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We Tested 41 Baby Formulas for Lead and Arsenic

While some formulas had concerning levels, there are safer choices. After seeing our results, the FDA is pledging further action.

By Lauren Kirchner
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Consumer Reports recently tested 41 types of powdered formula for a number of toxic chemicals, including arsenic, lead, BPA, acrylamide, and PFAS. We looked at established formulas like Enfamil and Similac, newer startups like Bobbie, popular store brands, and imported brands.

Some of the results were concerning: about half of the samples we tested contained potentially harmful levels of at least one contaminant. But it was also reassuring to see that the other half of the samples showed low or no levels of concerning chemicals - showing that there are many good options on the market.

On March 18, a day after CR shared our test results with the Food and Drug Administration, the agency announced a new initiative to strengthen its oversight of the formula industry, including increased testing for heavy metals and other contaminants.

"It's very encouraging to see the FDA issue this announcement immediately after Consumer Reports shared our findings about contaminants in infant formula," said Brian Ronholm, head of food policy for CR. "We look forward to seeing the details of how they intend to implement the plan, and we hope the FDA is provided adequate resources and staffing to actually follow through on their promises."

Photo: Scott Meadows/Consumer Reports

Why Safe Formula Matters

Kathryn Caves of Denver hadn't intended to feed her newborn formula. But when her daughter was born early, breastfeeding proved more difficult than she had expected. Caves started her daughter on formula in the hospital while she worked to increase her breast milk supply, and continued to supplement with it throughout her baby's infancy.

"So many people rely on formula—even people like me, who never intended to use it but came to rely on it," Caves says. "It's just what you have to do. You just kind of trust that it's going to be safe."

Shayla Hunter of Harrisburg, Pa., knew ahead of time that she would be buying formula because her son was born via a surrogate. "I did some research before he was born, about different ingredients and different formula companies and the claims they were making," Hunter says. "You just want to make sure your kid is fed and getting what they need, but it's so important for the formula to be clean, for their development."

All parents want to feed their babies in a way that is nutritious and safe. For the millions of parents who rely on formula—because they can't breastfeed, they choose not to, or they supplement breastmilk with formula—that formula is a crucial source of nutrition during their babies' first important months of life. About 1 in 5 newborns in the U.S. start out eating formula exclusively, according to the Centers for Disease Control and Prevention. By 6 months of age, 3 out of 4 babies are consuming formula as part of their diet.

But despite being among the most tightly regulated foods on the market, infant formula isn't necessarily spared from the effects of environmental pollution on its ingredients, or from contamination through the manufacturing process. Gaps in the formula

industry's safety procedures were on stark display during the 2022 formula shortage caused by a deadly bacteria found in a manufacturing facility. Staff and budget cuts at the Food and Drug Administration early this year may compound the issue and weaken oversight of infant formula production in the U.S. even further.

And what about the heavy metals that Consumer Reports tests have found in baby food and fruit juice? What about PFAS that CR tests have found in cow's milk and food packaging? How are the infant formula industry and the FDA keeping these per- and polyfluoroalkyl substances, aka "forever chemicals"—and other toxins—out of this most essential food?

This is why CR decided to analyze dozens of the most popular baby formulas on the market: for arsenic, lead, BPA, acrylamide, and other toxins.

All of the contaminants we found in our tests are, unfortunately, common in our food supply and environment; many have been found in studies of breastmilk as well. But just as importantly, many of our formula test results showed that safer alternatives are widely available, and that it is possible to produce baby formula that doesn't contain worrisome contaminants and chemicals.

"We really want these results to be empowering for parents," says Sana Mujahid, PhD, a mom and CR's manager of food safety research and testing. "If you are just at the beginning of your formula journey, there are plenty of safer choices from major brands like Enfamil and Similac and smaller brands like Bobbie. If you are already giving your child one of the formulas on our list with comparatively higher levels of contaminants, there are several steps you can take."

Here are the results of our tests, and where these toxins may have come from.

What We Found in Our Tests

Arsenic

The problem: Arsenic is a heavy metal that is both naturally occurring and carcinogenic to humans. It originates in the earth's crust, but can contaminate groundwater as well as soil and the food that grows in it. Arsenic pollution can also result from industrial processes such as fracking and pesticide manufacturing.

The Agency for Toxic Substances and Disease Registry has rated arsenic the most toxic substance in the environment, and the most toxic form of arsenic is known as inorganic arsenic, a known carcinogen for people of all ages. Consumer Reports tests in the past have found elevated levels of inorganic arsenic in fruit juice, baby food, and bottled water.

"Arsenic in high levels, of course, is a poison," says Mark R. Corkins, MD, professor of pediatrics at the University of Tennessee Health Science Center in Memphis. "Over time, it increases your risk for certain cancers. So, long term, arsenic is a big concern."

The results: CR's tests on baby formula involved two steps. An initial test measured total arsenic, and then a second test broke out the inorganic arsenic, the most toxic kind.

Our tests found the highest inorganic arsenic level in Abbott Nutrition's EleCare Hypoallergenic, at 19.7 parts per billion (ppb), and the second highest in Similac Alimentum at 15.1 ppb, also made by Abbott. Abbott told CR in a statement that the company had concerns about our methodology and that heavy metals exist in the environment and that these substances "may be present in trace amounts in food products, including all brands of infant formula and even human breast milk." There are no established limits for arsenic in formula, but for comparison, the Environmental Protection Agency limits arsenic in municipal drinking water to 10 ppb; the FDA has the same limit for bottled water.

We also calculated a "hazard quotient," or the level below which no adverse health effects would be expected to occur, assuming a 3-month-old infant of average size eating an average amount each day. While most of the formulas we tested were below our hazard quotient for arsenic, in all, seven of the 41 formulas were over the limit, and two more were very close to it.

What the experts say: "This is a pretty outrageous situation, I must say," said David Carpenter, MD, director of the Institute for Health and the Environment at the State University of New York at Albany, when he heard the results of CR's tests. Both he and Corkins speculated that the source of the arsenic in the formula may be contaminated drinking water that was used during the manufacturing process before it was dehydrated for packaging—though it is not possible to know for sure.

If the arsenic is coming from water used in the manufacturing process, it can be filtered out or otherwise removed. If, on the other hand, heavy metals are introduced through another ingredient, like a protein source, there is no easy way to extract them; the manufacturer has to instead source other ingredients that are not contaminated.

"There is no excuse for having arsenic in baby food or formula," Carpenter says. "Absolutely none.

The industry should be bending over backward to be certain it's not there."

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Lead

The problem: Another heavy metal in the natural-but-still-toxic category is lead. While lead is known for harming child development through exposure to paint and old pipes, it can also contaminate food through the soil it's grown in, or through water used for irrigation. The neurological effects of lead on babies and children exposed to it can be profound.

Whereas arsenic exposure presents a more troubling long-term risk, lead has more serious immediate implications, Corkins says. Lead exposure has been linked to attention deficit hyperactivity disorder, behavior problems, and lowered IQ. "Because of the way it affects brain development, when you're talking about kids, in the short term I worry more about lead."

Given its pervasive nature in the environment, though, it is difficult to get water or food to be truly free of lead. This is why the FDA's oversight plan is called Closer to Zero. Its guidance to manufacturers of food for babies or toddlers is to keep lead at or under 10 or 20 ppb, depending on the ingredients, but Closer to Zero guidance doesn't include formula. The EPA takes action only if a public water supply is found to have lead over 15 ppb, even though its "non-enforceable goal" is 0 ppb.

The results: As we had expected, CR's tests found lead in almost all the formulas. Lead levels ranged from 1.2 ppb to 4.2 ppb, which is below the FDA's Closer to Zero goal, but CR's experts believe those levels are too high. They prefer to use the more conservative Maximum Allowable Dose Level (MADL) set by the California Office of Environmental Health Hazard Assessment because it is the most protective standard available. In 18 of the formulas we tested, the lead intake for the average 3-month-old would fall between 50 and 100 percent of the more conservative MADL limit.

This is important because formula isn't the only potential source of lead exposure for most babies. There's also household dust and soil, for instance, or other foods for babies over 6 months who eat both formula and solids. CR tested powdered formula in its dry form, but mixing with tap water that contains any lead would also increase the daily exposure level.

CR analyzed 41 of the most popular powdered baby formulas on the market for heavy metals, BPA, PFAS, and other chemicals.
Photos: Consumer Reports

What the experts say: "It's virtually impossible to get to zero with lead," says Steven Abrams, MD, professor of pediatrics at the University of Texas at Austin Dell Medical School. "Having said that, the lower the better."

"We know that there is no safe level of lead exposure," says Hannah Gardener, a professor in the department of neurology at the University of Miami who has researched heavy metal contamination in infant formulas. "Obviously babies need to eat. So there needs to be plenty of food and formula choices at the lowest end of the range of contamination. Manufacturers need to do many things to protect consumers, including rigorous and repeated testing of their products and disclosing the contamination levels to consumers."

PFAS

The problem: CR also tested all the formulas for PFAS. Sometimes called "forever chemicals," PFAS are human-made pollutants that are as pervasive in the environment as they are long-lasting in our bodies. New research seems to come out every day about the potential harm done to human immunity, fertility, and longevity as the PFAS we are exposed to accumulates in our blood.

The results: CR's scientists were not surprised to find at least some of the thousands of PFAS compounds in almost all the formulas we tested. However, many of the compounds present are more obscure, and less widely understood, than the so-called legacy compounds whose health risks are well known, and for which the EPA has set limits in drinking water. The only one of these older compounds we found in the formulas was PFOS, and we found it in several formula products.

These results aren't included in the chart below because we tested only one sample from each type of formula, which isn't a robust enough test to say which products have it and which ones don't. But CR believes that this is a subject that deserves a closer look.

What the experts say: "I don't think parents can choose their way away from PFAS in their infant's diet–it's more of a closer to zero mentality that we need to start taking, when it comes to PFAS in food," says Courtney Carignan, an environmental epidemiologist at Michigan State University in East Lansing. However, testing and filtering the drinking water you use to mix powdered formula is a good action step for parents concerned about PFAS, according to Carignan.

Other Concerning Chemicals We Found

The problem: We also tested for bisphenol A (BPA) and acrylamide, two more chemicals that are known to be harmful to babies' health. BPA is a human-made chemical used to make plastics more sturdy, and research has demonstrated its tendency to leach out of plastic into food, as well as its propensity to interfere with normal hormone functioning. BPA is banned from use in baby bottles and infant formula containers–according to experts, any BPA found in formulas could be from a plastic container used to hold one of its ingredients.

Acrylamide may not be as well known as the others above; it's what's called a "process contaminant," the byproduct of a chemical reaction that occurs during the manufacturing process. The FDA has previously warned consumers about acrylamide in high-carbohydrate foods that are made with high-temperature cooking, like fried and baked potatoes and cereal. We decided to test for its presence in formula because, while the FDA has not yet set limits for acrylamide in food, the EPA has classified it as a likely carcinogen.

The results: Our tests detected BPA and acrylamide in just one formula–Enfamil's Nutramigen, a commonly recommended alternative to cow's milk formula for babies sensitive to milk protein. Mead Johnson, the maker of the formula, disputed CR's finding, saying it "contradicts hundreds of results from several years of testing done on both raw materials and finished products by Mead Johnson's food safety experts under a food safety program specifically tailored to infant formula." The other 40 formulas in our test contained no BPA or acrylamide. And while manufacturers often replace BPA with similar compounds, such as BPS or BPF, that may pose the same health concerns, we did not find these in any formula.

What the experts say: The results of CR's tests show great improvement within the industry. Experts we spoke to were glad to hear that only one formula contained BPA, and said that if we had done this same test 10 years ago, we likely would have found much more. Still, BPA is harmful in small amounts, so it is still concerning to detect it at all in something meant for newborns.

"BPA has hormone-like activities, which means it doesn't take very much to exert a very powerful influence," says Patricia Hunt, PhD, a professor at Washington State University's School of Molecular Biosciences in Pullman. "BPA's effects on development are concerning, because babies' brains and bodies are still developing, and there are so many different organ systems that can be affected."

Some Good News From CR's Tests

We tested all the formulas for two other heavy metals, too: cadmium and mercury, which each carry their own health risks. Mercury was not detected in any of the formulas, and cadmium was found in such low levels that CR's experts do not find it concerning.

The tests also included an analysis of each formula's potassium content. This was a check on the formula's nutrition content, not its potential contamination. In 2024 the FDA put out warnings for certain formulas because they had excessive levels of potassium, which can be dangerous. The good news here is that none of the potassium levels measured in CR's tests were over the maximum limit set by the FDA. Some of the formulas tested below the lower limit, but they weren't so low as to be of concern.

And here's the best news for parents: Aside from the most concerning results for arsenic, lead, BPA, and acrylamide, our tests found that there are still many safer infant formula options widely available on the market.

To determine the potential risk posed by the infant formulas in CR's tests, we used internationally recognized health-based daily exposure limits for lead, inorganic arsenic, cadmium, mercury, BPA, and acrylamide. Our results indicate which products had comparatively higher levels, and are not assessments of whether a product exceeds a legal standard. We used those levels because there are no federal limits for contaminants in infant formula, and CR's scientists believe these levels are the most protective available. Read the full methodology (PDF) and see the full test results (PDF).

✓ Not deteted/low levels ! Levels nearing daily limits ✗ Levels over daily limits

Top Choices listed alpabetically

Aptamil
First Infant Milk*
Danone

✓ BPA ✓ Cadium
✓ Lead ✓ Inorganic aresenic
✓ Arcylamide ✓ Mercury

Baby's Only Organic
Complete Nutrition
Bobbie Baby

✓ BPA ✓ Cadium
✓ Lead ✓ Inorganic aresenic
✓ Arcylamide ✓ Mercury

Bobbie
Organic
Bobbie Baby

✓ BPA ✓ Cadium
✓ Lead ✓ Inorganic aresenic
✓ Arcylamide ✓ Mercury

Bobbie
Organic Gentle
Bobbie Baby

✓ BPA ✓ Cadium
✓ Lead ✓ Inorganic aresenic
✓ Arcylamide ✓ Mercury

Bubs
Stage 1 Easy-digest
Goat Milk
Bubs

✓ BPA ✓ Cadium
✓ Lead ✓ Inorganic aresenic
✓ Arcylamide ✓ Mercury

Bubs
Stage 1 Organic
Grass Fed
Bubs

✓ BPA ✓ Cadium
✓ Lead ✓ Inorganic aresenic
✓ Arcylamide ✓ Mercury

Dr. Brown's
GentlePro
Perrigo

✓ BPA ✓ Cadium
✓ Lead ✓ Inorganic aresenic
✓ Arcylamide ✓ Mercury

Earth's Best
Organic Dairy
Hain Celestial Group

✓ BPA ✓ Cadium
✓ Lead ✓ Inorganic aresenic
✓ Arcylamide ✓ Mercury

Enfamil
A.R.
Mead Johnson

✓ BPA ✓ Cadium
✓ Lead ✓ Inorganic aresenic
✓ Arcylamide ✓ Mercury

Enfamil
Enspire Optimum
Mead Johnson

✓ BPA ✓ Cadium
✓ Lead ✓ Inorganic aresenic
✓ Arcylamide ✓ Mercury

Enfamil
Gentlease
Mead Johnson

✓ BPA ✓ Cadium
✓ Lead ✓ Inorganic aresenic
✓ Arcylamide ✓ Mercury

Enfamil
NeuroPro
Mead Johnson

✓ BPA ✓ Cadium
✓ Lead ✓ Inorganic aresenic
✓ Arcylamide ✓ Mercury

Enfamil
NeuroPro Gentlease
Mead Johnson

✓ BPA ✓ Cadium
✓ Lead ✓ Inorganic aresenic
✓ Arcylamide ✓ Mercury

HiPP
Dutch Organic
Stage 1
HiPP International

✓ BPA ✓ Cadium
✓ Lead ✓ Inorganic aresenic
✓ Arcylamide ✓ Mercury

Holle
Bio Organic Stage 1
Cornu Holding

✓ BPA ✓ Cadium
✓ Lead ✓ Inorganic aresenic
✓ Arcylamide ✓ Mercury

Kendamil
Whole Milk
Kendal Nutricare

✓ BPA ✓ Cadium
✓ Lead ✓ Inorganic aresenic
✓ Arcylamide ✓ Mercury

Kirkland Signature
(Costco)
ProCare
Perrigo

✓ BPA ✓ Cadium
✓ Lead ✓ Inorganic aresenic
✓ Arcylamide ✓ Mercury

Member's Mark
(Sam's Club)
Advantage Premium
Perrigo

✓ BPA ✓ Cadium
✓ Lead ✓ Inorganic aresenic
✓ Arcylamide ✓ Mercury

Parent's Choice
Advantage Premium
Perrigo

✓ BPA ✓ Cadium
✓ Lead ✓ Inorganic aresenic
✓ Arcylamide ✓ Mercury

Similac
Advance
Abbott Nutrition

✓ BPA ✓ Cadium
✓ Lead ✓ Inorganic aresenic
✓ Arcylamide ✓ Mercury

Up&Up (Target)
Premium
Perrigo

✓ BPA ✓ Cadium
✓ Lead ✓ Inorganic aresenic
✓ Arcylamide ✓ Mercury

✓ Not deteted/low levels ! Levels nearing daily limits X Levels over daily limits

Good Choices listed alpabetically

A2 Platinum
A2 Milk Company

✓ BPA ! Lead ✓ Arcylamide
✓ Cadium ✓ Inorganic aresenic ✓ Mercury

ByHeart Whole Nutrition
ByHeart

✓ BPA ! Lead ✓ Arcylamide
✓ Cadium ✓ Inorganic aresenic ✓ Mercury

Happy Baby Organics Sensitive*
Danone

✓ BPA ! Lead ✓ Arcylamide
✓ Cadium ✓ Inorganic aresenic ✓ Mercury

Kendamil Organic
Kendal Nutricare

✓ BPA ! Lead ✓ Arcylamide
✓ Cadium ✓ Inorganic aresenic ✓ Mercury

Neocate Hypoallergenic
Danone

✓ BPA ! Lead ✓ Arcylamide
✓ Cadium ✓ Inorganic aresenic ✓ Mercury

Parent's Choice Infant
Perrigo

✓ BPA ! Lead ✓ Arcylamide
✓ Cadium ✓ Inorganic aresenic ✓ Mercury

Similac 360 Total Care
Abbott Nutrition

✓ BPA ! Lead ✓ Arcylamide
✓ Cadium ✓ Inorganic aresenic ✓ Mercury

Similac 360 Total Care Sensitive
Abbott Nutrition

✓ BPA ! Lead ✓ Arcylamide
✓ Cadium ✓ Inorganic aresenic ✓ Mercury

Similac Sensitive
Abbott Nutrition

✓ BPA ! Lead ✓ Arcylamide
✓ Cadium ✓ Inorganic aresenic ✓ Mercury

Similac Soy Isomil
Abbott Nutrition

✓ BPA ! Lead ✓ Arcylamide
✓ Cadium ✓ Inorganic aresenic ✓ Mercury

✓ Not deteted/low levels ! Levels nearing daily limits X Levels over daily limits

Worse Choices listed alpabetically

Dr. Brown's SoothePro
Perrigo

✓ BPA ✓ Lead ✓ Arcylamide
✓ Cadium X Inorganic aresenic ✓ Mercury

EleCare Hypoallergenic
Abbott Nutrition

✓ BPA ! Lead ✓ Arcylamide
✓ Cadium X Inorganic aresenic ✓ Mercury

Enfamil Nutramigen
Mead Johnson

X BPA ! Lead X Arcylamide
✓ Cadium X Inorganic aresenic ✓ Mercury

Enfamil ProSobee Simply Plant-Based
Mead Johnson

✓ BPA ✓ Lead ✓ Arcylamide
✓ Cadium X Inorganic aresenic ✓ Mercury

Kabrita Goat Milk-Based
Ausnutria

✓ BPA ! Lead ✓ Arcylamide
✓ Cadium X Inorganic aresenic ✓ Mercury

PurAmino Hypoallergenic
Mead Johnson

✓ BPA ! Lead ✓ Arcylamide
✓ Cadium X Inorganic aresenic ✓ Mercury

Similac Alimentum
Abbott Nutrition

✓ BPA ! Lead ✓ Arcylamide
✓ Cadium X Inorganic aresenic ✓ Mercury

Similac NeoSure
Abbott Nutrition

✓ BPA ! Lead ✓ Arcylamide
✓ Cadium X Inorganic aresenic ✓ Mercury

Similac Total Comfort
Abbott Nutrition

✓ BPA ! Lead ✓ Arcylamide
✓ Cadium ! Inorganic aresenic ✓ Mercury

Up&Up (Target) Soy
Perrigo

✓ BPA ! Lead ✓ Arcylamide
✓ Cadium ! Inorganic aresenic ✓ Mercury

*These formulas were tested by CR but are no longer available for sale in the U.S.

Infant Formula Companies Respond

We tested 41 types of formula, made by 14 companies, but the U.S. market is almost completely dominated by just a handful of formula manufacturers. About half of all formula bought in the U.S. is bought through the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), and almost all of that is made by just two companies: Abbott and Mead Johnson. Abbott makes Similac and EleCare, while Mead Johnson makes Enfamil and PurAmino.

So what these two companies do has an enormous impact on the formula market as a whole—just look at the ripple effect that shutting down one Abbott plant in 2022 had on the entire nation's formula supply.

A third company, Perrigo, is responsible for making many familiar store brands—including Costco's Kirkland Signature, Sam's Club's Member's Mark, Target's Up&Up, and Walmart's Parent's Choice, as well as Dr. Brown's.

Together the formula made by these three companies—Abbott, Mead Johnson, and Perrigo—makes up 79 percent of the U.S. market, according to 2022 estimates.

CR sent questions to all the companies about the types of contaminants they test their ingredients and products for, their thresholds for allowed contaminants, and what the companies thought might be the sources of any of the contaminants that we found in our tests. We also reached out to companies producing formulas where we didn't find contaminants, to try to learn what they were doing right.

Similac and EleCare manufacturer Abbott Nutrition and Enfamil manufacturer Mead Johnson both sent detailed responses to CR's test results and questions. These companies, which dominate the formula market, have products that appear in every category, from "Top Choices" to "Worse Choices." Both companies challenged CR's results and emphasized that heavy metals or chemicals are never intentionally added to their products. They also said trace levels of heavy metals in the food supply are not an issue that is unique to infant formula.

"Abbott has a multi-step quality process in place for heavy metals to ensure that levels satisfy all relevant regulatory requirements in all countries we serve," wrote Hakim Bouzamondo, MD, a vice president at Abbott Nutrition, adding that he disagreed with CR's using California's extra-conservative metrics to assess risk.

A Mead Johnson spokesperson described the company's "stringent testing protocols" and wrote that the company is "committed to providing the highest levels of quality and safety for all our infant formula products as is evidenced by the fact that parents and pediatricians have trusted our infant nutritional products for nearly 120 years."

Perrigo, which makes Dr. Brown's formula and many popular store brands we tested, including Kirkland, Parent's Choice, Member's Mark, and Up&Up, also told us that it routinely screens its formulas for heavy metals. "These compounds and PFAS are also found in breast milk," a spokesperson wrote. "Their levels in infant formula are insignificant and well below regulations in the United States and around the world."

The parent company for Kabrita, a goat-milk-based formula we put in our Worse Choices category because it contained both arsenic and lead in our tests, told CR that the levels we found fall under regulatory limits, and said that it is unique in publishing its heavy metal testing data on its website for every can of formula it sells.

ByHeart, whose formula landed in our Good Choices category, told us that "It is ByHeart's goal to limit [heavy metals] to the lowest levels reasonably achievable," which it strives to do through constant testing and careful supplier selection.

Danone, the maker of the Neocate formula in our Good Choices category, said that while the FDA has not yet set safety levels for heavy metals in baby formula, Danone stays within EU guidelines. Danone's other two formulas in our test, from Happy Baby Organics and Aptamil, are no longer for sale in the U.S. but fell in the Top Choices range based on testing.

Bobbie's formulas are all in our Top Choices category, including its Baby's Only Organic brand. Laura Modi, Bobbie's CEO and co-founder, told CR, "We pride ourselves on being test obsessed," adding that "not a single batch leaves the facility until it goes through 2,000 quality checkpoints."

A2, Bubs, and the makers of Earth's Best, HiPP, Holle, and Kendamil did not respond to CR's requests for comment.

Just because consuming toxins is to some extent a fact of life does not mean that food manufacturers cannot and should not do better, CR's food safety experts say—especially manufacturers of a food as crucial to health and development as infant formula.

"Manufacturers should be continuously testing all of their incoming raw ingredients, their processes, their packaging, and their outgoing products for contaminants like these," says James E. Rogers, PhD, Consumer Reports' director of product and food safety research and testing. "The fact that

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>
> **JAMES E. ROGERS, PHD**
> Director of Food Safety Research and Testing, Consumer Reports

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Who Is Responsible for Keeping Infant Formula Safe?

That infant formula is regulated at all is a relatively new phenomenon, and it's the direct result of the activism of two extremely motivated mothers.

Carol Laskin and Lynne Pilot both had baby boys who got severely ill and were treated at the hospital in 1979 due to a chloride deficiency after one formula company quietly changed its ingredients. Laskin remembers when she learned that the formula was the source of her son's medical issues and called the FDA to alert them. She asked what the exact regulations were for baby formula. She was shocked to hear the answer: "There aren't any." Whatever guidelines existed were voluntary, he said.

"I said, 'How can you not have any regulation of baby formula? It's the only nutrition that some kids get for the first six months of their lives, how can you justify that?'" Laskin recalls today. "He said, 'We've been trying for years to get Congress to give us the power.'"

"I said, 'That's insane. I'm going to change that. I'm going to get you that power.'" Laskin laughs: "At which point, he hung up on me because he thought I was a crazy person."

Laskin soon connected with Lynne Pilot, after their sons were seen by the same pediatric kidney specialist; together they made a plan. The two of them and their families spoke to reporters and appeared on TV to spread their story. They asked other parents with similar experiences or questions to write to a post office box they set up; she said they got 50,000 letters. They relentlessly lobbied members of Congress. Eventually, their efforts succeeded. In 1980, the Infant Formula Act became law, giving the FDA the authority to make sure all formulas meet certain nutritional requirements.

Laskin thinks that some people in her life were surprised to see her transform into an activist. "I was a very shy person," she says. "But they hurt my baby. And neither Lynne nor I wanted any other parents to have to go through what we went through."

President Jimmy Carter invited Lynne Pilot (center) and Carol Laskin (right) to the Oval Office for the signing of the Infant Formula Act of 1980. Pilot is holding her son, Bradley; Laskin's son Benjamin is holding the president's phone.
Photo: Courtesy of Carol Laskin

Infant formula remains today one of the most highly regulated foods on the market. However, the focus of that regulation remains the nutritional components of formula, and preventing bacterial contamination. Less regulatory attention is paid to potential contamination of formula through toxins introduced by its raw ingredients.

Contaminants from the environment pose a problem for our entire food supply, CR experts say. But the problem is much more urgent for formula, given how vulnerable babies who depend on it are.

The FDA has said that it takes infant formula safety seriously. An FDA spokesperson tells CR that it has tested baby formula for contaminants as part of its Total Diet Study, a survey of foods for sale in the U.S., and that it found no PFAS in those samples, no acrylamide, and only low or no detectable levels of lead, total arsenic, and cadmium.

But this survey has been very limited: There are only six formula samples in the TDS data since 2018. A new survey focused on infant formula began in 2023; the data is not out yet. And the agency's Closer to Zero campaign to reduce heavy metals in food for kids does not apply to infant formula.

The FDA has had to rely on industry to do its own testing of its own products. But CR's test results suggest that this system of internal oversight may not be up to the challenge of keeping contaminants out of formula and other foods.

"There are action levels for some of these contaminants, particularly for lead, so if the FDA encounters high levels, they will take action," says Brian Ronholm, head of food policy for CR. "But the problem with this is, it's reactionary. There aren't enough

preventive controls."

The FDA has long been limited by a lack of both resources and authority to carry out all the oversight it's tasked with. In 2021, just $4.7 million (0.08 percent of the total agency's budget) was dedicated to infant formula protection, with only 19 full-time staffers. Budgets and staffing increased slightly following the 2022 shortage, but resources dedicated to keeping infant formula safe remain a tiny fraction of the agency's budget. Recent changes at the FDA's food program this year, including sudden staff cuts and a spending freeze, mean its capabilities could be cut back even more.

"An understaffed and underresourced agency could jeopardize our having a well-trained inspection force to protect our food system," Ronholm says. "You would think that trying to protect babies should be the highest food safety priority."

When CR initially reached out to the FDA with questions for this article (prior to the agency's announcement on March 18), the agency's response echoed the one Carol Laskin got from them in her phone call over four decades ago.

"Under current law, there is no express requirement for infant formula manufacturers to test ingredients or final products for chemical contaminants such as toxic elements," an FDA spokesperson told CR. "Such testing would help assess levels of contaminants in such foods, and FDA has previously sought from Congress an express requirement that manufacturers test food ingredients and final products for contaminants."

What Parents Should Know

Learning that there are heavy metals, PFAS, and other toxins in baby formula may be alarming, and CR's experts and advocates believe that the industry and regulators could be doing more to keep formula safe. But formula provides vital nutrients, and is the best (in fact, only) option for parents who can't or don't want to breastfeed.

CR's tests also revealed that there are many accessible, less expensive options available for formula-feeding families. This is important because finding the right formula can be a slow—and sometimes expensive—process of trial and error. Your baby may need a particular formulation for allergies or reflux, or your baby may simply not like the way a formula tastes, and reject it.

"Something that I didn't think about—and I don't think a lot of first-time parents think about ahead of time—was, of course you as the parent are choosing the formula, but you also have to see what your baby will tolerate," said Hannah Stoppelman, a CR staffer and mother who went through several brands of formula samples from her pediatrician before she found one that her newborn daughter could eat and keep down. "It's just not totally in your control."

With dozens of infant formulas on the market, it's hard to know which one your baby will take. Always talk to your pediatrician about your concerns.
Photo: Consumer Reports

Here's what else parents can keep in mind about the information in our tests.

Keep these test results in perspective. Environmental pollutants are pervasive in our food supply, and all the contaminants in our tests—arsenic, lead, BPA, acrylamide, and PFAS—have also been previously detected in breast milk, food, and water.

Talk to your pediatrician. If you're concerned about any of the results discussed here and you think you might want to switch the formula you feed your baby, talk to your pediatrician about it first. Sometimes switching formula is easy, but some babies may not tolerate experimenting with different brands.

Never ever try to make your own baby formula or offer alternative foods. It's unsafe from a nutrition standpoint, and if the goal would be to avoid heavy metals or other contaminants, keep in mind that whatever ingredients you'd be using for your own recipe would probably also contain them.

Getting the right concentrations of nutrients, electrolytes, and fluid in formula is crucial, and virtually impossible to do yourself, says Darria Long Gillespie, MD, board-certified emergency room physician and clinical assistant professor at the University of Tennessee Health Science Center. She also said that during the infant formula shortage, she saw infants brought into the emergency room with "dangerous electrolyte levels or low blood pressure, due to watered-down or homemade formula."

Use clean water to mix into your powdered formula. The EPA sets limits on contaminants in tap

water for most of the country, but not every part of it. If you drink water from a well, for instance, that water is not regulated by the EPA. So it's a good idea to get well water tested for heavy metals and PFAS before using it. You can contact your local health authorities with questions, and if you have concerns about environmental pollutants particular to your area, consider using bottled water or investing in a filtration system.

Remember, this isn't all on you. CR is recommending our top choices and pointing out choices with comparatively higher levels of contaminants based on our tests from a snapshot in time. But the presence of environmental and chemical contaminants in baby formula is not a problem that parents can necessarily buy their way out of. "I would encourage people to put the burden away from families onto lawmakers, the FDA, and the manufacturers, to make sure that the products that are out there, including the water that's used to mix it, are safe," as Steven Abrams, MD, the professor of pediatrics at the University of Texas at Austin Dell Medical School, puts it. "Just make it safe."

Correction: This article, published March 18, 2025, has been updated to reflect that Enfamil's Nutramigen formula did not have concerning levels of inorganic arsenic.