Office of Senate Floor Analyses
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UNFINISHED BUSINESS

Bill No: SB 646
Author: Weber Pierson (D)
Amended: 9/9/25 in Assembly
Vote: 21

SENATE HEALTH COMMITTEE: 11-0, 4/2/25
AYES: Menjivar, Valladares, Durazo, Gonzalez, Grove, Limón, Padilla, Richardson, Rubio, Weber Pierson, Wiener

SENATE ENVIRONMENTAL QUALITY COMMITTEE: 8-0, 4/30/25
AYES: Blakespear, Valladares, Dahle, Gonzalez, Hurtado, Menjivar, Padilla, Pérez

SENATE APPROPRIATIONS COMMITTEE: 6-0, 5/23/25
AYES: Caballero, Seyarto, Cabaldon, Grayson, Richardson, Wahab
NO VOTE RECORDED: Dahle

SENATE FLOOR: 38-0, 5/28/25
AYES: Allen, Alvarado-Gil, Archuleta, Arreguín, Ashby, Becker, Blakespear, Cabaldon, Caballero, Cervantes, Choi, Cortese, Dahle, Durazo, Gonzalez, Grayson, Grove, Hurtado, Jones, Laird, McGuire, McNerney, Menjivar, Niello, Ochoa Bogh, Padilla, Pérez, Richardson, Rubio, Seyarto, Smallwood-Cuevas, Stern, Strickland, Umberg, Valladares, Wahab, Weber Pierson, Wiener
NO VOTE RECORDED: Limón, Reyes

ASSEMBLY FLOOR: 58-0, 9/13/25 – Roll call not available.

SUBJECT: Prenatal multivitamins

SOURCE: American College of Obstetricians & Gynecologists
Environmental Working Group
Unleaded Kids

DIGEST: This bill 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.

Assembly Amendments of 9/9/25 distinguish between the testing responsibilities of the manufacturer and the disclosure responsibilities of brand owners, add additional information that is required to be disclosed on the brand owner's website, including a statement regarding the presence of heavy metals in multivitamins and foods, delay implementation to January 1, 2027, specify that multivitamins sold in the state after January 1, 2030 are required to comply with the labeling requirements, and make other changes to clarify and make more specific various provisions.

ANALYSIS:

Existing federal law:

1) Establishes, through the federal Food and Drug Administration (FDA), various requirements for food labels under the Federal Food, Drug, and Cosmetic Act (FD&C Act), which includes the Nutritional Labeling and Education Act and the Food Allergen Labeling and Consumer Protection Act. These include requiring specified nutrition information, a listing of all ingredients, and whether a produce contains any of eight major food allergens, such as milk, eggs, shellfish, tree nuts, etc. [21 United States Code (USC) §301, et seq. and 21 Code of Federal Regulations §101, et seq.]

2) Defines "dietary supplement" as a product intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance to supplement the diet by increasing the total dietary intake; or, a concentrate, metabolite, constituent, extract, or combination of any of these ingredients. Excludes from this definition something that is represented for use as a conventional food or as a sole item of a meal or the diet. [21 USC §322(ff)]

Existing state law:

1) 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. [Health & Safety Code (HSC) §109875 et seq. and §110380]

2) Requires a manufacturer of baby food for sale or distribution in this state, beginning on January 1, 2024, to test a representative sample of each production aggregate of the manufacturer's final baby food product, at least once per month, at a proficient laboratory, for arsenic, cadmium, lead, and mercury. Requires the laboratory to be able to quantify each toxic element to at least six micrograms to kilogram of food. [HSC §110962(b)(1)]

3) Requires a manufacturer of baby food for sale or distribution in this state to disclose product information for baby food sold on an after January 1, 2025, including making publicly available on the manufacturer's website the name and level of each toxic element present in a final baby food product. [HSC §110962(b)(2)]

4) Requires, if a baby food product is tested for a certain toxic element subject to an action level, regulatory limit, or tolerance established by FDA, to include a Quick Response (QR) code that links to a page on the manufacturer's website that contains test results for the toxic element and a link to an FDA website where consumers can find the most recent FDA guidance and information about the health effects of the toxic element on children. [HSC §110962(b)(B)]

5) Prohibits, under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65), 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]

6) Permits, under Proposition 65, 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; requires regulations implementing Proposition 65, to the extent practicable, to 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)]

This bill:

1) Requires a manufacturer of a bulk prenatal multivitamin product or a packaged prenatal multivitamin product that is sold, manufactured, delivered, held, or offered for sale in the state to test a representative sample of each lot of the manufacturer's bulk prenatal multivitamin product or packaged prenatal multivitamin product, beginning January 1, 2027, at a proficient laboratory for heavy metals.

2) Requires the laboratory, including a manufacturer's in-house laboratory, to meet all of the following criteria:

   a) Be accredited under the standards of the International Organization for Standardization's and the International Electrotechnical Commission's international standard regarding the general requirements for the competence of testing and calibration laboratories as they pertain to the testing of heavy metals, unless they contradict federal regulations, which shall control;

   b) Use an analytical method that is at least as sensitive and specific as described in the FDA's Elemental Analysis Manual for Food and Related Products: Inductively Coupled Plasma-Mass Spectrometric Determination of Arsenic, Cadmium, Chromium, Lead, Mercury, and Other Elements in Food Using Microwave Assisted Digestion; and,

   c) Demonstrate proficiency in quantifying each heavy metal to 10 micrograms or less of the heavy metal to kilogram of supplement through an independent proficiency test, and defines proficiency as achieving a z-score that is less than or equal to plus or minus two.

3) Requires both manufacturers and brand owners to provide test results to an authorized agent of CDPH upon their request. Permits a brand owner, if it does not manufacture the multivitamin product, to comply by providing the test results of the manufacturer they use to produce the multivitamin product.

4) Requires the brand owner of a packaged prenatal multivitamin product that is sold, manufactured, delivered, held, or offered for sale in the state, including prenatal multivitamins that are sold by a retailer or that are sold directly to consumers, beginning January 1, 2027, to disclose product information to the public consistent with all of the following:

   a) Make publicly available on the brand owner's website, for the duration of the product shelf life plus one month, all of the following: the name and level of each heavy metal present in each lot of a packaged prenatal

multivitamin product; information from the product's supplement facts panel, including the amount per serving of each ingredient; 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."

b) Provide descriptive information on its website to enable accurate identification of the prepackaged prenatal multivitamin product by the public, including information that makes the levels of heavy metals available to the public by lot;

c) An internet website hyperlink to the FDA where the public can find the most recent FDA website relating to heavy metals in food'; and,

d) On the brand owner's website describing a packaged prenatal multivitamin product, on the outermost package for products sold in retail stores, and on the product details page for a product sold online or directly to consumers, requires a statement that reads: "For information about heavy metal testing on this product" followed by a hyperlink to the website that contains the publicly available test results, or a website address, as appropriate.

5) Prohibits a person from selling, manufacturing, delivering, holding, or offering for sale, on or after January 1, 2030, a prenatal multivitamin that does not include the packaging or online statements specified by this bill..

6) Defines "heavy metals" as arsenic, cadmium, lead, and mercury, and defines various other terms for purposes of this bill, including "brand owner," "bulk" and "prepackaged" prenatal multivitamin products, and others.

Comments

According to the author of this bill:

Prenatal vitamins are essential for supplementing the nutritional needs of pregnant individuals, helping to prevent birth defects, low birth weight, and pregnancy complications. While a balanced diet is ideal, many Americans, including Californians, do not consume adequate nutrients. Prenatal vitamins commonly contain folic acid, iodine, iron, and other essential nutrients for a pregnant individual. Recent studies highlight concerns over toxic element contamination of prenatal vitamins with lead, arsenic, cadmium, and mercury. A U.S. Government Accountability Office (GAO) study found lead, a heavy metal with no safe level of exposure, in half of the sampled prenatal vitamins, with some independent studies finding contamination, exceeding California's Proposition 65 limits. Given the risks associated with heavy metal exposure and the absence of federal or state regulations specific to prenatal vitamins, legislative action is needed to enhance transparency, which allows consumers to make informed choices, incentivizes companies to reduce toxic element contamination, and, if needed, provide a basis for setting safety standards.

Background

FDA regulation of dietary supplements. Under the FD&C Act, as amended in 1994 by the Dietary Supplement Health and Education Act (often referred to as DSHEA), the FDA does not have the authority to approve dietary supplements for safety and effectiveness, or to approve their labeling, before the supplements are sold to the public. Instead, dietary supplements are regulated by the FDA in much the same manner as food, which means they are subject to requirements relating to good manufacturing practices, and must meet certain labeling standards, among other requirements. According to the FDA, it is the responsibility of dietary supplement companies to ensure their products meet the safety standards for dietary supplements and are not otherwise in violation of the law. Dietary supplement labels are required to have nutrition information in the form of a Supplement Facts label that includes the serving size, the number of servings per container, a listing of all dietary ingredients in the product, and the amount per serving of those ingredients. They also must have a statement on the front of the product identifying it as a "dietary supplement" or similar descriptive term (e.g., "herbal supplement" or "calcium supplement"). The FD&C Act requires that manufacturers and distributors who wish to market dietary supplements that contain a "new dietary ingredient" (NDI) to notify the FDA about these ingredients. An NDI is an ingredient that was not marketed in a dietary supplement in the U.S. prior to October 15, 1994. When notifying the FDA about an NDI, the notification must include information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing the NDI will

reasonably be expected to be safe under the conditions of use recommended or suggested in the labeling. While the FDA is not required to formally approve an NDI, it will consider a dietary supplement "adulterated" unless the NDI has been present in the food supply in the same chemical form that you plan to use in the dietary supplement, or the manufacturer has shown evidence of safety at least 75 days before being introduced or delivered for introduction into interstate commerce, including any citation to published articles.

Importance of prenatal vitamins. According to a study published in the journal Maternal Health, Neonatology and Perinatology in July of 2022, entitled, "Evidence Based Recommendations for an Optimal Prenatal Supplement for Women in the US: Vitamins and Related Nutrients," sub-optimal intake of vitamins from preconception through pregnancy increases the risk of many pregnancy complications and infant health problems. According to this study, in the U.S., dietary intake of vitamins is often below recommended intakes, especially for vitamin D, choline, and DHA, and that many studies suggest that insufficient vitamin intake is associated with a wide range of pregnancy complications (anemia, Cesarean section, depression, gestational diabetes, hypertension, infertility, preeclampsia, and premature rupture of membranes) and infant health problems (asthma/wheeze, autism, low birth weight, congenital heart defects, intellectual development, intrauterine growth restriction, miscarriage, neural tube defects, orofacial defects, and preterm birth). The study found that prenatal supplements vary widely in content, often contained only a subset of essential vitamins and the levels were often below recommendations. The study suggested that increasing prenatal vitamin supplementation to the levels recommended in the study may reduce the incidence of many pregnancy complications and infant health problems. A related study by the same authors focusing on minerals, including calcium, iron, magnesium, selenium, and zinc, made similar findings and recommendations regarding the need for supplementation, especially for iodine, magnesium, and iron. Numerous organizations, including the FDA, the Centers for Disease Control and Prevention, and the American College of Obstetricians and Gynecologists, emphasize the importance of taking a prenatal vitamin that contains at least 400 micrograms of folic acid each day at least one month before pregnancy and during the first 12 weeks of pregnancy, and to consult with an obstetric care provider to see if additional supplementation is recommended based on a person's health history. Folic acid can help prevent neural tube defects.

GAO report on prenatal supplements. The GAO published a report in December 2023 entitled "Prenatal Supplements: Amounts of Some Key Nutrients Different from Product Labels." The overall thrust of this report was that of the 12 supplement products tested; most of them had levels of nutrients that did not

correspond to the value on the label. The GAO report noted that FDA lacks authority to regulate dietary supplements with the same rigor as drugs, with oversight primarily occurring once the supplements are already on the market. The GAO recommended that Congress consider measures providing the FDA with sufficient authority to carry out oversight of dietary supplements. However, as part of the testing for this report, the supplement products were tested for heavy metal contamination, and six of the 12 products were found to have trace amounts of heavy metals, though not in amounts likely to cause a health concern based on metrics used by the FDA. Of the six products with trace amounts of heavy metals, all six had trace amounts of lead, and two had trace amounts of cadmium. Arsenic and mercury were below the detection limits in all of the samples. The highest average lead content found was 0.31 micrograms per daily serving, which is well below FDA's threshold of 8.8 micrograms of lead per day for individuals of a childbearing age. The report noted that while the FDA recognizes that a safe level of lead exposure has not been identified for fetal brain and cognitive development, based on existing data and other information, the FDA concluded that the levels found it its study were unlikely to pose a health concern. Regarding the two supplement products that contained cadmium, one was contained 0.52 micrograms per daily serving, and the other contained 0.32 micrograms per daily serving. The FDA uses a daily exposure limit of 0.21 – 0.36 micrograms of cadmium per kilogram of body weight per day for any individual, which corresponds to a limit of 14.3 – 24.5 micrograms per day for a 150-pound individual. Based on daily exposure limits used by the FDA, neither of the findings of cadmium in the tested supplements is likely to pose a health concern.

Why are these toxic elements in supplements and other food products? The FDA's "Closer to Zero" initiative is working to reduce childhood exposure to toxic elements in food. According to the FDA, arsenic, lead, cadmium and mercury may occur in the environment naturally (as elements in the earth's crust) and from human activities. Levels in the air, water, and soil used to grow crops, process foods, and raise animals can vary depending on natural geographical proximity to past or current pollution. The amount of arsenic, lead, cadmium, or mercury in certain foods depends on the amount in the environment and how much the plant or animal 'takes up' from the environment. The GAO report on prenatal supplements noted that the presence of heavy metals may not be from the manufacturing process, but rather the ingredients chosen for the vitamins or minerals they contain. For example, bioaccumulation (a build-up of environmental substances in an organism) can result in an increased presence of arsenic in rice (a source of iron and calcium) and mercury in fish (a source of omega-3 fatty acids). Additionally, research shows a correlation between calcium and lead in naturally occurring sources of calcium such as shells, bone, and rock.

FISCAL EFFECT: Appropriation: No Fiscal Com.: Yes Local: Yes

According to the Assembly Committee on Appropriations:

1) The California Department of Public Health estimates ongoing, annual costs of $169,000 starting in fiscal year 2026-27 to cover one full-time employee position to perform inspections and field audits, including remote inspections and desk audits, re-inspections, new license inspections, label review, and field visits to California firms holding out-of-state products (General Fund).
2) The Department of Justice (DOJ) anticipates increased workload for the Environmental Justice and Protection Section (EJPS) within DOJ's Public Rights Division to enforce this bill. The work anticipated by EJPS could require a significant increase in attorney hours. DOJ is unable to estimate at this time the additional number of Deputy Attorneys General, along with their legal complement, that might need to be hired. If DOJ does not pursue enforcement as authorized by this bill, DOJ would likely not incur any costs, but if DOJ hires staff to handle enforcement actions, costs could be in the low hundreds of thousands of dollars annually, at a minimum (Unfair Competition Law Fund).

SUPPORT: (Verified 9/10/25)

American College of Obstetricians & Gynecologists (co-sponsor)
Environmental Working Group (co-sponsor)
Unleaded Kids (co-sponsor)
A Voice for Choice Advocacy
American College of Obstetricians & Gynecologists – District IX
American Nurses Association\California
Black Women for Wellness Action Project
California Environmental Voters
California Medical Association
California Nurses for Environmental Health & Justice
California Nurse Midwives Association
California WIC Association
Center for Community Action and Environmental Justice
Center for Environmental Health
Center for Science in the Public Interest
Children Now
Cleanearth4kids.org
Consumer Federation of California
Consumer Reports Advocacy
Families Advocating for Chemical Toxics Safety

Friends Committee on Legislation of California
GMO Science
Healthy Babies Bright Futures
Indivisible Marin
Long Beach Alliance for Clean Energy
Mamavation
Maternal and Child Health Access
National Health Law Program
Non-Toxic Neighborhoods
Planned Parenthood Affiliates of California
Recolte Energy
Ritual
Unleaded Kids
www.GMOScience.org

OPPOSITION: (Verified 9/10/25)

Consumer Healthcare Products Association
Council for Responsible Nutrition
Natural Products Association

ARGUMENTS IN SUPPORT: This bill is co-sponsored by the American College of Obstetricians and Gynecologists District IX, the Environmental Working Group, and Unleaded Kids. The sponsors state that prenatal vitamins play a critical role in supporting healthy pregnancies, providing essential nutrients that help lower the risk of birth defects, low birth weight, and other complications. However, recent studies have raised concerns about contamination of these supplements with toxic elements known to pose serious health risks, especially to pregnant individuals and developing fetuses. The sponsors state that this bill addresses this critical gap by requiring manufacturers to test a representative sample from each production lot for arsenic, cadmium, lead, and mercury, and permits consumers to access this information via a QR code on product labels, linking to a webpage with FDA guidance on the health risks associated with these heavy metals. Sponsors state that California has long led the nation in protecting public health through transparency and accountability measures, and this bill builds on that progress by empowering pregnant individuals with vital information to choose safe and reliable prenatal supplements, free from harmful contaminants.

ARGUMENTS IN OPPOSITION: The Natural Produces Association (NPA) opposes this bill state that it would lead to significant consumer confusion for a variety of reasons. First, NPA states that it could lead to a misinterpretation of risk,

where consumers may mistakenly believe that prenatal vitamins are intentionally contaminated with substances even though these elements are naturally occurring and present in many foods, and that this warning could cause fear and hesitation that will lead some pregnant individuals to avoid essential prenatal vitamins. Second, NPA states that there will be a lack of context about natural occurrence, making consumers believe prenatal vitamins pose a unique health risk even thoug the levels are well below established safety thresholds. NPA points out that the FDA already regulates heavy metal limits in food and supplements based on scientific risk assessments and if enacted, this bill will conflict with federal law and cause confusion over whether prenatal vitamins sold in California are somehow different from those sold elsewhere. Finally, NPA states that this bill has the potential for unnecessary alarm and product avoidance, where women will stop taking prenatal vitamins altogether out of fear of toxicity, leading to greater health risks for both mother and baby.

Oppose unless amended. The Council for Responsible Nutrition and the Consumer Healthcare Products Association submitted a joint letter opposing this bill unless amended. The opponents argue that manufacturers do not intentionally add these elements to their products, but they may occur in certain raw materials, that federal regulations already require Good Manufacturing Practices, and that manufacturers already test these products for the presence of heavy metals. Opponents state that notifying consumers of the presence of these elements at any level will send mixed messages when those consumers are also encouraged by their doctor to take prenatal vitamins while pregnant. Opponents point out that the specified toxic elements are already regulated and enforced under California's Proposition 65, which requires a warning if the product might expose consumers to carcinogens or reproductive toxicants at protective levels set by the Office of Environmental Health Hazard Assessment. The opponents request that the provisions requiring public disclosure of laboratory test results on manufacturer websites, and the provisions mandating QR codes on product labels, be removed from the bill.

Prepared by: Vincent D. Marchand / HEALTH / (916) 651-4111
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