SENATE COMMITTEE ON HEALTH
Senator Akilah Weber Pierson, Chair

BILL NO: AB 2302
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VERSION: June 15, 2026
HEARING DATE: June 24, 2026
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SUBJECT: Food safety: infant formula

SUMMARY: Prohibits a person or entity from selling or manufacturing, delivering, holding, or offering for sale infant formula that has not been tested for arsenic, cadmium, lead, and mercury.

Existing law:
1) Defines, under federal law, "infant formula" as a food that purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk. [21 USC §321(z)]

2) Enacts the Sherman Food, Drug and Cosmetic Law (Sherman Law), enforced by the California Department of Public Health (CDPH), which provides broad authority for CDPH to enforce food safety requirements, including that food is not adulterated, misbranded, or falsely advertised. Food labeling requirements generally adopt federal food labeling laws as the state requirement, including nutrition labeling and allergen labeling, but CDPH is permitted, by regulation, to adopt additional food labeling regulations. [HSC §109875 et seq., and §110380]

3) Requires CDPH to review all changes to the federal definition of infant formula before those changes are incorporated by reference to the Sherman Law, as specified. [HSC §109951]

4) Prohibits a retail food facility from selling or offering for sale after the "use by" date infant formula or baby food that is required to have this date on its packaging pursuant to federal law. [HSC §114094.5]

5) Defines the following under the Sherman Law:
   a) "Label" as a display of written, printed, or graphic matter upon a food, drug, device, or cosmetic or upon its immediate container; and,
   b) "Manufacture" as the preparation, compounding, propagation, processing, or fabrication of any food, drug, device, or cosmetic, including repackaging or otherwise changing the container, wrapper, or labeling of any food, drug, device, or cosmetic in furtherance of its distribution. Prohibits the term "manufacture" from including repackaging from a bulk container by a retailer at the time of sale to its ultimate consumer. [HSC §109955 and §109970]

This bill:
1) Requires a manufacturer of infant formula for sale or distribution in this state to test a representative sample of each production aggregate of the final infant formula product, at a proficient laboratory, for "heavy metals" at least once per month. Defines "heavy metals" as arsenic, cadmium, lead, and mercury.

2) Permits a manufacturer to test the final infant formula product before packaging individual units of infant formula for sale or distribution.

3) Requires a brand owner to disclose information to consumers, commencing January 1, 2028, for final infant formula products sold, manufactured, delivered, held, or offered for sale in the state—including, without limitation, final infant formula products that are sold by a retailer or that are sold online or directly to consumers—that is consistent with all of the following:
   a) Make publicly and easily available on the brand owner's website, in English and Spanish, for the duration of the product shelf life for a final infant formula product plus one month, the name and level of each heavy metal present in each production aggregate of a final infant formula product;
   b) Provide descriptive information on the website to enable accurate identification of the final infant formula product by consumers. Permits "descriptive information" to include, but not be limited to, product name, Universal Product Code (UPC), size, lot numbers, or batch numbers. Requires this information to be made available without requiring consumers to provide a UPC number, lot number, or proof of purchase; and,
   (c) Include on the product label—if a product is tested for a certain heavy metal subject to an action level, regulatory limit, or tolerance established by the U.S. Food and Drug Administration (FDA)—both: (1) a Quick Response (QR) code or other machine-readable code that links to a page on the brand owner's website containing test results for any of the heavy metals and a website link to an FDA site where consumers can find the most recent FDA guidance and information about the health effects of the heavy metal on children; and, (2) a statement that reads: "For information about heavy metal testing on this product, scan the QR code."

4) Requires the proficient laboratory that analyzes the final infant formula product for heavy metals to:
   a) Be accredited under the standards of the International Organization for Standardization/International Electrotechnical Commission 17025:2017 regarding the general requirements for the competence of testing and calibration laboratories;
   b) Use an analytical method that is at least as sensitive as that described in the FDA Elemental Analysis Manual 4.7; and,
   c) Demonstrate proficiency in quantifying each heavy metal to at least six micrograms of the heavy metal to kilogram of food (μg/kg) through an independent proficiency test. Specifies that "proficiency" means that laboratories achieve a z-score that is less than, or equal to, plus or minus two.

5) Requires both manufacturers and brand owners to provide test results to any CDPH authorized agent upon their request.

6) Permits a brand owner, if they do not manufacture the infant formula or final infant formula product, to comply with this bill by providing the test results of the manufacturer they use to produce the infant formula.

7) Prohibits a person or entity from selling or manufacturing, delivering, holding, or offering for sale infant formula that does not comply with the requirements in this bill.

FISCAL EFFECT: According to the Assembly Appropriations Committee, this bill results in costs of unknown but a likely absorbable amount to the CDPH, and costs of an unknown but potentially significant amount to the Department of Justice (DOJ) to bring enforcement actions

for violations of the provisions of this bill. Actual costs will depend on the number of enforcement actions pursued by DOJ and the amount of additional work created by each action, but costs may be in the hundreds of thousands of dollars annually (Unfair Competition Law Fund). Cost pressures of an unknown but potentially significant amount to the courts to adjudicate any additional filings (Trial Court Trust Fund, General Fund). Actual costs will depend on the number of cases filed and the amount of court time needed to resolve each case. It generally costs approximately $1,000 to operate a courtroom for one hour. Although courts are not funded based on workload, increased pressure on the Trial Court Trust Fund may create a demand for increased funding for courts from the General Fund. The state budget provides annual General Fund backfills to the Trial Court Trust Fund to offset revenue reductions, totaling approximately $117.3 million in 2025-26. The Legislative Analyst's Office recently warned of General Fund structural deficits of around $35 billion per year in the 2027-28 fiscal year and ongoing.

PRIOR VOTES:

Assembly Floor:	69 - 0
Assembly Appropriations Committee:	12 - 0
Assembly Environmental Safety and Toxic Materials	4 - 1
Assembly Health Committee:	13 - 0

COMMENTS:

1) *Author's statement.* According to the author, we have a responsibility to prioritize our babies' health and protect them from harm. During the first few months of life, babies rely almost entirely on formula for nutrition. This is also one of the most critical stages of development, where even small exposures to toxic elements, such as heavy metals, can have lasting impacts on brain development or lead to other health effects. California has already set the bar for protecting babies and pregnant mothers by ensuring that baby food and prenatal vitamins are regularly tested for toxic elements, such as heavy metals. This bill builds on that important work to ensure that parents and caregivers in our districts can make safe and informed choices about the formula they feed their babies. This bill focuses on safety, transparency, and accountability. Our parents deserve confidence in the formula they purchase for their babies.

2) *FDA's national strategy and increased authority sought.* In March 2023, the FDA released "The U.S. FDA's Immediate National Strategy to Increase the Resiliency of the U.S. Infant Formula Market," where they highlighted several events that led to the shortage of infant formula in 2022, beginning with information they received between September 2021 and January 2022 about four cases of illness or death in infants who consumed powdered infant formula. A series of Abbott Nutrition facility closures and voluntary recall of certain products contributed to the shortage, which was further compounded by a struggling recovery of the supply chain due to the COVID-19 pandemic and long-standing circumstances that shaped the production of infant formula in the U.S. over the years (infant formula supply is highly concentrated in a small number of manufacturers, which means a small problem can significantly affect overall supply. In 2022, four companies controlled 99% of the infant formula market). The FDA further states that they lacked authority, resources, and staff dedicated to predicting, detecting, and responding to supply chain issues for infant formula, even though they had been requesting authority since 2020. In 2022, the FDA conducted 34 inspections of foreign and domestic facilities that produce infant formula, meeting FDA's inspection targets for 2022. In November 2022, the FDA released a draft

outline of a strategy to prevent *Cronobacter sakazakii* illnesses associated with the consumption of powdered infant formula. And in March 2023, as part of the prevention strategy work, the FDA sent a letter to the powdered infant formula industry to share current safety information and call on the industry to take prompt action to improve processes and programs. Other actions the FDA has taken include:

a) Significantly expanding and improving a required infant formula online training course for investigators and other appropriate staff to ensure robust inspection;
b) Requiring staff who conduct or support inspections of powdered formula manufacturers to attend an interactive in-person inspection workshop with specific training on conducting infant formula inspections;
c) Creating a new Office of Critical Foods responsible for oversight, coordination, and activities related to critical foods, which is defined as infant formula and medical foods;
d) Expediting review of premarket infant formula submissions if an infant formula shortage has been identified;
e) Working with relevant federal agencies to work together to develop a National Strategy on Infant Formula to address supply chain resiliency; and,
f) Seeking additional authority to require that, among other things, manufacturers report to the FDA final product positive test results for relevant pathogens; conduct more frequent environmental monitoring in their facilities to identify relevant pathogens; and maintain the results of such testing for FDA inspection, either in person or remotely.

In its "Long-Term Strategy to Increase the Resiliency of the Infant Formula Supply," issued January 2025, the FDA states that since issuing the immediate national strategy in March 2023, the U.S. government has made significant strides toward improving the safety and security of the infant formula supply chain. Numerous federal agencies are involved in assuring the quality, safety, availability, and affordability of infant formula including the Centers for Disease Control and Prevention, the Centers for Medicare & Medicaid Services, and the U.S. Department of Agriculture. Strong collaboration between federal agencies is and has been essential to improving the resiliency of the infant formula supply. The FDA also recently developed federal legislative proposals to seek new authorities to modernize the regulation of critical foods and other foods marketed for consumption by infants and young children. These new authorities would help the FDA better understand levels of contaminants in foods, allow the FDA to monitor industry progress in reducing levels of contaminants over time, and help identify where the FDA should devote more time and resources. Specifically, the FDA requested new authority to:

a) Allow them to establish binding contamination limits in foods, including those consumed by infants and young children, via an administrative order process to provide a faster way to set and update binding limits as new scientific information becomes available;
b) Require industry to conduct testing of final products, including those marketed for consumption by infants and young children, for contaminants and maintain such records of these testing results for FDA inspection;
c) Require industry to report all product positive test results for relevant pathogens in infant formula;
d) Require industry to conduct more effective environmental monitoring in their facilities to identify the presence of relevant pathogens on surfaces from which the risk of critical food contamination is the greatest and maintain the results of such testing for FDA inspection, either in person or remotely;
e) Permit them to remotely access records of these test results, so they can request and review test results whenever necessary and in a more streamlined fashion;

f) Require a mandatory recall when they determine through any means that there is a reasonable probability that an article of infant or toddler food (other than infant formula) bears or contains a contaminant that renders the product adulterated; and,
g) Requested, in the FY 2025 FDA budget, that Congress clarify that they can impose additional conditions on notifications submitted by manufacturers of critical foods when there is a permanent discontinuance or interruption in manufacture that is likely to lead to a meaningful disruption in the U.S. supply, including requirements to submit specific information as part of the notification.

3) *Consumer Reports (CR) studies of heavy metals in powdered and liquid formula.* CR released findings from two studies of infant formula:
   a) In March 2025, CR tested 41 types of powdered formula for a number of toxic chemicals, including arsenic, lead, cadmium, and mercury. CR noted that all of the contaminants found are common in our food supply and environment; many have been found in studies of breastmilk as well. The 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. There are no established limits for arsenic in formula, but for comparison, the Environmental Protection Agency (EPA) limits arsenic in municipal drinking water to 10 ppb; the FDA has the same limit for bottled water. Experts 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, CR noted, it can be filtered out or otherwise removed. If 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. Concerning lead, CR's tests found it in almost all the formulas. Lead levels ranged from 1.2 ppb to 4.2 ppb, which is below the FDA goal, but CR's experts believe those levels are too high. One expert stated it is virtually impossible to get to zero with lead but the lower the better. Another expert stated "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." Mercury was not detected in any of the formulas, and cadmium was found in such low levels that CR's experts did not find it concerning.
   b) In March 2026, CR tested 49 more infant formulas for those same contaminants—following requests from readers to test some liquid formulas. The results showed there are still many safe, inexpensive options for parents on the market today, and many are available through the Special Supplemental Nutrition Program for Women, Infants, and Children. CR stated there is still much room for improvement as the most recent round of tests detected contaminants at potentially concerning levels in 26 of the 49 formulas tested. CR found 26 out of 49 formulas with inorganic arsenic at or above the EPA level of concern. But one expert stated, "The levels we found are not high enough to present an immediate health hazard or concern." None of the formulas tested were above CR's level of concern for lead. CR used California's maximum daily limit as a reference, but several formulas landed between half of that level and just below the level. Cadmium and mercury were found in several formulas, but in such low levels that CR's experts did not flag them as concerning.

CR ultimately stated parents should know that formula remains the best (and only) option for feeding young babies who are not breastfed. CR's tests also make clear that there are good, budget-friendly options for formula-fed babies. CR stated it used the lowest, most protective levels to measure contaminants and assess potential risks because infant formula is a baby's first and most important food, but low levels of contaminants do not necessarily mean that babies exposed to them will have adverse health outcomes.

4) *FDA Operation Stork Speed.* On its webpage regarding infant formula testing, last updated April 29, 2026, the FDA states it is committed to protecting babies and young children from exposure to contaminants. As part of Operation Stork Speed and their ongoing surveillance work, the FDA is testing infant formula for certain contaminants, such as lead, mercury, cadmium, arsenic, per- and polyfluoroalkyl substances, and pesticides, among others, to help ensure that infant formula remains safe, available, and nutritious for U.S. families. Through the FDA's rigorous oversight, monitoring, and testing protocols, it states, parents and caregivers can continue to feel confident about the safety of infant formula. The FDA's results to date represent the largest and most comprehensive examination of chemical contaminants in infant formula available on the U.S. market and affirm that infant formula is safe. This work builds upon the FDA's broader Closer to Zero initiative, which is meant to reduce dietary exposure to contaminants in foods to as low as possible, while maintaining access to nutritious foods. The initiative prioritizes foods for babies and young children because their smaller body sizes and developing organ systems make them more vulnerable to the potential effects of these contaminants.

5) *Double referral.* This bill is double referred. Should it pass out of this Committee, it will be referred to the Senate Committee on Environmental Quality.

6) *Prior legislation.* SB 646 (Weber Pierson, Chapter 602, Statutes of 2025) requires manufacturers of prenatal vitamins to test samples of the vitamins for arsenic, cadmium, lead, and mercury, and requires the brand owner of a multivitamin product to disclose the testing results and other information to the public.

   AB 228 (Wilson, Bains, Weber of 2023) would have required CDPH and the Office of Emergency Services, in coordination with other state agencies, to establish an infant formula stockpile, upon appropriation and as necessary. *AB 228 was held on the Assembly Appropriations Committee suspense file.*

   AB 899 (Muratsuchi, Chapter 668, Statutes of 2023) prohibits a person or entity from selling in the state or manufacturing, delivering, holding, or offering for sale any baby food that does not test a representative sample of each production aggregate of the manufacturer's final baby food product, at a proficient laboratory for the toxic elements arsenic, cadmium, lead, and mercury at least once per month.

   AB 1316 (Quirk, Chapter 507, Statutes of 2017) requires CDPH to revise its regulations for the Childhood Lead Poisoning Prevention Program to redefine the assessment of risks for the purposes of evaluating a child's risk for lead exposure.

   AB 688 (Pan, Chapter 681, Statutes of 2011), among other things, prohibits a retail food facility from selling or offering for sale after the "use by" date infant formula or baby food that is required to have this date on its packaging pursuant to federal law.

AB 455 (Chu, Chapter 679, Statutes of 2003) enacted the "Toxics in Packaging Prevention Act," which prohibits a manufacturer, importer, agent, or supplier, as defined, from offering for sale or for promotional purposes in this state a package or packaging component that includes a regulated metal, defined as lead, cadmium, mercury, or hexavalent chromium, if that regulated metal has been intentionally introduced into the package or packaging component during manufacturing or distribution.

7) *Support.* In a coalition letter that includes Children Now, as the sponsor of this bill, and other supporters made up of children's health, environmental health, and consumer safety groups, supporters state that existing federal regulations and requirements for manufacturing practice, quality control procedures, and quality factors for infant formula are more focused on the prevention of contaminants such as microbes, glass, and sanitizing agents, rather than on the presence of toxic elements. The FDA has not set safety levels for toxic elements in infant formula. This is particularly concerning given that experts at the American Academy of Pediatrics state that there is no safe level of lead exposure in children, and that even low levels of exposure have been shown to impair cognition and neurodevelopment. Arsenic exposure is also linked to harmful effects on neurodevelopment and increased risk of cancer, and early life exposures are especially dangerous for children. Cadmium exposure is linked to cognitive and behavioral impairments that can inhibit learning. Mercury exposure, especially in early life, is linked to neurotoxic and developmental harms. Supporters further argue that in March 2025 CR published a report after testing 41 types of powdered infant formula for toxic chemicals, including toxic heavy metals. At least half of the samples tested contained potentially harmful levels of at least one contaminant. For example, more than 20% of the formulas tested contained levels of arsenic close to or above the identified hazard quotient limit. The highest level of arsenic detected was almost double the FDA's limit for arsenic in bottled water. The findings from CR are very concerning; however, they also show that many formula manufacturers are successfully producing safer alternatives with no or low levels of the identified contaminants. The largest manufacturers—constituting nearly 80% of the national market—all had formula products in both the "best choices" (no or low levels of contaminants) and "worst choices" (levels of contaminants over daily limits) categories, demonstrating that they are currently capable of producing formulas without concerning levels of harmful contaminants.

8) *Oppose unless amended.* While the Infant Nutrition Council of America (INCA) appreciates the intent, this bill overlooks important differences between infant formula and the baby foods currently covered by California's heavy metals statute (AB 899 of 2023). Infant formula is already highly regulated under federal law in a way that other baby foods are not. To remove opposition, INCA respectfully requests that the current testing and reporting requirements originally set up for baby food be replaced with language mandating all manufacturers or brand owners who seek to sell infant formula products in the state to annually attest to CDPH through written documentation that their infant formula products are in compliance with European Commission Regulation (EU) 2023/915 and any action level, regulatory limit, or tolerance established for a covered element by the FDA. INCA argues their proposal transforms the bill into an easy to understand, helpful *safety* bill that provides useful, science-based, reassuring information that infant formula, one of the most important products that parents and caregivers purchase, is safe to consume because it meets a rigorous, science-based standard. INCA believes this proposal is a simple system where all Californians can be assured that the infant formula they feed their infants is safe because it is in compliance with the EU standard for trace heavy metals in infant formula, which is the most stringent evidence-based standard followed by many countries around the world.

Providing a formal attestation to CDPH is a strong commitment, one that is enforceable and has value for consumers because it ensures that all infant formula is safe to consume, whether from a well-established infant formula manufacturer or a recent start-up company that has just launched a new infant formula product. INCA further argues that consumers typically do not have the scientific background to assess what levels of heavy metals are safe to consume, and as a new parent, they are very likely to be alarmed by any number greater than zero. Applying a scientifically rigorous safety standard to all infant formula available for sale in California is paramount. Simply putting testing data on a website does not advance safety for infants and their families. Consumers are not equipped to know when a test result meets safety standards. Also, the current bill places the infant formula industry in the complex position of complying with the California law and adhering to strict FDA rules and regulation for their labels. Providing hard to interpret test results for a product that already tests under strict heavy metals limits set forth by the EU (and is the sole source of nutrition other than breastfeeding) may lead to parent anxiety and lower confidence in a product that we know is safe to consume. INCA is concerned that requiring infant formula to bear a statement about "heavy metal testing" might mislead parents and caregivers into thinking that these products are unsafe, and/or jeopardizing infant health with alternatives that truly are unsafe. They do not recommend any actions that might unjustifiably erode confidence in U.S. infant formula products; inadvertently threaten infants' health; and, further strain the availability of safe infant formula products that meet all FDA regulatory requirements. INCA reiterated that the FDA has stated heavy metals in infant formula do not indicate a public health concern.

SUPPORT AND OPPOSITION:

Support: Children Now (sponsor)
A Voice for Choice Advocacy
Alliance of Nurses for Healthy Environments
American Academy of Pediatrics, California
American Nurses Association/California
Breast Cancer Prevention Partners
California Children's Hospital Association
California Environmental Voters
California Health Coalition Advocacy
California League of United Latin American Citizens
California Medical Association
California Nurses for Environmental Health & Justice
California Public Interest Research Group
California WIC Association
Center for Community Action and Environmental Justice
Center for Environmental Health
Clean Water Action
Cleanearth4kids.org
Consumer Federation of California
Consumer Reports
County of Santa Clara
Environmental Working Group
Families Advocating for Chemical & Toxics Safety
Family Voices of CA
Friends Committee on Legislation of California
GMO Science
Green Science Policy Institute

Healthy Children Project
Jonas Philanthropies
Learning Disabilities Association of America
LIFT Economy
Maternal and Child Health Access
Non-Toxic Neighborhoods
Our Green Challenge
San Francisco Bay Physicians for Social Responsibility
Recolte Energy
Safe Passages
Sonoma County Youth Environmental Action Committee
Unleaded Kids
Three individuals

Oppose: Infant Nutrition Council of America (unless amended)

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