Date of Hearing: April 14, 2026

ASSEMBLY COMMITTEE ON ENVIRONMENTAL SAFETY AND TOXIC MATERIALS
Damon Connolly, Chair
AB 2302 (Celeste Rodriguez) – As Amended March 26, 2026

SUBJECT: Food safety: infant Formula

SUMMARY: Requires, under the state's Sherman Food, Drug, and Cosmetic Law (Sherman Law), manufacturers to test infant formula products for toxic elements (aluminum, arsenic, cadmium, lead, and mercury); requires brand owners to disclose specified information to the public on their websites, including the levels of toxic elements in their infant formula products; requires brand owners—if a product is tested for a toxic element subject to a standard established by the federal Food and Drug Administration (FDA)—to include a QR code on the product label that links to the brand owner's webpage containing toxic element test results and a link to an FDA website where consumers can find information about the health effects of toxic elements on children. Specifically, **this bill**:

1) Establishes the following definitions for the purposes of AB 2302:

    a) "Infant formula" has the same meaning as that established under federal law (21 United States Code (U.S.C.) § 321(z)), which states that infant formula is a "food which 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";

    b) "Final infant formula product" means the finished product of infant formula with a unique universal product code (UPC); specifies that "final infant formula product" does not mean the constituent ingredients of infant formula;

    c) "Brand owner" means the person who owns or licenses the trademark that is the most prominent trademark on the principal display panel of the final infant formula product label; specifies that the manufacturer of an infant formula for another person who owns the trademark is not the brand owner;

    d) "Manufacturer" means a person who is either of the following:

        i) A brand owner who manufactures, as specified, an infant formula; or,

        ii) A person who manufactures, as specified, but is not the brand owner of, an infant formula;

    e) "Product label" means a display of written, printed, or graphic material that is affixed to a product or its immediate container;

    f) "Product shelf life" means the time, measured in the number of months, between the date of manufacture and the expiration date for a final infant formula product;

    g) "Production aggregate" means a quantity of product that is intended to have uniform composition, character, and quality and is produced according to a master manufacturing order;

h) "Proficient laboratory" means a laboratory that meets criteria specified under AB 2302;

i) "Quick response (QR) code" means a machine-readable code, consisting of an array of squares, used for storing an internet website in order to access a web page;

j) "Representative sample" means a sample that consists of a number of units that are drawn based on rational criteria, such as random sampling, and intended to ensure that the sample accurately portrays the material being sampled; and,

k) "Toxic elements" means aluminum, arsenic, cadmium, lead, and mercury.

2) Requires a manufacturer of infant formula for sale or distribution in this state to test a representative sample of each production aggregate of the manufacturer's final infant formula product, at a proficient laboratory, for toxic elements at least once per month.

3) Authorizes a manufacturer to test the final infant formula product for toxic elements before packaging individual units for sale or distribution.

4) Requires a brand owner—for final infant formula products sold, manufactured, delivered, held, or offered for sale in the state—to disclose product information to consumers consistent with both of the following:

a) Make publicly and easily available on the brand owner's internet 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 toxic element present in each production aggregate of a final infant formula product; and,

b) Provide descriptive information on the internet website to enable accurate identification of the final infant formula product by consumers; provides that descriptive information may include, but is not limited to, product name, UPC, size, lot numbers, or batch numbers.

5) Requires a brand owner—if a product is tested for a toxic element subject to an action level, regulatory limit, or tolerance established by the FDA pursuant to the federal Food, Drug, and Cosmetic Act (FD&C)—to include on the product label both of the following:

a) A QR code or other machine-readable code that links to a page on the brand owner's internet website containing both of the following:

i) Test results for the toxic element; and,

ii) A link to an internet website of the FDA, where consumers can find the most recent FDA guidance and information about the health effects of the toxic element on children.

b) A statement that reads: "For information about toxic element testing on this product, scan the QR code."

6) Requires the proficient laboratory that analyzes the final infant formula product for toxic elements to meet all of the following criteria:

a) Be accredited under specified standards of the International Organization for Standardization/International Electrotechnical Commission regarding 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 toxic element to at least six micrograms of the toxic element to kilogram of food 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.

7) Requires both manufacturers and brand owners to provide test results to any authorized California Department of Public Health (CDPH) agent upon their request, as specified; provides that, if a brand owner does not manufacture the infant formula or final infant formula product, they may comply with this requirement by providing the manufacturer's test results.

8) Prohibits a person or entity from selling, manufacturing, delivering, holding, or offering for sale in this state infant formula that does not comply with AB 2302's requirements.

EXISTING LAW:

Under the federal FD&C:

1) Defines "infant formula" to mean a food which 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 Code of Federal Regulations (CFR) § 106.3)

2) Defines "production aggregate" to mean a quantity of product, or, in the case of an infant formula produced by continuous process, a specific identified amount produced in a unit of time, that is intended to have uniform composition, character, and quality, within specified limits, and is produced according to a master manufacturing order. (21 CFR § 106.3)

3) Defines "representative sample" to mean a sample that consists of a number of units that are drawn based on rational criteria, such as random sampling, and intended to ensure that the sample accurately portrays the material being sampled. (21 CFR § 106.3)

4) Specifies minimum good manufacturing practices that are to be used in, and the facilities or controls that are to be used for, the manufacture, processing, packing, or holding of an infant formula; specifies that failure to comply with federal regulations for the manufacture, processing, packing, or holding of infant formula shall render the formula adulterated. (21 CFR § 106.5, *et seq.*)

5) Specifies nutrient testing requirements for infant formula, including that manufacturers test a representative sample of each production aggregate of finished products for nutrient levels. (21 CFR § 106.91, *et seq.*)

6) Requires a manufacturer to establish controls to ensure that federally-mandated nutrient levels are maintained in the formula, and that the formula is not contaminated with microorganisms or other contaminants. (21 CFR § 106.5)

7) Prohibits the introduction or delivery for introduction into interstate commerce of any food that is adulterated or misbranded. (21 U.S.C. § 331(a))

8) Authorizes the establishment of a tolerance, regulatory limit, or action level for an added poisonous or deleterious substance in food, as follows (21 CFR § 109.4):

   a) A tolerance may be established by regulation to prohibit any detectable amount of the substance in food;

   b) A regulatory limit may be established by regulation to prohibit any detectable amount of the substance in food. The regulatory limit established represents the level at which food is adulterated; and,

   c) An action level may be established to define a level of contamination at which a food may be regarded as adulterated. Whenever an action level is established or changed, a notice shall be published in the Federal Register, call attention to the material supporting the action level, and invite public comment on the action level.

9) Specifies that a regulatory limit may be established if there is no tolerance for an added poisonous or deleterious substance in a particular food; specifies that an action level will be withdrawn when a tolerance or regulatory limit for the same substance and use has been established. (21 CFR § 109.6)

Under the state's Sherman Law:

10) Establishes the Sherman Law, administered by CDPH, which regulates the manufacture, packaging, labeling, and advertising of food, drugs, and cosmetics. (Health and Safety Code (HSC) § 109875-111929.4)

11) Establishes the following definitions:

   a) "Person" means any individual, firm, partnership, trust, corporation, limited liability company, company, estate, public or private institution, association, organization, group, city, county, city and county, political subdivision of this state, other governmental agency within the state, and any representative, agent, or agency of any of the foregoing. (HSC § 109995)

   b) "Label" means a display of written, printed, or graphic matter upon a food, drug, device, or cosmetic or upon its immediate container. (HSC § 109955)

   c) "Manufacture" means the preparation, compounding, propagation, processing, or fabrication of any food, drug, device, or cosmetic; provides that the term "manufacture" includes repackaging or otherwise changing the container, wrapper, or labeling of any food, drug, device, or cosmetic in furtherance of the distribution of the food, drug, device, or cosmetic; provides that the term "manufacture" does not include repackaging

from a bulk container by a retailer at the time of sale to its ultimate consumer. (HSC § 109970)

12) Requires all labels of foods, drugs, devices, or cosmetics to conform to federal requirements, as specified. (HSC § 110340)

13) Requires, beginning on January 1, 2024, manufacturers of baby food for sale or distribution in this state to test a representative sample of each production aggregate of the manufacturer's final baby food product for toxic elements (arsenic, cadmium, lead, and mercury); disclose, on and after January 1, 2025, specified information to consumers on the manufacturer's website, including the levels of toxic elements present in each production aggregate; and, include a QR code on the product label that links to the manufacturer's website containing test results for toxic elements, for those toxic elements for which the FDA has established an action level, regulatory limit, or tolerance. (HSC § 110962(b))

14) Establishes the following laws pertaining to heavy metal testing in prenatal multivitamins:

    a) Requires, commencing on January 1, 2027, manufacturers of prenatal multivitamins to test their products for heavy metals (arsenic, cadmium, lead, and mercury).

    b) Requires, commencing January 1, 2027, brand owners, for packaged prenatal multivitamin products—including, without limitation, prenatal multivitamins that are sold by a retailer or that are sold directly to consumers—to disclose specified information to the public on their websites, including heavy metal levels in their prenatal multivitamins.

    c) Requires heavy metal testing information to be made available to the public without having to provide a UPC number, lot number, or proof of purchase.

    d) Requires brand owners to include, on the same webpage showing heavy metal levels, nutrient information and the following statement:

        "Prenatal multivitamins containing certain minerals critical to support an expectant person’s health and proper development of their fetus may contain trace levels of heavy metals that occur in the environment naturally or from human activities. The levels of heavy metals in prenatal multivitamin ingredients may vary depending on whether and at what levels the prenatal multivitamin contains these ingredients, as well as the location from which the ingredients are sourced. Certain foods containing minerals critical to support an expectant person's health and proper development of their fetus may also contain heavy metals. For more information, speak with your physician about choosing a prenatal multivitamin that meets your specific nutrient needs."

    e) Requires, for products shipped to retailers, the outermost "package," as defined under federal law, of a packaged prenatal multivitamin product to include a statement that reads: "For information about heavy metal testing on this product, visit," followed by the web address where the above information is posted.

    f) Requires, for a product sold online or directly to consumers, the product details page for the product, on an internet website where the product is sold, to include a statement that

reads: "For information about heavy metal testing on this product, visit," followed by a hyperlink to the internet website where the above information is posted.

Under the state's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65):

15) Prohibits a person, in the course of doing business, from knowingly and intentionally exposing any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual. (HSC § 25249.6)

16) Provides that any person who violates the above provision may be enjoined in any court of competent jurisdiction and shall be liable for a civil penalty not to exceed $2,500 per day for each violation in addition to any other penalty established by law. (HSC § 25249.7)

17) Authorizes a warning to be provided by general methods, such as labels on consumer products, posting of notices, placing notices in public news media, and the like, provided that the warning is clear and reasonable; provides that regulations implementing Proposition 65 shall, to the extent practicable, place the obligation to provide any warning materials on the producer or packager rather than on the retail seller, except where the retail seller itself is responsible for introducing a chemical known to the state to cause cancer or reproductive toxicity. (HSC § 25249.11(f))

FISCAL EFFECT: Unknown.

COMMENTS:

Need for the bill: 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. AB 2302 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. AB 2302 focuses on safety, transparency, and accountability. Our parents deserve confidence in the formula they purchase for their babies."

Consequences of heavy metal exposure in children: This bill requires infant formula manufacturers to test for aluminum, arsenic, cadmium, lead, and mercury. Below are descriptions of these heavy metals and their health implications for children.

1) *Aluminum:* According to the federal Agency for Toxic Substances and Disease Registry (ATSDR), aluminum is the most abundant metal in the earth's crust. It is always found combined with other elements and used in many applications, including the production of beverage cans, pots and pans, housing materials, and foil. Aluminum is also used as a food additive and, as a result, eating large amounts of processed foods may expose individuals to

higher levels of aluminum than a person who generally consumes unprocessed foods. High levels of aluminum have caused brain and bone disease in children with kidney disease. The bone damage results from aluminum in the stomach, which prevents children from absorbing phosphate, a chemical needed for healthy bones. The ATSDR also notes that aluminum is found in breast milk, as well as soy- and milk-based infant formulas, and that only a small amount of aluminum enters an infant's body through breastfeeding. Typical aluminum concentrations range from 0.0092 to 0.049 milligrams per liter (mg/L) for breast milk; 0.46-0.93 mg/L for soy-based infant formula, and 0.058-0.15 mg/L for milk-based infant formula.

2) *Arsenic:* According to the ATSDR, children are exposed to arsenic in many of the same ways that adults are, although children may be at higher risk of exposure because of normal hand-to-mouth activity. Since arsenic is found in soil, water, food, and air, children may take in arsenic in the air they breathe, the water they drink, and the food they eat. In addition, since children tend to eat or drink less of a variety of foods and beverages than adults do, ingestion of contaminated food, juice, or infant formula made with arsenic-contaminated water may represent a significant source of exposure.

   Some of the effects of arsenic exposure in children may be similar to those noted in adults, including irritation of the stomach and intestines, blood vessel damage, skin changes, and reduced nerve function. There is also some evidence that long-term exposure to inorganic arsenic in children may lower IQ scores, and that exposure in early life (including gestation and early childhood) may increase mortality in young adulthood.

3) *Cadmium:* According to the ATSDR, in the United States (U.S.), the primary source of cadmium exposure for nonsmokers is from the food supply. In general, potatoes, grains, peanuts, soybeans, sunflower seeds, and leafy vegetables such as lettuce and spinach contain high levels of cadmium. Because cadmium binds strongly to organic matter, it can enter the food supply by accumulating in aquatic organisms and agricultural crops.

   According to a literature review by Flannery et al. (2022) in *Regulatory Toxicology and Pharmacology*, 90% of cadmium exposure is dietary in those who are not exposed through smoking or occupation. In adults, cadmium is known to accumulate in organs over time, leading to kidney dysfunction and decreased bone density, among other adverse effects. More studies are needed to better understand the adverse effects of cadmium exposure in infants and children, although the ATSDR states that the health effects seen in children from exposure to toxic levels of cadmium are expected to be similar to the effects seen in adults (kidney and lung damage). A few studies in animals suggest that younger animals absorb more cadmium than adults, and that young animals are more susceptible than adults to bone loss and decreased bone strength resulting from cadmium exposure.

4) *Lead:* According to the Centers for Disease Control and Prevention (CDC), research shows that there is no safe level of lead and even very low levels can have negative and irreversible health effects, especially in children. Childhood lead exposure can seriously harm a child's health and cause well-documented adverse effects, including brain and nervous system damage, slowed growth and development, learning and behavior problems, and hearing and speech problems. These health impacts can in turn lead to decreased attention and underperformance in school among lead-exposed children. One study by Evens et al. (2015), published in *Environmental Health*, examined data for nearly 58,000 children attending Chicago public schools and found that increasing blood lead levels were associated with

increasing failure rates on standardized reading and math tests. The authors found that this effect persisted, even when they controlled for other predictors of school performance, including poverty, race, ethnicity, gender, maternal education, birth weight, and prematurity. Among children with the lowest blood lead levels, even small increases in blood lead levels were associated with what the authors described as "steeper failure rates."

5) *Mercury:* According to the ATSDR, food is the most common route of exposure to mercury. Most people are exposed to organic mercury compounds (typically methylmercury) in foods such as fish, seafood, and rice. The health effects of mercury exposure depend on a number of factors, including the amount and form of mercury, route and length of exposure, and age. All forms of mercury can affect the nervous system and kidneys. People who eat foods with high levels of methylmercury may experience tremors, coordination problems, impaired vision, impaired learning and memory, and mood changes. Some children born in communities that ate food with high levels of organic mercury had learning, sensory, and movement problems. In people exposed to high levels of methylmercury in their diets, birth defects have occurred. In addition, research shows that some humans and animals that ate mercury compounds had high blood pressure and alterations in their immune systems, and animals that ate high levels of mercury compounds showed decreased fertility and/or birth defects.

The FD&C and contaminants in food: Under the FD&C, the FDA is authorized to establish tolerances, regulatory limits, or action levels for contaminants in food. Exceedance of established regulatory limits or action levels can be used to deem a food "adulterated," which gives the FDA the authority to initiate enforcement actions that can range from issuing a letter notifying the individual or firm of a violation and requesting correction, to criminal prosecution of the individual or firm. The FDA maintains that while action levels are a useful tool for driving down contaminant levels in foods, the agency does not need an action level for a contaminant to take enforcement action. By law, food manufacturers and processors have a responsibility to implement preventive controls as needed to minimize or prevent exposure to chemical hazards—including lead, arsenic, cadmium, and mercury.

Infant formula under the FD&C: The FD&C contains numerous requirements for infant formula, particularly as they pertain to nutrient content and good manufacturing practices. Specifically, the FDA has established manufacturer requirements relating to nutrient content, nutrient quantity, nutrient quality control, recordkeeping, reporting, and product recalls under the FD&C. In addition, the FD&C requires persons responsible for the manufacture or distribution of infant formula to register with the FDA and to make a submission to the FDA for any new infant formula, which includes any infant formula that has had a major change in its formulation or processing. After the first processing of a new infant formula, but before marketing, persons responsible for the manufacture or distribution of infant formula must submit to the FDA a written verification demonstrating that the formula complies with the FD&C's requirements.

In 2014, the agency revised its infant formula regulations to establish quality factors, current good manufacturing practices, and revised quality control procedures. Manufacturers are required to establish controls that ensure mandated nutrient levels are maintained, and that the formula is not contaminated with microorganisms or other contaminants. Notably, FDA regulations on good manufacturing practices only explicitly mention "heavy metals" in a provision stating that manufacturers "shall not reprocess or otherwise recondition an ingredient,

container, or closure rejected because it is contaminated with microorganisms of public health significance or other contaminants, such as heavy metals." (21 CFR § 106.4(e)(3))

FDA action and California's leadership on heavy metals in foods intended for babies and young children: In April 2021, the FDA announced the Closer to Zero initiative, which identifies actions the FDA will take to reduce exposure to lead, arsenic, cadmium, and mercury in foods eaten by babies and young children to the lowest levels possible. The FDA has prioritized babies and young children because their smaller body sizes and metabolism make them more vulnerable to the harmful effects of contaminants. To meet the goals of Closer to Zero, the FDA is focusing on:

1) Research and analysis, to include developing new and improved testing methods to measure lower levels of contaminants in food;

2) Regulation, to include establishing action levels, increasing targeted compliance and enforcement activities, and monitoring levels over time to determine possible adjustments to action levels; and,

3) Consultation, to include encouraging adoption of agricultural and processing best practices by industry to lower levels of environmental contaminants in agricultural commodities and products.

As of the writing of this analysis, the FDA had only completed action levels for lead in certain kinds of foods intended for babies and young children. The action levels are as follows:

- 10 parts per billion (ppb) for fruits, vegetables (excluding single-ingredient root vegetables), mixtures (including grain- and meat-based mixtures), yogurts, custards/puddings, and single-ingredient meats;

- 20 ppb for single-ingredient root vegetables; and,

- 20 ppb for dry infant cereals.

In its 2025 report, *The Closer to Zero Journey,* a nonprofit called the Clean Label Project said the following about the FDA's progress on the Closer to Zero initiative and AB 899 (Muratsuchi, Chapter 668, Statutes of 2023). Notably, AB 899, which established heavy metal testing and public transparency requirements for baby food, served as the model for AB 2302.

> "Despite its promising goals, progress within the [Closer to Zero] program has been slow. Most recently on January 6, 2025, the FDA released final guidance on lead action limits in baby food. While an important step in the right direction, guidance for additional categories and product types has yet to be released. In the meantime, a patchwork of state and federal legislation has emerged to fill the regulatory void. Some of these proposed laws have already been passed, highlighting the urgency to address heavy metal contamination in baby food even in the absence of enforceable limits from [Closer to Zero]…
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> In October 2023, California set a new standard for addressing heavy metals in baby food with the passage of California Assembly Bill 899 (AB 899), emphasizing transparency and rigorous testing. Starting January 2024, baby food manufacturers selling in California must test their products monthly for arsenic, cadmium, lead, and mercury using a 'proficient

> laboratory' capable of detecting toxic elements at levels as low as six micrograms per kilogram of food (µg/kg), equivalent to six parts per billion (ppb). By January 2025, these test results must be publicly accessible on the manufacturer's website, ensuring consumers have direct access to detailed safety information. Additionally, if a product is tested for a toxic element subject to an FDA action level, regulatory limit, or tolerance, manufacturers must include a QR code on the product label. This code will link consumers to a webpage displaying test results, related FDA educational materials, and other relevant details. With minimal federal regulations in this space and California's economic influence, AB 899 has effectively become the de facto national benchmark for baby food safety, setting a precedent for transparency and accountability across the industry."

Building on the Clean Label Project's assessment of AB 899's nationwide impact, Unleaded Kids and Consumer Reports (CR), which have been tracking its implementation, state the following:

> "The testing and disclosure approach in AB 899 has been incredibly successful at providing a market incentive for baby food brands to reduce toxic elements in products by giving parents the opportunity to choose items with the lowest levels that still meet their child's nutritional needs. We have seen contaminant levels in a company's portfolio of products steadily go down as they found ways to improve their ingredient sourcing and processing. In addition, some companies have aggressively marketed their low levels and their transparency."

In March 2025, the FDA announced "Operation Stork Speed," a new initiative aimed at strengthening oversight of the formula industry, to include, among other things, increased testing for heavy metals and other contaminants. Federal Health and Human Services Secretary, Robert F. Kennedy, Jr. recently announced that the FDA is planning to release results from the Operation Stork Speed review of infant formula products in April 2026, focused on the presence of contaminants, including cadmium, mercury, and lead.

In March 2026, the American Society for Nutrition posted the article, "[FDA] expert panel on infant formula 'Operation Stork Speed,'" which describes the FDA's efforts to convene a panel of experts from academia, industry, and community stakeholders to address infant formula nutrient specifications, regulatory frameworks, safety protocols, marketing practices, and specialized applications. In the article, the American Society for Nutrition states that "73% of infants receive infant formula at some point in their first year…Despite new discoveries in infant nutrition, infant formula regulations have remained largely unchanged since the 1980s."

In addition, three papers summarizing the panel's findings and recommendations have been released. In the second release, "[FDA] expert panel on infant formula 'Operation Stork Speed' June 2025: Part 2, regulatory and safety considerations," the authors note that "increased transparency from the United States FDA regarding the frequency of testing and the most recent contaminant levels is critical for rebuilding consumer trust in the safety of United States formulas."

State actions on heavy metals in infant formula: In 1986, California voters approved a ballot initiative, the Safe Drinking Water and Toxic Enforcement Act of 1986, commonly referred to as Proposition 65, to address concerns that "hazardous chemicals pose a serious potential threat to their health and well-being, [and] that state government agencies have failed to provide them with adequate protection…" Proposition 65 requires the state to publish a list of chemicals known to cause cancer or birth defects or other reproductive harm. This list, which must be updated at least once a year, currently includes approximately 900 chemicals. Proposition 65

also prohibits businesses from knowingly and intentionally exposing any individual to a chemical known to the state to cause cancer or reproductive toxicity, without first giving clear and reasonable warning, which can take the form of product labels or notices. The Office of Environmental Health Hazard Assessment (OEHHA) administers the Proposition 65 program, including an evaluation of all currently available scientific information on substances considered for placement on the Proposition 65 list.

OEHHA has established safe harbor levels for many of the chemicals on the Proposition 65 list. Exposure levels that are below these safe harbor levels are exempt from the requirements of Proposition 65. The safe harbor levels for the heavy metals specified in AB 899 are 10 µg/day for arsenic, 4.1 µg/day for cadmium, and 15 µg/day for lead and lead compounds. No safe harbor level has been specified for mercury; businesses that expose individuals to mercury are required to provide a Proposition 65 warning, unless they can show that the anticipated exposure level will not pose a significant risk of cancer or reproductive harm.

In 2018, California Attorney General Xavier Becerra announced the issuance of two cease and desist letters and a lawsuit filed against two businesses, Nutraceutical Corp. and Graceleigh Inc., due to the discovery of dangerously elevated levels of lead in their toddler formulas (formulas that are generally intended for children over 12 months of age). Testing conducted by the California Department of Justice on two products—Peaceful Planet Toddler Supreme and Sammy's Milk Free-Range Goat Milk Toddler Formula—revealed that these formulas contained enough lead to result in exposure between 13 and 15 times the level allowed under California law without a Proposition 65 warning. Both formulas also exceeded the FDA's provisional tolerable total daily intake limit. In the lawsuit, the Attorney General alleged that the two companies had violated California's Unfair Competition Law, False Advertising Law, and Proposition 65. In response to the lawsuit, the two companies pulled the products out of California.

Also in 2018, the Attorney General and ten district attorneys filed a lawsuit against Perrigo Company after testing showed that the company's infant and toddler formula products contained levels of lead that exceeded the Proposition 65 warning threshold. In 2022, the Attorney General announced a settlement with Perrigo Company that sets maximum lead levels of 5-7 ppb for most of these products, levels that are much lower than applicable guidance levels established for this type of product by any U.S. regulatory authority.

Reports of heavy metals in infant formula: Over the last decade, several reports and investigations have documented the presence of heavy metals in infant formula. Below is an overview of this documentation.

In 2017, the Clean Label Project released findings from an investigation of heavy metal levels in over 530 baby and toddler food products, including formulas, cereals, jars, pouches, juices, drinks, and snacks. The organization reports that lead was detectable in 36% of the products; cadmium was detected in 58% of the products; soy-based formulas contained seven times the amount of cadmium as compared to other formulas; and, arsenic was detected in 65% of all products tested and found in nearly 80% of the formulas tested. It does not appear that the majority of these findings were published in a peer-reviewed journal, and it is difficult, based on materials available on Clean Label Project's website, to assess the investigation's methodology.

In 2019, an author associated with the Clean Label Project co-published a peer-reviewed article entitled "Lead and cadmium contamination in a large sample of United States infant formulas

and baby foods," in *Science of the Total Environment*. This article appears to present a subset of findings from the Clean Label Project's investigation. The article contains the following findings: out of 91 infant formula samples, 22% exceeded Proposition 65 lead guidelines; 23% exceeded Proposition 65 cadmium guidelines; and 14% exceeded the tolerable cadmium intake levels established by the World Health Organization for a four-month-old baby.

In March 2025, CR released results from tests on 41 types of powdered formula for a number of toxic chemicals, including arsenic and lead. One year later, CR released the results from testing for 49 more infant formulas. Regarding the test results from these investigations, CR states:

> "In March 2025, Consumer Reports reported finding lead and arsenic in several powdered infant formulas, and bisphenol A and acrylamide in one formula as well. For a variety of reasons, these contaminants are unfortunately common in our food supply and environment (and have been found in studies of breast milk as well). In response, [federal] regulators pledged to ramp up oversight, increase testing of ingredients and finished products, and keep formula safe.
>
> Now, a year later, CR has tested 49 more infant formulas for those same contaminants—following requests from readers to test liquid formulas and more alternative-protein formulas (such as soy-milk- and goat-milk-based formulas), as well as additional hypoallergenic formulas.
>
> Fortunately, the results of our tests show that 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, or WIC.
>
> Among the liquid and ready-to-feed formulas we tested, one-third landed in our list of top choices, with contaminant levels that were either very low or not detected at all. And over half of the powdered formulas we tested were top choices for low or undetected contaminant levels.
>
> But our tests also indicate that there is still room for improvement, despite industry and government promises—including the [FDA]'s announcement of its Operation Stork Speed campaign the day after CR shared its initial findings in March 2025. Our most recent round of tests detected contaminants at potentially concerning levels in 26 of the 49 formulas we tested."

Implications for equity: Infant formula can be an essential and life-giving food for many babies. However, the potential presence of heavy metals raises both short- and long-term health concerns. Higher rates of infant formula use among certain socioeconomic, racial, and ethnic groups can mean that babies from these communities are more likely to be exposed, if heavy metals are present in their formula. In 2022, the Kaiser Family Foundation released an analysis of formula use using nationwide data from the CDC. The analysis showed that:

- More than half (54%) of infants born in 2018 received formula, either exclusively or as a supplement, by three months of life.

- Infants in low-income families, infants of color, and infants living in rural communities are more likely to use formula. Infants in lower income households are less likely than those in higher income households to report exclusive breastfeeding through the first three months of

life. Similarly, data show that lower shares of Black and Hispanic infants are exclusively breastfed through their first three months of life compared to White infants. CDC data also show Black infants born in 2018 are less likely to have ever been breastfed compared to Asian, White, and Hispanic infants. Infants living in rural areas are also less likely to have ever been breastfed than those in urban areas.

- The majority of children under the age of one covered by Medicaid and the Children's Health Insurance Plan (CHIP) are infants in low-income families and infants of color. Over one-third (34%) of all children who reported receiving formula during the first 12 months of their life were covered by Medicaid/CHIP only.

- Almost half of all formula in the U.S. is purchased by families enrolled in the Women, Infants, and Children program (WIC). WIC is a nationwide program designed to support low-income women, infants, and children up to age five found to be at nutritional risk.

How will consumers make sense of the test results? Infant formula manufacturers, represented by the Infant Nutrition Council of America (INCA), have raised concerns that consumers may not be able to make sense of heavy metal test results, and that this may drive some consumers to seek unsafe alternatives to infant formulas, such as home-made formula. According to INCA, even in countries where standards for infant formula have been set, there is no "labeling requiring disclosure of testing results to consumers, due to the fact that consumers cannot interpret this data and its relationship to human health."

This concern emerges in part due to the absence of government standards that establish safe levels for most of these contaminants in food. As noted above, with respect to baby foods and infant formula, the FDA has only established an action level for lead in baby food; there are no infant formula-specific standards currently in place, and none even for the other three heavy metals that "Closer to Zero" aimed to establish when it was initiated back in 2021. Although the FDA's "Operation Stork Speed" aims to examine heavy metals in infant formula, it is unclear when, or if, action levels for heavy metals in infant formula will materialize from this initiative.

AB 899 (Muratsuchi, Chapter 668, Statutes of 2023), similar to this bill, requires on-product labeling (specifically, a QR code that brings consumers to the manufacturer's website with test results) only if a baby food is tested for a heavy metal for which the FDA has established a standard (i.e., an action level, regulatory limit, or tolerance). This AB 899 requirement went into effect on January 1, 2025. Five days later, on January 6, 2025, the FDA established action levels for lead in certain types of food intended for babies and young children; as of the writing of this analysis, no standards for baby food have been established for any of the other heavy metals specified in AB 899. Despite this, organizations such as Unleaded Kids and CR, as noted above, note the positive impacts of AB 899 on the baby food market and consumer transparency.

That said, INCA points out that infant formula may be the sole source of nutrition for many babies, and it is critical that they receive the full complement of nutrients provided in these products. As noted in the Environmental Safety & Toxic Materials Committee analysis for SB 646 (Weber Pierson, Chapter 602, Statutes of 2025), very similar concerns emerged during stakeholder discussions about how to contextualize heavy metal test results for consumers, to avoid frightening them away from taking prenatal multivitamins, which are essential for healthy pregnancies. Unlike AB 899, SB 646 does not hinge on-product labeling (i.e., the QR code) on the existence of federal standards; instead, SB 646 simply requires on-product labeling, and

ensures that key information, intended to contextualize the test results and remind consumers that prenatal multivitamins are essential, is presented to consumers on the website.

Suggested committee amendments: For the purposes of technical clean-up, and to further clarify AB 2302's timeline and consumer transparency provisions, the Committee may wish to consider amending this bill as follows:

1) Make minor technical clean-up changes to fix an incorrect cross-reference;

2) Add a compliance date of January 1, 2028, to provide brand owners with time to post required information, including test results, to their websites;

3) Add the clause "including, without limitation, final infant formula products that are sold by a retailer or that are sold online or directly to consumers" to AB 2302's requirement for brand owners to post information to their websites, to clarify that the requirement applies to products sold by both brick-and-mortar and online retailers; and,

4) Add a requirement that the information brand owners must post to their websites, including test results, "shall be made available to consumers without requiring them to provide a UPC number, lot number, or proof of purchase." This provision ensures that brand owners cannot require UPC numbers, lot numbers, or proofs of purchase as a means of preventing consumers from accessing the information required under AB 2302. This provision also aligns with current law for prenatal multivitamins under SB 646 (Weber Pierson, Chapter 602, Statutes of 2025).

This bill: AB 2302 requires manufacturers to test infant formula products for toxic elements (aluminum, arsenic, cadmium, lead, and mercury), and brand owners to disclose specified information to the public on their websites, including the levels of toxic elements in their infant formula products. This bill also requires brand owners—if a product is tested for a toxic element subject to an action level, regulatory limit, or tolerance established by the FDA—to include a QR code on the product label that links to the brand owner's webpage containing toxic element test results. AB 2302 closely follows the models established by AB 899 and SB 646, which require heavy metal testing and disclosure for baby food products and prenatal multivitamins, respectively. Similar to those bills, AB 2302 stands to offer parents and caregivers a level of transparency about heavy metals in infant formula that could help them make informed choices.

Arguments in support: Writing in support, a coalition of environmental and health organizations write:

> "In March 2025, Consumer Reports published a report after testing 41 types of powdered infant formula for toxic chemicals, including toxic elements. 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 Consumer Reports 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…

California has already set a precedent for raising standards for regulation of toxic elements in infant formula. In 2022, the California Attorney General's office reached a settlement with formula manufacturer Perrigo to improve the safety of the company's infant formula products, after levels of lead exceeding the Proposition 65 warning threshold were detected in the company's products. The settlement requires Perrigo to conduct annual testing of representative production lots of infant formula to confirm that the maximum lead level outlined in the settlement is not exceeded. In 2024, the Attorney General's office reached a similar settlement with Mead Johnson. This bill would build on those efforts by providing an industry-wide solution.

We urge you to support AB 2302 to protect California babies from harmful toxic elements in the formula they rely upon to grow and thrive. This will empower parents and caregivers to make informed choices about the formula that they feed to their babies. It will also provide pediatricians with valuable data to inform their recommendations to patients."

Arguments in opposition: According to INCA, writing in an opposed-unless-amended position:

"Our industry already tests for heavy metals as part of our longstanding commitment to provide safe, high quality infant formula products. As the results of those tests show, our products comply with heavy metals standards established by the European Food Safety Authority, the European Commission, Joint FAO/WHO Expert Committee on Food Additives, and Codex…

While INCA appreciates the intent of AB 2302, this current draft overlooks important differences between infant formula and the baby foods currently covered in heavy metals legislation in several other states. Infant formula is already highly regulated under federal law in a way that other baby foods are not…According to both FDA and industry testing, heavy metals are present in infant formula at trace levels that are far lower than those that have been reported in many baby foods. Indeed, the FDA stated in March 2025 that its recent testing 'd[id] not indicate that [heavy metals] are present in infant formula at levels that would trigger a public health concern.'

Moreover, the FDA is still in the process of determining action levels for heavy metals in infant formulas—unlike non-formula baby foods, for which certain action levels have already been established...The FDA announced its intent to set formula-specific action levels in March 2025 as part of its Operation Stork Speed—an effort we support. And just recently, the Department of Health and Human Services announced that it will publish a report in April 2026 addressing cadmium, mercury, and lead in infant formula—a precursor to setting federal action levels…

Absent FDA guidance, a number like '1 part per billion cadmium' would not communicate anything meaningful to parents about the formula's safety or compliance with FDA regulations…Adding infant formula could conceivably lead parents and caregivers to resort to alternative feeding options (such as homemade formulas) that do not meet FDA safety and quality standards for complete nutrition in infants and lack the nutrients necessary for infant growth and development, which can be dangerous to infants' health and wellbeing.

We are also concerned that including infant formula in AB 2302 would be required to bear a statement about 'toxic element testing.' The word 'toxic' is not only inaccurate as it relates to trace levels of heavy metals in infant formula but potentially alarming for parents. Again, the FDA has stated that heavy metals in infant formula do not indicate 'a public health concern.' Absent such a demonstrated concern requiring formulas to bear the word 'toxic' might mislead parents and caregivers into thinking that these products are unsafe, and/or jeopardizing infant health with alternatives that truly are unsafe."

Related legislation:

1) SB 646 (Weber Pierson, Chapter 602, Statutes of 2025). Requires manufacturers of prenatal multivitamins to test their products for specified heavy metals; requires brand owners to disclose specified information to the public on their websites, including heavy metal levels in their prenatal multivitamins; requires prenatal multivitamins shipped to retailers to have a link to the brand owner's website for test results on the label; requires the internet website where a prenatal multivitamin is sold online to include a link to the brand owner's website for test results; and, requires brand owners to include, on the same webpage showing heavy metal levels, nutrient information and a specified statement that explains the importance of prenatal multivitamins for a healthy pregnancy, that prenatal multivitamins may contain trace levels of heavy metals that can vary depending upon ingredients used, and that consumers should speak with a physician for more information.

2) SB 754 (Durazo, Chapter 604, Statutes of 2025). Requires manufacturers of disposable tampon or pad products to maintain information regarding the concentrations of lead, arsenic, cadmium, and zinc on and after December 31, 2026; requires a manufacturer to provide technical documentation, including analytical test results, to the Department of Toxic Substances Control (DTSC) upon request; and authorizes DTSC to publish any analytical test results received from manufacturers or obtained through its own testing.

3) AB 899 (Muratsuchi, Chapter 668, Statutes of 2023). Requires, under the state's Sherman Law, manufacturers of baby food for sale or distribution in California to test a representative sample of the final product, as specified, and to disclose information, as specified, to consumers about the levels of arsenic, cadmium, lead, and mercury present in each final product; prohibits the sale, manufacture, or distribution of products in the state that do not comply with AB 899's requirements.

REGISTERED SUPPORT / OPPOSITION:

Support

Children Now (sponsor)
A Voice for Choice Advocacy
Alliance of Nurses for Healthy Environments
American Nurses Association California
Breast Cancer Prevention Partners
California Health Coalition Advocacy
California LULAC
California Nurses for Environmental Health & Justice
California WIC Association
California Public Interest Research Group

Center for Community Action and Environmental Justice
Center for Environmental Health
Clean Water Action
Cleanearth4kids.org
Consumer Reports
Environmental Working Group
Facts: Families Advocating for Chemical & Toxics Safety
Friends Committee on Legislation of California
GMO Science
Green Science Policy Institute
Healthy Children Project, INC.
Jonas Philanthropies
Learning Disabilities Association of America
Learning Disabilities Association of California
Lift Economy
Non-toxic Neighborhoods
Our Green Challenge
Physicians for Social Responsibility - San Francisco Bay
Recolte Energy
Safe Passages
San Francisco Bay Physicians for Social Responsibility
Sonoma County Youth Environmental Action Committee
Unleaded Kids

Opposition

Infant Nutrition Council of America

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