
SENATE COMMITTEE ON ENVIRONMENTAL QUALITY

Senator Allen, Chair

2023 - 2024 Regular

Bill No: AB 496

Author: Friedman

Version: 3/8/2023

Urgency: No

Consultant: Gabrielle Meindl

Hearing Date: 6/7/2023

Fiscal: No

SUBJECT: Cosmetic safety

DIGEST: Prohibits, commencing January 1, 2027, a person or entity from manufacturing, selling, delivering, holding or offering for sale in commerce any cosmetic product that contains any of the 26 intentionally added ingredients specified in this bill.

ANALYSIS:

Existing law:

- 1) Requires, pursuant to the federal Food, Drug & Cosmetic Act (FD&C Act), cosmetics produced or distributed for retail sale to consumers for their personal care to bear an ingredient declaration. (21 Code of Federal Regulations 701.3)
- 2) Defines, pursuant to the Sherman Act, "cosmetic" as any article, or its components, intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to, the human body, or any part of the human body, for cleansing, beautifying, promoting attractiveness, or altering the appearance. Provides that the term "cosmetic" does not include soap. Makes it unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any cosmetic that is adulterated. Makes it unlawful for any person to adulterate any cosmetic. Makes it unlawful for any person to receive in commerce any cosmetic that is adulterated or to deliver or proffer for delivery any such cosmetic. (Health & Safety Code (HSC) § 109900)
- 3) Requires, pursuant to the Safe Consumer Cosmetic Act (Cosmetics Act), a manufacturer of a cosmetic that is subject to regulation by the federal Food and Drug Administration (FDA) to submit to the California Department of Public Health (CDPH) a list of its cosmetic products sold in California that contain any ingredient that is a chemical identified as causing cancer or reproductive toxicity. (HSC § 111792)

- 4) Prohibits, pursuant to 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)
- 5) Requires the Department of Toxic Substances Control (DTSC), under the state's Green Chemistry regulations, to establish a process to identify and prioritize chemicals or chemical ingredients in consumer products that may be considered a chemical of concern. (HSC § 25252)
- 6) Requires DTSC to develop and maintain a list of Candidate Chemicals that exhibit a hazard trait and/or an environmental or toxicological endpoint and is either 1) found on one or more of the statutorily specified authoritative lists or 2) is listed by DTSC using specified criteria. (California Code of Regulations § 69502.2 (b))
- 7) Prohibits, commencing January 1, 2025, a person or entity from manufacturing, selling, delivering, holding, or offering for sale in commerce any cosmetic product that contains 13 chemical ingredients banned from use in cosmetics by the European Union (EU).

UNCODIFIED INTENT LANGUAGE:

- 1) Provides that it is the intent of the Legislature to enact a prohibition on the presence of intentionally added ingredients in cosmetics that is consistent with the prohibition on the presence of intentionally added ingredients in cosmetics that was enacted by the EU. (Added by AB 2762, Chapter 314, Statutes of 2020).

This bill:

- 1) Prohibits, commencing January 1, 2027, a person or entity from manufacturing, selling, delivering, holding or offering for sale in commerce any cosmetic product that contains any of the 26 intentionally added ingredients specified in this bill classified as carcinogenic, mutagenic, or toxic for reproduction.

Background

- 1) *Public health concerns with cosmetics.* Cosmetic products are sold to consumers across California, including to children who are still in the formative years of development. These products are used as part of daily beauty and cleansing routines, often times on the skin's most sensitive areas,

like the face, eyelids, and lips. Cosmetic products are most heavily used by women, including those of childbearing age, increasing the likelihood of exposing mothers, fetuses, and nursing children to substances that can cause cancer and reproductive toxicity. That is why it is so important that cosmetic products are safe, properly labeled, and free of contamination.

- 2) *State cosmetic regulatory requirement.* California has two laws governing the safety of cosmetics. The first is the Sherman Act, which is administered by CDPH to regulate cosmetics. It broadly defines a cosmetic as any article, or its components, intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to, the human body, or any part of the human body, for cleansing, beautifying, promoting attractiveness, or altering the appearance.

Pursuant to the Sherman Act, any cosmetic is considered to be adulterated "if it bears or contains any poisonous or deleterious substance that may render it injurious to users." However, adulteration, in many instances, refers to tampering with a product after the manufacturer has completed its manufacturing. Selling adulterated cosmetics can lead to civil and administrative penalties, embargoes, and even bans on products.

The other law is the California's Cosmetics Act, established by SB 484 (Migden, Chapter 729, Statutes of 2005). It requires that for all cosmetic products sold in California, the manufacturer, packer, and/or distributor named on the product label shall provide CDPH a list of all cosmetic products that contain any ingredients known or suspected to cause cancer, birth defects, or other reproductive harm. CDPH maintains an active, searchable database with all of the data collected from manufacturers under the Cosmetics Act. It is required to make that data user-friendly and available to the public. To date, 867 companies have reported 119,089 products to CDPH. CDPH does not have any enforcement authority or penalty authority over the manufacturers that are covered, so not all manufacturers are currently complying and submitting their products' information. State law does not currently contain a mechanism that would allow the state to compel these manufacturers to comply.

- 3) *Federal cosmetics regulatory requirements.* Neither the FDA nor CDPH require premarket safety testing, review, or approval of cosmetic products.

Under the FD&C Act, cosmetics and their ingredients are not required to be approved before they are sold to the public, and the FDA does not have the authority to require manufacturers to file health and safety data on cosmetic

ingredients or to order a recall of a dangerous cosmetic product.

- 4) *What we know about the chemicals listed in the bill vis-à-vis the EU.* The EU, which includes 27 member countries mostly across Europe, develops policies to ensure the free movement of people, goods, services, and capital within the internal market, and enacts legislation to maintain common policies to have cohesion amongst the 27 members on things from trade to agriculture.

The EU Cosmetics Directive (Directive) was adopted in 1976 and formed on the basis of commonly agreed to safety standards relative to cosmetics. On September 15, 2022, the European Commission published Regulation (EU) 2022/1531 to amend Cosmetics Regulation (EC) No. 1223/2009 for the use of certain ingredients classified as carcinogenic, mutagenic, or toxic for reproduction (CMR substances) in cosmetic products.

The EU Directive requires member states to take all necessary measures to ensure that only cosmetic products which conform to the provisions of the Directive and its Annexes can be put on the market. Additionally, the Directive requires member states to prohibit the marketing of cosmetic products containing ingredients listed in the Directive and its Annexes. The regulation defines "cosmetic product" as "any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odors." The scope of products covered under the EU's definition of cosmetics is broader than the scope of products covered under California's definition of cosmetics.

- 5) *Prior legislation.* AB 2762 (Muratsuchi, Chapter, 314, Statutes of 2020) bans a list of specified ingredients from cosmetics products consistent with the EU's Annex II of regulation No 1223/2009, which lists the substances prohibited in cosmetic products sold in the EU. While AB 2762 was moving through the legislative process, industry stakeholders weighed in and formally opposed the bill while it was being heard in the Assembly Environmental Safety and Toxic Materials Committee. Specifically in opposition to AB 2762, the Personal Care Products Council, Fragrance Creators Association, California Chamber of Commerce, and other industry groups were oppose unless the bill was further amended. They collectively stated,

"The undersigned organizations support better alignment with the health and safety standards set forth by the European Union that prohibit the intentional

use of specified ingredients which are listed in the EU Cosmetics Regulation 1223/2009, ANNEX II, List of Substances Prohibited in Cosmetic Products. In order to achieve this goal, AB 2762 needs further amendments. The authors have already publicly committed to aligning California law with the EU regulation – not anything more or less. We remain committed to achieving this goal. As such, we have submitted draft language that we believe would fully align AB 2762 with the EU regulations."

Comments

- 1) *Purpose of Bill.* According to the author, "Personal care products and cosmetics should be non-toxic for everyone. If you consider that the European Union prohibits over 1,600 chemicals in such products, a ban in California on these noxious carcinogens and endocrine disrupters is long overdue. AB 496 continues our progress toward cleaner, healthier, and environmentally-safer products."
- 2) *Consistency with the European Union.* The intent of this bill is to be consistent with the approach of the EU's cosmetic regulation. All of the chemicals listed in AB 496 have been fully banned in the EU Directive and its Annexes and consequently have already been removed from cosmetic products sold in the EU. The approach in AB 496 is modeled after AB 2762 and reflects a strategy specifically requested by industry stakeholders when they were negotiating amendments to AB 2762 – aligning California's bans on cosmetic ingredients with ingredients that are also banned in the EU.

California does not have a rigorous scientific process to evaluate chemical ingredients in cosmetics. Until such time that California has a process, it seems reasonable to protect California consumers in the same manner that consumers in the EU have been protected. It is important to note that the cosmetic products for sale in the EU have been reformulated to remove the ingredients banned in the Directive and therefore could also be sold in California if this bill were to pass and become law.

- 3) *Should California be different than the EU?* Industry representatives who negotiated AB 2762 had argued that it would be helpful to industry if California conformed its list of banned ingredients to the EU's list. In a shift from industry's previous position on AB 2762, opposition to AB 496, is now asking for one of the chemicals in the bill to be removed even though it is already banned in the EU, so that it could continue to be sold in California. If the Legislature were to agree to remove a chemical banned in the EU from the

state's ban list, this would effectively create a list in California that no longer aligns with the EU. This would arguably open the door to future conversations about additional chemicals that California would like to ban, even when these chemicals are not currently banned in the EU.

- 4) *The case for and against the exclusion of lilial.* The fragrance industry is opposed to AB 496 unless the bill is amended to remove lily aldehyde, also known as lilial, from the bill's list of prohibited cosmetic ingredients. The industry maintains that the EU did not base their restriction on risk, but made a hazard-based decision. This hazard-based action "does not consider existing safety assessments of the Research Institute for Fragrance Materials nor the International Fragrance Association Standards that support the safe use on risk considerations."

However, the sponsors of AB 496 counter that the EU's Risk Assessment Committee and its Scientific Committee on Consumer Safety have evaluated both the hazards and risks of lilial and concluded that the chemical poses reproductive and developmental dangers to humans under industry standards of use. Moreover, the sponsors maintain that "lilial's harmful effects in consumer products are recognized under California law and regulation, since lilial is listed as a Candidate Chemical under the Department of Toxic Safety Control's Safer Consumer Products Program."

Related/Prior Legislation

AB 2771 (Friedman, Chapter 804, Statutes of 2022). Prohibits any person or entity from manufacturing, selling, delivering, holding, or offering for sale in commerce any cosmetic product that contains any per- or polyfluoroalkyl substance (PFAS).

AB 2762 (Muratsuchi, Chapter 314, Statutes of 2020). Prohibits, beginning January 1, 2025, the manufacture, sale, delivery, holding, or offering for sale in commerce of any cosmetic product containing specified intentionally added ingredients.

SOURCE: Environmental Working Group

SUPPORT:

Active San Gabriel Valley

Alliance of Nurses for Healthy Environments

American Bird Conservancy

American College of Obstetricians and Gynecologists District IX

As You Sow

Attn: Grace
Ban Sup (single Use Plastic)
Beautycounter
Booni Doon
Brand Geek
California Health Coalition Advocacy
California Nurses for Environmental Health and Justice
California Product Stewardship Council
California Water Service
Calpirg
City and County of San Francisco
Clean Water Action
Codex Labs Corp
Consumer Federation of California
Dietrick Institute for Applied Insect Ecology
Eco Plum
Educate. Advocate.
Environmental Working Group
Families Advocating for Chemical and Toxics Safety
Feminists in Action Los Angeles
Friends Committee on Legislation of California
Friends of The Earth
Green Science Policy Institute
Grove Collaborative
Healthy Highways
Indivisible Alta Pasadena
Indivisible California Green Team
Indivisible Ventura
Inna Organics
Intelligent Nutrients
Jonas Philanthropies
Just the Goods
Long Beach Environmental Alliance
Moms Across America
National Association of Environmental Medicine
National Stewardship Action Council
Nontoxic Neighborhoods
Olita
Osea Skincare
Poison Free Malibu
Prima
Queers 4 Climate
Rooted in Resistance
San Francisco Baykeeper

Save Our Shores
Seventh Generation
Sierra Club California
Socal 350 Climate Action
Sonoma Safe Agriculture Safe Schools (Sonoma Sass)
The Keep a Breast Foundation
Women for A Healthy Environment
Women's Voices for The Earth
Worksafe

OPPOSITION:

Fragrance Science & Advocacy

ARGUMENTS IN SUPPORT: According to a coalition of supporters, including the sponsor of the bill, the Environmental Working Group:

"This important bill will add to the list of chemicals that California does not allow in cosmetics sold in the state. In particular, AB 496 prohibits the sale in California of beauty and personal care products containing any one of 26 highly toxic chemicals that pose public health harms, such as increased risk of cancer, harm to the reproductive system, and harm to aquatic life with long-lasting effects. The environmental risks of these 26 chemicals are particularly concerning because cosmetics are regularly washed off after use. Because of their toxicity, all of the AB 496-listed chemicals are prohibited from being used in cosmetics sold in the European Union.

Out of the more than 10,000 chemicals used to formulate beauty and personal care products, the United States Food and Drug Administration has only ever banned or restricted 11. In contrast, the European Union prohibits or restricts the use of nearly 1,600 chemicals including the AB 496 chemicals in cosmetics, and many other countries tightly regulate cosmetics sold to their citizens. According to CDPH's Safe Cosmetics Program, at least 88 different carcinogens and reproductive toxicants are intentionally added to thousands of cosmetic products sold in California today. Also, even after a manufacturer has reformulated a product to comply with European standards, the manufacturer often continues to sell the originally-formulated product to Californians."

ARGUMENTS IN OPPOSITION: According to the Fragrance Creators Association:

"Fragrance Creators Association (Fragrance Creators) is writing to express our opposed unless amended position on AB 496. We appreciate your goal of limiting the use of ingredients in cosmetics that pose a risk to California consumers. We would like to raise a concern regarding the proposal to prohibit the fragrance ingredient p-BMHCA (2-(tert-butylbenzyl propionaldehyde) (CAS Number: 80-54-6) commonly known as Lilial® and also known as Lily aldehyde. We must respectfully request that this ingredient be removed from the legislation, as the body of science does not show there is a risk to consumers when the ingredient is used in alignment with industry safety standards and applicable regulatory requirements.

AB 496 seeks to align cosmetic ingredient restrictions with those adopted by the European Union (EU). Unfortunately, the EU did not base their restriction on risk, but made a hazard-based decision. For over 50 years, the Research Institute for Fragrance Materials (RIFM)s purpose has been to gather and analyze scientific data, engage in testing and evaluation, distribute information, cooperate with official agencies and to encourage uniform safety standards related to the use of fragrance ingredients. According to RIFM's assessment, Lilial may be safely used in cosmetic products below certain specific concentration limits set in an IFRA Standard."

-- END --