SENATE THIRD READING
SB 1249 (Galgiani)
As Amended August 28, 2018
Majority vote

SENATE VOTE: 21-9

Committee	Votes	Ayes	Noes
Judiciary	9-0	Mark Stone, Cunningham, Chau, Chiu, Holden, Kalra, Maienschein, Reyes, Gabriel	
Appropriations	11-6	Gonzalez Fletcher, Bloom, Bonta, Calderon, Carrillo, Chau, Eggman, Friedman, Eduardo Garcia, Nazarian, Reyes	Bigelow, Brough, Fong, Gallagher, Obernolte, Quirk

SUMMARY: Prohibits cosmetic manufacturers from selling or offering for sale any cosmetic product in this state that was developed or manufactured using an animal test conducted or contracted by the manufacturer, or any supplier of the manufacturer, on or after January 1, 2020, unless a specific exemption applies. Specifically, **this bill**:

1) Provides that, notwithstanding any other law, it is unlawful for a manufacturer to import for profit, sell, or offer for sale in this state, any cosmetic if the cosmetic was developed or manufactured using an animal test that was conducted or contracted by the manufacturer, or any supplier of the manufacturer on or after January 1, 2020.

2) Defines key terms, including:

   a) "Animal test" means the internal or external application of a cosmetic, either in its final form or any ingredient thereof, to the skin, eyes, or other body part of a live, nonhuman vertebrate.

   b) "Ingredient" means any component of a cosmetic as defined by Section 700.3 of Title 21 of the Code of Federal Regulations.

   c) "Supplier" means any entity that supplies, directly or through a third party, any ingredient used in the formulation of a manufacturer's cosmetic.

3) Provides that the prohibition in 1), above, does not apply to the following circumstances:

   a) An animal test of the cosmetic that is required by a federal or state regulatory authority if all of the following apply:

      i) The ingredient is in wide use and cannot be replaced with another ingredient capable of performing a similar function.

ii) A specific human health problem is substantiated and the need to conduct animal tests is justified and is supported by a detailed research protocol proposed as the basis for the evaluation.

iii) There is not a nonanimal alternative method accepted for the relevant endpoint by the relevant federal or state regulatory authority.

b) An animal test was conducted to comply with a requirement of a foreign regulatory authority if no evidence derived from the test was relied upon to substantiate the safety of the cosmetic sold in California by the manufacturer.

c) An animal test that was conducted on any product or ingredient subject to the requirements of Chapter V of the Federal Food, Drug, and Cosmetic Act (21 United States Code Section (U.S.C.) 351 et seq.).

d) An animal test that was conducted for noncosmetic purposes in response to a requirement of a federal, state, or foreign regulatory authority, if no evidence derived from the test was relied upon to substantiate the safety of the cosmetic sold in California by the manufacturer. Further provides that a manufacturer is not prohibited from reviewing, assessing, or retaining evidence from an animal test conducted pursuant to this provision.

4) Establishes that these provisions do not apply to either of the following:

a) A cosmetic, if the cosmetic, in its final form, was sold in California or tested on animals prior to January 1, 2020, even if the cosmetic is manufactured after that date.

b) An ingredient, if the ingredient was sold in California or tested on animals prior to January 1, 2020, even if the ingredient is manufactured after that date.

5) Authorizes violations of these provisions to be enforced by the district attorney of the county in which the violation occurred, or by the city attorney of the city in which the violation occurred.

6) Authorizes a district attorney or city attorney**,** upon a determination that there is a reasonable likelihood of a violation of this act, to review the testing data upon which a cosmetic manufacturer has relied in the development or manufacturing of the relevant product sold in the state.

7) Establishes that information provided under 6) shall be protected as a trade secret as defined in Civil Code Section 3426.1(d). Requires a district attorney or city attorney, consistent with the procedures described in Civil Code Section 3426.5, to enter a protective order with a manufacturer before receipt of such information from a manufacturer, and to take other appropriate measures necessary to preserve the confidentiality of information provided under this provision.

8) Makes a violation of these provisions punishable by a fine of $5,000 and an additional $1,000 for each day the violation continues, with the fine paid to the entity authorized to bring the action.

9) Provides that, notwithstanding any other provision of this act, cosmetic inventory found to be in violation of this bill may be sold for a period of 180 days.

10) Prohibits any county or political subdivision of the state from establishing or continuing any prohibition on or relating to animal tests that is not identical to the prohibitions set forth by this bill, and that does not include the exemptions contained in this bill.

11) Provides for a delayed operative date of January 1, 2020 for this act.

FISCAL EFFECT: According to the Assembly Appropriations Committee, negligible direct state costs, if any.

COMMENTS: In 2000, California became the first state in the country to make it unlawful for manufacturers and contract testing facilities to test cosmetic products on animals when appropriate alternative methods of testing exist. (SB 2082 (O'Connell), Ch.476, Stats. of 2000.) A national and international movement to further eliminate animal testing of cosmetic products has been growing in recent years, with the European Union (EU) recently adopting regulations to prohibit the importation and sale of cosmetics that have been tested on animals, with certain exemptions. It is still legal for cosmetic manufacturers to import, sell and market products in this state that have been tested on animals, however, as long as the testing was carried out elsewhere and the product subsequently imported into California for sale. The author's office and the sponsor of this bill, Social Compassion in Legislation (SCIL), perceive this as a serious problem and believe that the time is right to enact even stronger measures in California to prohibit this. Accordingly, this bill seeks to enact a strong rule against the sale in California of any cosmetic that was developed or manufactured using an animal test conducted or contracted by the manufacturer, or any supplier of the manufacturer, on or after January 1, 2020, unless a specific exemption applies.

The previous version of the bill was opposed by the Personal Care Products Council (PCPC), the California Manufacturers & Technology Association, and the California Retailers Association, among many others. These industry and products associations objected to the broad prohibitive rule in this bill, which they contend would force them to withdraw their products from the California marketplace and subject them to civil penalties under circumstances outside of their control. Opponents objected that they nevertheless stand to be punished by for animal testing conducted by other entities outside the industry, or required by government regulatory agencies in other states or countries as a condition of selling in a certain market. Significant Assembly amendments to the bill have reportedly removed the opposition of the Personal Care Products Council and other industry opponents, although a complete accounting of each individual group previously in opposition was not available at the time of this analysis.

Exemptions from rule prohibiting sale. The bill specifies four sets of conditions that would exempt a manufacturer from the underlying prohibition of the sale in California of cosmetics tested on animals, as detailed below.

Exemption 1: As required by a federal or state regulatory authority. The first exemption is allowed where animal testing is required by a federal or state regulatory authority, if all of the following apply: (1) The ingredient is in wide use and cannot be replaced with another ingredient capable of performing a similar function; (2) A specific human health problem is substantiated and the need to conduct animal tests is justified and is supported by a detailed research protocol proposed as the basis for the evaluation; (3) There is not a nonanimal

alternative method accepted for the relevant endpoint by the relevant federal or state regulatory authority. According to the author, an exemption is appropriate for testing required by a federal or state regulatory body in those rare cases where no viable alternative tests are available to substantiate the safety of the product, and thus such products should not be prohibited from sale in California.

Exemption 2: As required by a foreign regulatory agency. The second exemption allows animal testing of a cosmetic that is conducted to comply with a formal requirement of a foreign regulatory authority, if no evidence derived from the test was relied upon to substantiate the safety of the cosmetic sold in California by the manufacturer. Previously, opponents argued that China and other countries still require testing of cosmetics, and that this exemption might force them to leave the California market because, after January 1, 2023, it would have effectively prohibited them from selling any cosmetic product in California that has undergone animal testing required by a foreign regulatory agency. Recent amendments seek to address the opposition's concerns by removing the three-year sunset date that would have eliminated this exemption after January 1, 2023, effectively making this exemption permanent.

Exemption 3: Noncosmetic testing required by a state, federal, or foreign regulatory agency. Recent amendments provide a limited exemption for animal testing conducted for a noncosmetic purpose in response to a requirement of a state, federal, or foreign regulatory agency, as long as no evidence derived from the test was relied upon to substantiate the safety of the cosmetic sold in California by the manufacturer. According to proponents, this exemption is intended to be a catch-all exemption for all testing that is not for cosmetic purposes—many examples of which were previously raised by opponents of the bill. If, for example, the California Department of Toxic Substances Control required animal testing for hazardous waste disposal, or the federal EPA required animal testing for environmental reasons, then these tests would be exempted by the bill as amended.

Exemption 4: Noncosmetic testing as required by federal law pertaining to drugs. Opponents expressed concern that this bill "would unfairly discriminate against and disadvantage broad-based, multi-product sector companies who may have pharmaceutical drugs, over the counter (OTC) drugs, cleaning products, and more, in addition to their cosmetics business, that are required to test for purposes in those sectors that have nothing to do with the cosmetic application." Examples of products that are perceived of as cosmetics but classified as drugs under Chapter V of the federal Food, Drug, and Cosmetic Act are fluoride toothpaste, sunscreen, hair growth products, dandruff shampoo, and other products that make a health claim. To address this concern, recent amendments provide an exemption for an animal test that was conducted on any product or ingredient subject to the requirements of Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 *et seq*.)

Concerns about manufacturer liability arising from animal testing by others. Opponents previously expressed concern that the bill makes manufacturers liable for animal testing on products and components conducted by others, including academic researchers, members of other industries, and even competitors within the cosmetic industry. They previously stated: "To place the liability on a manufacturer to pull products from sale in California, the moment an ingredient is tested on an animal, regardless of the conclusion of the test or the manufacturers' knowledge of the testing, would be unworkable."

In response to these concerns, the author has amended the bill to more narrowly make manufacturers liable only for testing occurring within their supply chain. The author explains that animal testing is not generally being conducted by the manufacturers themselves, but rather by suppliers of ingredients or third parties, and it is not necessarily even done via contract or on behalf of manufacturers. According to the author, existing "cruelty-free" manufacturers already require their suppliers to sign agreements ensuring that the source of the supplied ingredients did not test them on animals. Thus, the author contends that the amendments to the bill reflect the industry-standard contractual practices used by "cruelty-free" companies and can be easily replicated by other cosmetic companies to comply with this bill if it is enacted into law.

Grandfathering clause. This bill contains a separate provision to "grandfather" in cosmetic products and ingredients that were sold in California or tested on animals prior to January 1, 2020, the effective date of this bill should it become law. Recent amendments clarify that this bill's prohibitions do not apply to an ingredient if the ingredient was sold in California or tested on animals prior to January 1, 2020, even if the ingredient is manufactured after that date. These amendments are intended to assure manufacturers that any product tested or sold in California before January 1, 2020 can still remain on store shelves after that date. In addition, amendments negotiated with the California Retailers Association now provide for a 180-day "sell-through period," which allows any cosmetic inventory found to be in violation of this bill to be sold for a period of 180 days, notwithstanding any other provision of this act.

Trade secret protections. Existing law authorizes a district attorney or city attorney to review the testing data upon which a cosmetic manufacturer has relied in the development or manufacturing of cosmetic products sold in California. Recent amendments to the bill establish that such data provided to the district attorney or city attorney shall be protected as a trade secret as defined in Civil Code Section 3426.1(d). As amended, the bill also requires the district attorney or city attorney, consistent with existing procedures described in Civil Code Section 3426.5, to enter a protective order with a manufacturer before receipt of such information from a manufacturer, and to take other appropriate measures necessary to preserve the confidentiality of the information provided to them for review.

Preemption clause. In order to ensure a single set of rules applies uniformly across the state, recent amendments prohibit any county or political subdivision of the state from establishing or continuing any prohibition on or relating to animal tests that is not identical to the prohibitions set forth by this bill, and that does not include the same exemptions set forth in this bill.

Analysis Prepared by: Anthony Lew / JUD. / (916) 319-2334 FN: 0005103 FN: