring companies to recall products.

In the 2020 guidance for manufacturers on inorganic arsenic in rice cereals, FDA officials wrote that they set action levels as opposed to regulatory limits when technological or other changes might require adjustment of the amount of a substance allowed in the near future.

Finalized action levels in juices aren't scheduled to be complete until April 2024.

The Closer to Zero schedule has in the coming years deadlines for first drafting, then finalizing guidelines for arsenic, cadmium, and mercury. The agency, however, already has blown past its own deadlines for drafting action levels for lead in baby foods other than juice.

David Acheson, who previously served as associate commissioner for foods and chief medical officer at the FDA's food center, said FDA's response to heavy metals has typically been one of "putting out fires" rather than implementing a "fundamental strategic plan."

"They've known all along that it's a risk," Acheson said of the metal content in baby food.

The FDA was always waiting for more science and concerned it would pick limits that were too stringent, the source with knowledge of the House investigations said.

The agency also has had to balance where it put its resources. Lead contamination competes for FDA attention with listeria, E. coli, and salmonella, the source said.

Mayne said the process takes time, and the FDA must work with the White House and the Office of Management and Budget before issuing proposals.

"I would say that issues of lead in baby food certainly meet that criteria of a very complicated issue where, again, we're trying to balance advancing our health with some of those unintended consequences," Mayne said.

When the FDA has set limits, the industry has moved quickly to meet them, Faber said. He pointed to changes made by farmers, including rotating crops, after the FDA set a draft guidance level for amount of arsenic allowed in apple juice at 10 ppb.

"The problem is the FDA has been extraordinarily slow to set limits, and there's really no good reason why," Faber said.

90% Standard

In measuring the effects of consuming heavy metals for the purpose of creating action levels, the EPA calculates how much money is lost when society collectively loses IQ points.

Using the EPA's methods, the Environmental Defense Fund estimates that eliminating lead in babies' diets would prevent the loss of 1 million IQ points to the children born every year. Those kids would then earn an additional $17 billion dollars over their lifetimes, said Tom Neltner, EDF's senior director for safer chemicals.

"If you think, can I reduce children's exposure by 6% and save $1 billion a year?" Neltner asked. "How much is it worth to society to get a billion dollars of children's brains back?"

But the FDA's calculation method for determining the allowable level of lead in juices is different.

The 10 ppb level set for apple juice is based on protecting 90% of children, leaving the 10% of kids who drink the most juice still exposed to higher levels. It was designed to impact no more than 5% of the market, meaning less than 5% of the products would need to be changed.

In effect, the FDA ultimately acts based on how much of the market will be affected, Neltner said.

"The 90th percentile is, 'How many children are we going to be ok with having higher levels than our goal?'" Neltner said. "They've decided 10% is good. They've never explained it."

In an emailed response, an FDA spokeswoman said the 90% standard is based on "taking into consideration what is achievable," also considering that children consume different amounts of certain foods.

"We note the importance of minimizing the potential for unintended consequences on the availability of nutritious foods," the spokeswoman wrote.

Chance for Change

Krishnamoorthi, along with Sens. Amy Klobuchar (D-Minn.), Tammy Duckworth (D-Ill.), and others sponsored the proposed Baby Food Safety Act which would have limited the levels of inorganic arsenic to between 10 and 15 ppb, cadmium and lead to between 5 and 10 ppb and mercury to 2 ppb – a more stringent standard for all baby foods than Closer to Zero's guidance on juices.

The bill would have bypassed the FDA's process of creating draft action levels, then setting those as enforceable action levels later.

"Industry is not willing to put in place what's required to lower the levels of these toxic heavy metals and baby food and so government has to make sure that this food is safe," Krishnamoorthi said in an interview.

The House Energy and Commerce Committee, then led by Rep. Frank Pallone (D-N.J.), didn't call a hearing on the issue or vote on the bill after it was introduced in March 2021.

When asked about the bill in November, his office released a statement saying, "The Chairman looks forward to continuing to work with FDA and members of Congress to ensure the safety of baby food products."

Krishnamoorthi said he plans to introduce it again in the new Congress.

> Have questions about this story? Bloomberg Law reporters be answering questions during a Reddit AMA on Tuesday, Jan. 10 from 1-3 p.m. ET. Ask your question in advance.

In Parents' Hands

There are different methods to limit the amounts of heavy metals that get into baby foods for different

fruits and vegetables, Faber said. For most products, it's a matter of weeding out batches of ingredients with high metal levels.

Strategic planting is key.

Carefully choosing where you grow rice for baby foods, for example, can limit the amount of arsenic in finished products.

“The last time the FDA acted on arsenic in rice, what happened was a lot of sourcing switched from Louisiana to California,” Faber said.

The FDA is working closely with the Department of Agriculture to figure out how to further eliminate metals from crops, but until there’s a standard, there’s not much incentive for manufacturers to switch suppliers, Faber said.

A Gerber spokesperson said the company has changed where it sources its rice, from states where arsenic levels are generally higher to those that are lower. It has a program to help find sources of rice flour below the 100 ppb FDA guidance level.

The company also has funded arsenic reduction research at the University of Arkansas that ultimately should result in new irrigation strategies for farmers.

Gerber also has added oat and wheat cereal options for babies, which are known to generally contain lower levels of arsenic than rice.

A spokesperson for Little Spoon said the company has partnered with the Clean Label Project, a national nonprofit that aims to bring transparency to product labeling, to verify its finished product testing for heavy metals and other contaminants. Some manufacturers say they want more oversight.

“We wholeheartedly support any regulation that puts the power back in the hands of parents and caretakers who deserve to have trust and confidence in what they feed their children,” said Angela Vranich, co-founder and chief product officer for Little Spoon, which sells its organic baby foods online.

A spokesman for Yumi, another online brand, said it has eliminated rice, which it says is responsible for 60% of heavy metals in baby foods, from its products. The company also conducts finished product testing, studies data on which produce to use in its products, and partners with the Clean Label Project.

How to make better choices

Many foods have some level of heavy metal in them and preparing your own frui doesn't eliminate them. But parents can cut down on their children's exposure b certain foods and following these tips.

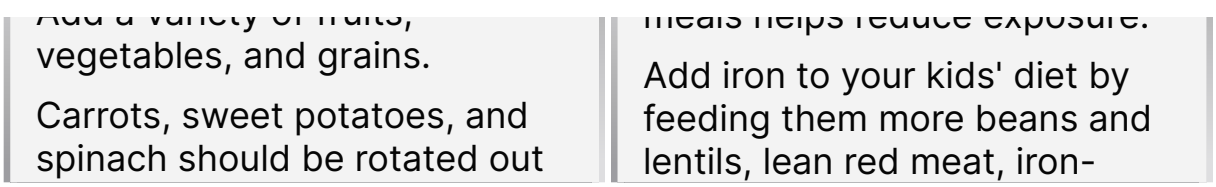
Add variety

Serving the same favorite foods every day can concentrate one or more heavy metals in a child's diet.

Add a variety of fruits

Serve regular meals

Skipping a meal is linked to higher blood lead levels in kids and greater lead absorption in adults. Serving regularly timed meals helps reduce exposure



Source: Healthy Babies Bright Futures • Graphic by Gary Harki

Parents shouldn't panic, there are ways for them to address the problem, said Charlotte Brody, national director of Healthy Babies Bright Futures, which has published recommendations for parents on how to feed kids and avoid high metal levels.

"It's hard enough to raise little kids. And it's especially hard to get your kids to eat nutritious meals. And parents have plenty of other things to worry about," Brody said. "In a world of intractable problems, this is one that parents can do something to solve today and that the baby food companies and the food industry can address in time."

For instance, serving a variety of foods and not skipping meals helps prevent concentrations of metals from accumulating in children. And limiting the amount of rice kids eat cuts down on inorganic arsenic.

The bottom line is that products sold for children should be safe, said Lauren Zajac, an associate professor in the Department of Environmental Medicine and Public Health and the Department of Pediatrics at the Icahn School of Medicine at Mount Sinai in New York.

"The burden shouldn't be on parents or the public to be risk assessors," she said. "The default should be healthy."

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