Date of Hearing: May 14, 2020

ASSEMBLY COMMITTEE ON ENVIRONMENTAL SAFETY AND TOXIC MATERIALS Bill Quirk, Chair

AB 2762 (Muratsuchi) – As Introduced February 20, 2020

SUBJECT: Cosmetics: safety

SUMMARY: Amends the Sherman, Food, Drug and Cosmetic Act (Sherman Act) to expand the definition of an adulterated cosmetic. Specifically, **this bill**:

- 1) Establishes the Toxic-Free Cosmetics Act.
- 2) Provides that, beginning January 1, 2022, a cosmetic is adulterated if it contains any amount of the following intentionally added ingredients:
 - a) Dibutyl phthalate;
 - b) Diethylhexyl phthalate;
 - c) Formaldehyde;
 - d) Paraformaldehyde;
 - e) Methylene glycol;
 - f) Quaternium-15;
 - g) Mercury;
 - h) Isobutylparaben;
 - i) Isopropylparaben;
 - j) m-Phenylenediamine and its salts;
 - k) o-Phenylenediamine and its salts; and,
 - 1) The following long-chain per- and polyfluoroalkyl substances (PFAS) and their salts:
 - i) Perfluorooctane sulfonate (PFOS);
 - ii) Perfluorooctanoic acid (PFOA);
 - iii) Perfluorodecanoic acid (PFDA); and,
 - iv) Perfluorononanoic acid (PFNA).
- 3) Provides that a cosmetic is adulterated if it contains a chemical, other than those listed above, that has been identified by the California Department of Public Health (CDPH) by regulation after a stakeholder process. Authorizes CDPH to identify additional chemicals only if the chemical is listed as a banned substance in Annex II of Regulation No. 1223/2009 of the European Parliament and of the European Council or in any updates to that Annex.
- 4) Provides that, if a cosmetic product made through manufacturing processes intended to comply with this part contains a technically unavoidable trace quantity of a chemical listed above or identified and added by CDPH, and that trace quantity stems from impurities of natural or synthetic ingredients, the manufacturing process, storage, or migration from packaging, that trace quantity shall not cause the cosmetic product to be adulterated.
- 5) Provides that failure to comply with any of the following is a violation of the Sherman Act:
 - a) The requirements of the Sherman Act;
 - b) A request by the Division of Environmental and Occupational Disease Control (Division) pursuant to existing statutory authority for information, data, or statistics; and,

- c) Guidelines or instructions issued by the Division to implement the Sherman Act.
- 6) Requires the Division to report all violations of the Sherman Act to the Department of Justice.
- 7) Establishes the intent of the Legislature to enact a prohibition on the presence of chemicals in cosmetics that is consistent with the prohibition on the presence of chemicals in cosmetics that was enacted by the European Union (EU).

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 (CFR) 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 subject to regulation by the federal Food and Drug Administration (FDA) to submit to 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) 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))

FISCAL EFFECT: Unknown.

COMMENTS:

Need for the bill: According to the author, "No one knowingly wants to use face powder contaminated with asbestos, lipstick that contains lead, or baby shampoo with formaldehyde.

AB 2762 would clarify in statute that cosmetics containing some of the most well-known carcinogens, reproductive toxicants, and endocrine disruptors are adulterated cosmetics, and cannot be sold in the state, protecting Californians against harmful chemicals in cosmetic products they use every day."

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.

State cosmetic regulatory requirements: 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, 613 companies have reported 75,279 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. There is no way to compel these manufacturers to comply.

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.

What we know about the chemicals listed in the bill vis-à-vis the EU: The EU, which includes 28 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 28 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. This Directive was reevaluated in 2009 and an EU-wide Cosmetics Products Regulation was enacted in July 2013.

EU regulation No 1223/2009 on cosmetics establishes rules to be complied with by any cosmetic product made available on the market, in order to ensure the functioning of the internal market and a high level of protection of human health. 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.

Annex II of regulation No 1223/2009 lists the substances prohibited in cosmetic products. 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 2762 have been fully banned in the EU under Annex II.

Establishing a prohibition: As the bill is currently written, a cosmetic would be deemed adulterated if it contained one or more of the listed intentionally added ingredients. However, the cosmetics and personal care products industry contend that a product could be adulterated by a third party after the product has been manufactured. As a case in point, skin creams that have recently been found on the market laced with mercury and found in violation of the Sherman Act as adulterated products were not made by the manufacturer with mercury; rather, the skin creams were adulterated after the fact by a below-board retail entity, which was no fault of the manufacturer. Therefore, to reconcile the semantics of the bill while maintaining legal responsibility on the manufacturer for producing cosmetics without the listed ingredients, the Committee may wish to amend the bill as follows:

(a) <u>Beginning January 1, 2022, except as provided in subdivision (c), a cosmetic is adulterated if it contains any amount of the following intentionally added ingredients:</u> Commencing January 1, 2025, no person or entity shall manufacture, sell, deliver, hold, or offer for sale in commerce any cosmetic product that contains any of the following intentionally added ingredients:

In addition, the EU cosmetics regulation references prohibited ingredients, not adulteration; therefore, the proposed Committee amendment will further align the bill with the EU's regulatory approach for banned ingredients.

COVID-19 pandemic: The provisions of this bill directly affect the companies that manufacture cosmetic and personal care products for sale in California, and those companies are currently reeling from the impacts the coronavirus pandemic has had on the economy and the shift in consumer product needs.

As personal hygiene has become the most important method for preventing spread of the virus, consumers have increased their purchasing power of soaps and sanitizers. Hospitals and other health care centers are also in high need of the same line of products. Cosmetic and personal care product companies have refitted their factories to increase production and supply of sanitizer products to help combat COVID-19. On top of the abrupt manufacturing shift, the

cosmetics industry has also been hit hard by an economic slowdown of unprecedented proportions, and will have to rebuild their workforce (layoffs and furloughs) and rebuild their respective companies. As a result, they would need more time in order to work on compliance with any new mandate.

In recognition of the pandemic's impacts on the cosmetic industry, the Committee may wish to consider delaying implementation from 2022 to 2025.

(a) <u>Beginning January 1, 2022, except as provided in subdivision (c), a cosmetic is adulterated if it contains any amount of the following intentionally added ingredients: Commencing January 1, 2025, no person or entity shall manufacture, sell, deliver, hold, or offer for sale in commerce, any cosmetic product that contains any of the following intentionally added ingredients:</u>

The pandemic has also impacted the Legislative timelines for considering legislation this year, and legislation has been prioritized based on whether it addresses the ongoing pandemic and other ancillary priorities. Legislation proposing any workload that is unrelated to the state's current crises (COVID19 pandemic, wildfires, homelessness) for state agencies directly involved with managing those crises have been postponed to future legislative sessions.

As it relates to AB 2762, the author notes that toxic chemicals can impair or suppress immune systems, and preventing unnecessary exposure to toxic chemicals in consumer products can protect public health in times like this. However, the provision in the bill authorizing CDPH to list additional chemicals would create pressure on the department to do workload unrelated to the current pandemic crisis at hand. Therefore, the Committee may wish to consider deleting the provision providing new cosmetic authority to CDPH entirely as follows:

(b) Except as otherwise provided in subdivision (c), a cosmetic is adulterated if it contains a chemical, other than those listed in subdivision (a), that has been identified by the department by regulation after a stakeholder process. Additional chemicals may only be identified if the chemical is listed as a banned substance in Annex II of Regulation No. 1223/2009 of the European Parliament and of the Council or in any updates to that Annex.

Enforcement of new cosmetics: The bill creates new violations of the Sherman Act; however, the Sherman Act already contains strong enforcement provisions that would apply to the provisions of this bill. Therefore, the Committee may wish to consider amending the bill to delete section 111794, entirely, to clarify that the existing enforcement authorities of CDPH pursuant to the Sherman Act apply to the provisions of this bill.

Additional technical amendments:

- 1) Where the bill mirrors the EU's cosmetic regulation permitting technically unavoidable trace amounts of unintended chemicals, there is a reference to 'adulteration' that needs to be struck for consistency with the aforementioned proposed Committee amendments to move away from the term adulteration. Therefore, the Committee may wish to correct that provision as follows:
 - (b) If a cosmetic product made through manufacturing processes intended to comply with this part contains a technically unavoidable trace quantity of an ingredients chemicals

listed in subdivision (a) <u>or identified pursuant to subdivision (b)</u>, and that trace quantity stems from impurities of natural or synthetic ingredients, the manufacturing process, storage, or migration from packaging, that trace quantity shall not cause the cosmetic product to be <u>in violation of this section</u> <u>adulterated</u>.

- 2) A Chemical Abstracts Service number (CAS#) is the universally recognized unique identifier of chemical substances and is often found on packaging and on articles of commerce. To make it unambiguous as to which chemicals will not be permitted in cosmetics sold in California under the provisions of this bill, the Committee may wish to add the CAS #s to each of the ingredients listed in the bill.
- 3) The PFASs and their salts listed in the bill represent an incomplete list of what is banned by the EU cosmetics regulation. The Committee may wish to flush out the list of prohibited PFAS substances to be consistent with the EU regulation.
- 4) To provide further clarification, the Committee may wish to define "ingredient" as follows:
 - (d) The term ingredient means any single chemical entity or mixture used as a component in the manufacture of a cosmetic product, as that term is defined in Section 111791.5(d) of the Health and Safety Code.
- 5) Remove the title act until a new title can be agreed upon by the authors and stakeholders.

SECTION 1. This act shall be known, and may be cited, as the Toxic Free Cosmetics Act.

Arguments in support: Environmental Working Group and Breast Cancer Prevention Partners, among others, state, "Today, personal care and beauty products (generally termed cosmetics) that are sold in California and the United States are largely unregulated. Manufacturers can use practically any chemical to formulate a cosmetic product, including chemicals with well-established links to cancer, reproductive harm or birth defects. Equally troubling, neither federal nor state laws require premarket testing by cosmetic manufacturers or their regulatory agencies to ensure that these products are safe before they hit store shelves. 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 1,400 chemicals in cosmetics, and many other countries tightly regulate cosmetics sold to their citizens. ... Californians need and deserve the same protections from harmful cosmetics provided to people that shop for the exact same products in the European Union and numerous other countries."

Arguments in opposition: The Personal Care Products Council, Fragrance Creators Association, California Chamber of Commerce, and other industry groups are oppose unless the bill is further amended. They collectively state, "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."

Double referral: This bill was double referred to the Assembly Environmental Safety & Toxic Materials Committee and the Assembly Health Committee; however, due to the COVID-19 pandemic and state-wide shelter in place orders that have truncated the legislative calendar for considering legislation, this bill will only be heard by the Environmental Safety & Toxic Materials Committee.

REGISTERED SUPPORT / OPPOSITION:

Support

Black Women for Wellness (Cosponsor)

Breast Cancer Prevention Partners (Cosponsor)

Environmental Working Group (Cosponsor)

California Public Interest Research Group (CALPIRG) (Cosponsor)

100% pure

Alaska Community Action on Toxics

American College of Obstetricians & Gynecologists - District IX

Beautycounter

Biossance

Breast Cancer Action

Breast Cancer Over Time

California Baby

California Health Coalition Advocacy

California Healthy Nail Salon Collaborative

California League of Conservation Voters

California Product Stewardship Council

Center for Environmental Health

Clean Water Action

Coalition for Clean Air

Consumer Federation of California

Earth Mama Organics

Eco Plum Sustainable Swag

Eighty2degrees Design Studio

Environment America

Environment CA

Eo Essential Oils

Friends Committee on Legislation of California

Han Skincare

Innersense

Juice Beauty

Just the Goods

National Stewardship Action Council

Natural Resources Defense Council (NRDC)

Oz Naturals

San Francisco Bay Area Physicians for Social Responsibility

Sanitation Districts of Los Angeles County
Science and Environmental Health Network
Seventh Generation Advisors
Seventh Generation Inc.
Sierra Club California
Skin Owl
Smart Oakland
Sprout San Francisco
US PIRG
W.S. Badger Company
Women's Voices for the Earth

Opposition

American Chemistry Council
Government Affairs & Legal Fragrance Creators Association
Mc Hugh, Koepke & Associates
Personal Care Products Council
Policy Advocate

Analysis Prepared by: Paige Brokaw / E.S. & T.M. /