SENATE COMMITTEE ON ENVIRONMENTAL QUALITY
Senator Blakespear, Chair
2025 - 2026 Regular

Bill No:	AB 2302		
Author:	Celeste Rodriguez		
Version:	5/18/2026	**Hearing Date:**	7/1/2026
Urgency:	No	**Fiscal:**	Yes
Consultant:	Alyssa Poletti		

SUBJECT: Food safety: infant formula

DIGEST: This bill requires infant formula manufacturers to test for heavy metals (arsenic, cadmium, lead, and mercury) and make results available on their internet website.

ANALYSIS:

Existing federal law:

1) Defines, under federal law, "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 United States Code (U.S.C.) § 321(z))

2) Authorizes, by regulation, the establishment of tolerances, regulatory limits, and action limits for added poisonous or deleterious substances.

    a) Provides that a tolerance may prohibit any detectable amount of the substance in food;

    b) Provides that a regulatory limit may prohibit any detectable amount of the substance in food. The regulatory limit established represents the level at which food is adulterated under the federal Food, Drug and Cosmetic Act (FDCA);

    c) Provides that an action level may be established to define a level of contamination at which a food may be regarded as adulterated. Requires a notice to be published in the Federal Register whenever an action level is established or changed, as specified. (21 Code of Federal Regulations (CFR), Part 109); and,

    d) Authorizes a regulation to be established to identify a food containing a naturally occurring poisonous or deleterious substance which will be

deemed to be adulterated under the FDCA. States that these regulations do not constitute a complete list of such foods.

3) Requires an infant formula to be deemed to be adulterated if it: (1) does not provide the required nutrients; (2) does not meet the quality factor requirements; or (3) the processing of such infant formula is not in compliance with the good manufacturing practices and the quality control procedures. Further sets out requirements for the nutrient content, quality factor, current good manufacturing practice (CGMP), and quality control procedures and requires the Health and Human Services Secretary to establish these requirements by regulation (21 U.S.C. § 350a)

4) Establishes the federal regulations for the composition, labeling and safety of infant formula (21 CFR Part 106 & 107)

Existing state law:

5) Establishes the Sherman Food, Drug, and Cosmetics Law (Sherman Law), administered by the California Department of Public Health (DPH), which regulates the packaging, labeling, and advertising of drugs and devices, including dietary supplements. (Health & Safety Code (HSC) §§ 109875-111929.4)

6) Adopts, under Sherman Law, the federal definition of infant formula. Requires DPH 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)

7) Defines the following under the Sherman Law:

   a) A "label" to mean a display of written, printed, or graphic matter upon a food, drug, device, or cosmetic or upon its immediate container. (HSC § 109955)

   b) "Manufacture" to mean the preparation, compounding, propagation, processing, or fabrication of any food, drug, device, or cosmetic. Includes in the definition 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. Does not in the definition include repackaging from a bulk container by a retailer at the time of sale to its ultimate consumer. (HSC § 109970)

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

9) Authorizes, for purposes of enforcement of the Sherman Law, any authorized agent of DPH, upon presenting appropriate credentials and at a reasonable time, to do any of the following:

   a) Enter any factory, warehouse, or establishment in which any food, drug, device, or cosmetic is manufactured, packed, or held; enter any vehicle that is being used to transport or hold the food, drug, device, or cosmetic; or enter any place where any food, drug, device, or cosmetic is suspected of being held in violation of the Sherman Law; and,

   b) Inspect any factory, warehouse, establishment, vehicle, or place, and all pertinent equipment, raw material, finished and unfinished materials, containers, and labeling in the factory, warehouse, establishment, vehicle, or place. In the case of any factory, warehouse, establishment, or consulting laboratory in which any food, drug, device, or cosmetic is manufactured, packed, or held, requires the inspection to include any record, file, paper, process, control, and facility that has a bearing on whether the food, drug, device, or cosmetic is adulterated or misbranded, or falsely advertised within the meaning of this part or whether it has been or is being manufactured, packed, transported, sold, or offered for sale in violation of the Sherman Law. (HSC § 110140)

10) Defines "health officer" (LHO) to mean the health officer appointed by a county board of supervisors, by the governing body of a city, by the governing body of a city and county, or by a local health district board. Authorizes DPH upon the request of an LHO, to authorize a local health department (LHD) to enforce the Sherman Law and the regulations adopted pursuant to it that pertain to retail food establishments, as defined by regulation, if DPH determines that the LHD has sufficient personnel with adequate training to do so. Authorizes an LHD, that is authorized by DPH, to enforce the Sherman Law to make inspections, take samples, make laboratory examinations, impose and remove embargoes, hold informal hearings, certify facts to the district attorney, and institute proceedings for the forfeiture, condemnation, and destruction of food found to be adulterated or misbranded. Gives the LHO and their deputies the same powers and authorities as an inspector of DPH's Bureau of Food and Drug to enforce, as specified. Limits the enforcement to the area under the jurisdiction of the LHD. (HSC § 111015, *et seq.*)

11) Establishes, through the initiative process, Proposition 65, commonly known as the Safe Drinking Water and Toxic Enforcement Act of 1986, which requires businesses to provide warnings to Californians about significant exposures to chemicals that cause cancer, birth defects, or other reproductive harm. Specifies that these chemicals can be in the products that Californians

purchase, in their homes or workplaces, or that are released into the environment. Proposition 65 prohibits California businesses from knowingly discharging significant amounts of listed chemicals into sources of drinking water. Proposition 65 requires California to publish a list of chemicals known to cause cancer, birth defects, or other reproductive harm. This list, which must be updated at least once a year, has grown to include approximately 900 chemicals since it was first published in 1987. (HSC §§ 25249.5 - 25249.14)

12) Requires, through SB 646 (Weber Pierson, Chapter 602, Statutes of 2025) commencing on January 1, 2027, manufacturers of prenatal multivitamins to test their products for heavy metals (arsenic, cadmium, lead, and mercury) and to disclose specified information to the public on their websites, including heavy metal levels in their prenatal multivitamins.

This bill:

1) Requires a manufacturer of infant formula for sale and 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 heavy metals at least once per month.

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

3) Requires a manufacturer to provide test results to any authorized agent of the Department of Public Health (DPH) upon their request pursuant to existing law 5) and 6) below.

4) Requires final formula products sold, manufactured, delivered, held or offered for sale in the state to disclose product information to consumers consistent with the following:

    a) Make publicly and easily available on the manufacturer'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 heavy metal present in each production aggregate of a final infant formula product; and,

    b) Provide descriptive information of the internet website to enable accurate identification of the final infant formula product by consumers. Authorizes descriptive information to include, but not be limited to, product name, universal product code (UPC), size, lot numbers or batch numbers.

5) Requires, if a product is tested for a certain heavy metal subject to an action level, regulatory limit, or tolerance established by existing law 9) below, the manufacturer to include on the product label both of the following:

    a) A Quick Response (QR) code or other machine-readable code that links to the manufacturer's internet website containing both of the following:

        i) Test results for the heavy metal, as provided pursuant to 4) a) above; and,

        ii) An internet website link to an internet website of the United States Food and Drug Administration (FDA) where consumers can find the most recent FDA guidance and information about the health effects of the heavy metal on children.

        iii) A statement that reads: "For information about heavy metal in this product, scan the QR code."

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

    a) Be accredited under the standards of the International Organization for Standardization/International Electrotechnical Commission (IEC) 17925:2017 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 (ug/kg) through an independent proficiency test. Proficiency means that laboratories achieve a z-score that is less than, or equal to, plus or minus two.

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

8) Defines several relevant terms including "heavy metals" as arsenic, cadmium, lead, and mercury.

Background

1) *Infant formula use in the US and California*. Infant formula is an important source of nutrition for many babies in the U.S., whether used exclusively or in combination with breastfeeding. Although breastfeeding is recommended as the

optimal choice of nutrition for most infants, many infants in the U.S. rely on infant formula for some or all of their nutrition. According to DPH's website, many low- to medium-income parents who recently gave birth depend entirely or partially on infant formula because they are unable to exclusively breastfeed long term.[1] In California and beyond, breastfeeding initiation and duration rates are lower in communities of color, as well as working and low-income families.[1]

2) *FDA regulations on formula*. According to the FDA's website, the FDA does not approve infant formulas. However, infant formula manufacturers must notify FDA before marketing a new formula in the United States by providing the FDA with a new infant formula submission.[2] The notification review process ensures that all products meet required nutritional and safety requirements. If an infant formula product is sold in the U.S. and does not meet all applicable requirements, the FDA has the authority to take steps to remove it from the market to protect the health of infant consumers.[2]

   a) *Nutrition*. The FDA regulations specify 30 nutrients that must be included in any infant formula sold in the United States.[2] New infant formulas are reviewed to ensure they contain adequate protein and support healthy growth in infants. The FDA also requires that all ingredients used in infant formula be approved food additives or generally recognized as safe (GRAS) and suitable for such use.[2]

   b) *Sanitation*. Infant formula manufacturers must follow sanitary controls that are required by federal law to prevent contamination of infant formula during manufacturing. [2]

   c) *Labeling*. The FDA has specific requirements for infant formula labels. Information on infant formula labels that is most helpful for caregivers of infants includes directions for preparation and use, a pictogram showing the major steps for preparing infant formula, and a "use by" date.[2] Labels are also required to provide information that is truthful and not misleading.

   d) *Manufacturing practices*. 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

[1] CDPH, *Infant Formula.* https://www.cdph.ca.gov/Programs/CFH/Pages/Infant-Formula-Availability/Infant-Formula-Availability.aspx
[2] US FDA, *Infant Formula Homepage.* https://www.fda.gov/food/resources-you-food/infant-formula-homepage

microorganisms of public health significance or other contaminants, such as heavy metals." (21 CFR § 106.4(e)(3))

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

   a) *Arsenic.* According to the US Agency for Toxic Substances and Disease Registry (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.[3]

   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]

   b) *Cadmium:* According to the ATSDR, in the US 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.[4]

   In adults, cadmium is known to accumulate in organs over time, leading to kidney dysfunction and decreased bone density, among other adverse effects.[5] 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).[4]

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[3] ATSDR, *Clinician Brief: Arsenic*. https://www.atsdr.cdc.gov/environmental-medicine/hcp/clinician-briefs/arsenic.html

[4] ATSDR, *Toxicological Profile for Cadmium.* https://www.atsdr.cdc.gov/toxprofiles/tp5.pdf

[5] Schaefer, H. R., et al. (2023) *Reassessment of the cadmium toxicological reference value for use in human health assessments of foods*, Regulatory Toxicology and Pharmacology. https://www.sciencedirect.com/science/article/pii/S0273230023001551

c) *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.[6] 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.[7] 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.[8] 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."

d) *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. [9] Some children born in communities that ate food with high levels of organic mercury had learning, sensory, and movement problems.[10] In people exposed to high levels of methylmercury in their diets, birth defects have occurred.[10]

4) *Heavy metals in infant formula*. 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

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[6] CDC (2025) *About Childhood Lead Poisoning Prevention*. https://www.cdc.gov/lead-prevention/about/index.html
[7] CDC (2024) *Lead Exposure Symptoms and Complications.* https://www.cdc.gov/lead-prevention/symptoms-complications/index.html
[8] Evens, A. (2015) *The impact of low-level lead toxicity on school performance among children in the Chicago Public Schools: a population-based retrospective cohort study*, Environmental Health. https://pubmed.ncbi.nlm.nih.gov/25889033/
[9] ATSDR, *Toxicological Profile for Mercury*. https://www.atsdr.cdc.gov/toxprofiles/tp46.pdf
[10] ATSDR, *Mercury – ToxFAQs.* https://www.atsdr.cdc.gov/toxfaqs/tfacts46.pdf

foods," in *Science of the Total Environment*.[11] This article presents 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. OEHHA has established safe harbor levels for many of the chemicals on the Proposition 65 list.[12] 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 2302 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.

In 2025, Consumer Reports (CR) tested 41 types of powdered formula for a number of toxic chemicals, including arsenic, lead, BPA, acrylamide, and PFAS. CR reviewed well-known brands, newer startups, popular store brands, and imported brands.[13] About half of the samples tested contained potentially harmful levels of at least one contaminant.

In March 2025, the FDA announced a new initiative called Operation Stork Speed to strengthen its oversight of the formula industry, which includes, among other things, increased testing for heavy metals and other contaminants and other foods children consume.[14] The FDA currently does not have safety levels set for heavy metals in infant formula. The EU limits are 0.02, 0.02, 0.02, and 0.01 mg/kg for arsenic, cadmium, lead, and mercury in powder formula, respectively, and 0.01 mg/kg for arsenic, cadmium, and lead in liquid formula.[15] The EU does not have a safety level for mercury in liquid formula.

Comments

1) *Purpose of 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

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[11] Gardener, H., et al. (2019) *Lead and cadmium contamination in a large sample of United States infant formulas and baby foods*, Science of the Total Environment. https://www.sciencedirect.com/science/article/abs/pii/S0048969718334442

[12] OEHHA. *Proposition 65 No Significant Risk Levels (NSRLs) and Maximum Allowable Dose Levels (MADLs)* https://oehha.ca.gov/proposition-65/general-info/proposition-65-no-significant-risk-levels-nsrls-and-maximum-allowable-dose-levels-madls

[13] Kirchner, L (2025) *We Tested 41 Baby Formulas for Lead and Arsenic,* Consumer Reports. https://www.consumerreports.org/babies-kids/baby-formula/baby-formula-contaminants-test-results-a7140095293/

[14] US FDA*, Operation Stork Speed*. https://www.fda.gov/food/infant-formula-homepage/operation-stork-speed

[15] Eurofins (2026) *Infant Formula Chemical Contaminants and Maximum Allowable Limit*. https://www.eurofinsus.com/food-testing/services/eurofins-food-and-supplement-certifications/eurofins-infant-formula-product-certification/infant-formula-chemical-contaminants-and-maximum-allowable-limits/

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. 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."

2) *Missing action levels and regulatory limits*. This bill requires an infant formula label to include a QR code or other machine-readable code that links to the manufacturer's internet website containing the toxic element test results, a link to an internet website where consumers can find FDA guidance and information about the health effects of the toxic element on children, and a statement directing consumers to the QR code for toxic element information on the product. These provisions apply if a product is tested for a certain toxic element subject to an action level, regulatory limit, or tolerance established by the FDA pursuant to federal regulations. The FDA currently does not have safety levels set for heavy metals in infant formula. Therefore, a portion of the bill's implementation will have to wait for the FDA to set the appropriate action levels.

3) *Senate Health Committee Commitments*. This bill was heard in the Senate Health committee on June 24, 2026. The Chair insisted that AB 2302's passage be contingent on turning the bill from labeling to a ban on the sale of infant formula if the product contains heavy metals above either the maximum action levels in European Commission Regulation (EU) 2023/915 or the FDA action levels, whichever is more protective. Nothing in these amendments is changing the testing of products, so the current monthly testing requirements will be retained. These author amendments will be taken in this committee.

DOUBLE REFERRAL:

This measure was heard in Senate Health Committee on June 24, 2026, and passed out of committee with a vote of 9-0.

Related/Prior Legislation

SB 646 (Weber Pierson, Chapter 602, Statutes of 2025) requires manufacturers of prenatal multivitamins to test their products for specified heavy metals and requires brand owners to disclose specified information to the public on their websites, including heavy metal levels in their prenatal multivitamins.

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.

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 and prohibits the sale, manufacture, or distribution of products in the state that do not comply with AB 899's requirements.

SOURCE: Children Now

SUPPORT:

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 Lulac
California Medical Association (CMA)
California Nurses for Environmental Health & Justice
California Wic Association
Calpirg, California Public Interest Research Group
Center for Community Action and Environmental Justice (CCAEJ)
Center for Environmental Health
Children Now
Clean Water Action
Cleanearth4kids.org

Consumer Federation of California
Consumer Reports
County of Santa Clara
Environmental Working Group
Facts: Families Advocating for Chemical & Toxics Safety
Family Voices of CA
Friends Committee on Legislation of California
Gmo Science
Green Science Policy Institute
Jonas Philanthropies At Impact Assets
Learning Disabilities Association of America
Learning Disabilities Association of California
Lift Economy
Maternal and Child Health Access
Non-toxic Neighborhoods
Our Green Challenge
Physicians for Social Responsibility - San Francisco Bay
Recolte Energy
Safe Passages
Sonoma County Youth Environmental Action Committee
Unleaded Kids

OPPOSITION:

Infant Nutrition Council of America

-- END --