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Via portal at: https://oehha.ca.gov/comments

Dear Ms. Vela:

The Consumer Brands Association, the California Chamber of Commerce, and the below-listed organizations (hereinafter, "Coalition") thank you for the opportunity to submit comments regarding the Office of Environmental Health Hazard Assessment's Proposed Amendments to Title 27, California Code of Regulations, Article 6 Clear and Reasonable Warnings, dated October 27, 2023 ("Proposal"). The Coalition appreciates OEHHA's extension of the public comment period to January 3, 2024. The Coalition consists of more than 40 California-based and national organizations and businesses of varying sizes that collectively represent nearly every major business sector that would be directly impacted by OEHHA's Proposal.

As explained below, the Proposal fails to address the issues that OEHHA cites as its basis, while also threatening to impose an even greater burden on businesses without countervailing benefits to consumers. Accordingly, the Coalition respectfully requests that OEHHA withdraw its Proposal, or at least substantially modify it to lessen its detrimental impacts.

1. The Proposal Will Impose Significant Costs and Disruption on Businesses.

In August 2016, OEHHA adopted major changes to the "clear and reasonable" safe harbor warning regulations, which included the creation of the "long-form" and "short-form" warnings. These amendments were adopted after extensive consultation with stakeholders, including many members of the Coalition. The changes amounted to a significant overhaul to the previous safe harbor regime that had been in place for three decades, forcing businesses to revamp their labels, signs, and website and catalog labeling, all at great expense.

Now, barely five years after those regulations took effect in August 2018, OEHHA proposes yet another round of changes that would require businesses to revamp their Proposition 65 warning programs to bring them within the safe harbor regime. Because businesses find it critical to stay within this regime in order to reduce the expense of fending off the increasing proliferation of Proposition 65 bounty hunters, this Proposal would force businesses to abandon their current warning programs that were carefully designed based on OEHHA's implicit promise that the new safe harbor regulations would provide certainty and confidence inherent in a long-term program. If adopted, the Proposal will force businesses to make costly label changes on every product that currently bears a short-form warning. Each short-form warning label will have to be reviewed and revised to identify a chemical for each toxicity endpoint. These changes, as well as others discussed below, will entail a cost- and time-intensive overhaul of any company's warning program, without delivering benefits to consumers.

OEHHA estimates the costs of the Proposal on short-form warnings at \$14,538.327.67, or \$4,273.46 per business. But these estimates are premised on a number of unwarranted assumptions about both the number of affected businesses and the costs for each business, including:

- Assumption: Proposition 65 exempts businesses with fewer than 10 employees. Reality: This exemption has proven illusory in practice because larger businesses in the stream of commerce require that smaller businesses indemnify and defend them against Proposition 65 claims. For example, if a business with 8 employees wishes to sell its products online, the online retailer who will be subject to suit under Proposition 65 will require the small business to provide the warning on its products and to provide the retailer with the warning language to be posted on the product description page. The impacts of the Proposal therefore will fall on many more businesses than OEHHA has estimated.
- Assumption: The Proposal does not impose regulatory requirements on businesses, but instead provides businesses with an option for safe harbor compliance. Reality: Despite OEHHA's characterization, in reality the safe harbor warnings are not simply "non-mandatory guidance." Because of the enormous risk and expense of litigation that comes with using warnings that vary from those the agency has approved as safe harbors, businesses have no practical choice but to comply with the safe harbor regulations. Cal.

Chamber of Commerce v. Becerra, 529 F. Supp. 3d 1099, 1119 (E.D. Cal. 2021) (noting that "the seas beyond the safe harbor are so perilous that no one risks a voyage," and thus businesses "almost uniformly use[] the safe harbor [warning]"); Cal. Chamber of Commerce v. Council for Educ. & Rsch. on Toxics, 29 4th 468, 479 (9th Cir. 2022) (affirming district court's finding that "only the safe harbor warning is actually useable in practice"). As a result, the Proposal will – as a practical matter – impose regulatory requirements on many more businesses than OEHHA has estimated.

- Assumption: The expense of changing a label on a product is \$4,273 per business.

 Reality: OEHHA's estimate fails to account for a variety of costs. Among other things, OEHHA's estimate fails to account for the time of a company's employees, as well as outside consultants such as regulatory professionals and attorneys, to oversee and review analytical testing, draft revised language, and review drafts of revised labels.

 Furthermore, OEHHA has failed to account for the expense of communicating new warning language to each of a company's online retailers. The manufacturer of the product that will bear the ultimate expense of Proposition 65 claims by private enforcers often does not know much less have communications with the panoply of online retailers that may offer its product, and the Proposal's requirement that warnings be provided both on the label of the product and on the product description webpage will impose significant expense on product manufacturers.
- Assumption: Only manufacturing businesses in California will incur costs as a result of the new short-form warning regulations. Reality: OEHHA's economic impact assessment ignores the significant expense that retailers and distributors will incur as a result of the Proposal's new safe harbor warning requirements. In fact, OEHHA's singular focus in its economic impact analysis is the manufacturing sector, which excludes all of the other businesses that occupy the rest of the supply chain, including distributors and retailers. Manufacturers of many consumer products that reach California consumers are located overseas and one or more steps removed from the retailer who sells the product. Online retailers who sell these products and wish to avail themselves of the revised safe harbor protections will have to communicate the new short-form warning language to their suppliers, often via distributors, and ensure that warnings are provided on product labels. Brick and mortar retailers in California who do not post signage will also have to communicate the new warning language to their suppliers. These efforts involve substantial costs that OEHHA has not considered.
- Assumption: OEHHA is adequately equipped to estimate the percentage of products that provide Proposition 65 safe harbor warnings. Reality: OEHHA's expertise does not include the insight into the labeling decisions that California businesses make. Before OEHHA can credibly estimate the percentage of products affected by the new safe harbor warning, it should consult the businesses that are responsible for deciding whether and how to label their products. In its economic analysis, OEHHA did not engage with

manufacturing businesses or trade associations, instead relying on its "experience and professional judgment." Any estimation based on this incomplete data is a poor reflection of the real-world business environment that is guaranteed to underestimate the Proposal's economic impacts.

2. The Proposal is Not Justified.

OEHHA expressly "decline[d] to add the requirement to name a chemical in the short-form version" when it adopted the modern safe harbor regulations in 2016. See Final Statement of Reasons, Proposed Repeal of Article 6 and Adoption of New Article 6 Regulations for Clear and Reasonable Warnings (Sept. 1, 2016). In so doing, OEHHA acknowledged that because "certain classes of products commonly carry the short-form warning," the agency "can identify chemical exposures related to those products on its website." Id.

With the present Proposal, however, OEHHA abandons that reasoning, but without explaining why its earlier statement was incorrect or in need of revision. In the Coalition's view, the reasoning behind OEHHA's earlier decision still applies, if not more forcefully today. Now that businesses have been relying on the short-form warning for some time, OEHHA has the advantage of assessing which classes of products "commonly carry" the short-form warning. With the benefit of that knowledge, OEHHA can more effectively identify potential chemical exposures from those types of products through its own website—an option that courts have encouraged. *See, e.g., Nat'l Assoc. of Wheat Growers v. Bonta*, 85 F.4th 1263, 1283 (9th Cir. 2023) (suggesting that OEHHA can post information about certain chemical exposures from consumer products on its own website or conduct its own advertising campaign); *CalChamber*, 529 F. Supp. 3d at 1121 (same).

Indeed, OEHHA's sole indication of any effort it has expended in this regard is its reference to having sent 40 letters to businesses in a four-year period (10 letters per year) seeking additional information about the chemicals for which a short-form warning was provided. OEHHA notes no effort to enlist the assistance of trade associations such as the Coalition members in providing this information and, similarly, fails to account for the reluctance of individual businesses – who are regularly targeted in thousands of Proposition 65 notices of violation per year – to voluntarily provide any information that is not required by law and that will be available to the legion of private enforcers of Proposition 65.

Furthermore, OEHHA does not claim that the short-form Proposal will actually provide consumers with useful information on which they can base decisions that further the purposes of Proposition 65. Instead, OEHHA relies on a consumer survey from 2016 showing simply that consumers prefer a warning that specifies the chemical name. While it is certainly not surprising that consumers prefer more information over less, that is the wrong question. Satisfying

consumer preference is no justification for the coercive regulation proposed by OEHHA. See *Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 74 (2d Cir. 1996) (holding that "consumer curiosity alone is not a strong enough state interest to sustain the compulsion of even an accurate, factual statement" under the First Amendment).

The right question is whether the name of one chemical per endpoint helps to achieve the legitimate goal of providing a "clear and reasonable warning" so that consumers can take action to reduce their potential exposures. OEHHA does not indicate that consumers need the specific name of the chemical at issue in order to make an informed decision about whether to purchase or use a product, or whether to modify their use of the product in some manner to reduce their potential risk. Indeed, OEHHA has no information on which to base any prediction as to how consumers will use the information provided.

3. The Proposal Will Not Address the Root Causes of Overwarning.

The Coalition disagrees that the Proposal will meaningfully address the problem of overwarning. OEHHA's stated rationale can be summed up in one sentence: "OEHHA anticipates that if a business must identify a chemical exposure, businesses will be less likely to use the warning prophylactically and more likely to warn only when the Act requires it." *See* Initial Statement of Reasons (Oct. 27, 2023). But OEHHA fails to explain how it arrived at this cause-and-effect relationship, which overlooks the root causes of overwarning and is based not on any data or even consultation with affected businesses but instead on pure supposition.

Indeed, the Proposal manufactures an explanation for the phenomenon of overwarning, placing the blames on businesses rather than on overly aggressive private enforcers of Proposition 65 who exploit the statute's burden-shifting and the ambiguities in its application that OEHHA has neglected to clarify despite decades of experience. Indeed, the Proposal sidesteps the business community's most pervasive concerns that actually explain why most companies simply decide to warn—and likely will continue to warn—even when they believe it is unnecessary. The Proposal does not address the true culprits of overwarning, namely Proposition 65's unique burden-shifting framework, the vague standards for warning thresholds, and the heavy expense and time involved in litigation.

A private enforcer need only present a single lab result showing a detection of a listed chemical at some level in order to satisfy their *prima facie* burden. Once that low bar is satisfied, the defendant business bears the expense of proving that the level of chemical in the product is sufficiently low that no warning is required. That is very difficult and expensive to do, as courts have acknowledged on multiple occasions. *See, e.g., CalChamber*, 29 F.4th at 480 (9th Cir. 2022) ("Proving the [chemical] level is lower than the No Significant Risk Level requires expensive testing and costly expert testimony. . . . [which] smaller businesses often cannot afford") (cleaned up); *CalChamber*, 529 F. Supp. 3d at 1109 (E.D. Cal. 2021) ("[G]iven the high standard of scientific proof required by [the statutory exemption], 'it may take a full scale

scientific study to establish the amount of the carcinogen is so low that there is no need for a warning.") (quoting *Consumer Def. Grp. v. Rental Hous. Indus. Members*, 137 Cal. App. 4th 1185, 1215 (2006)).

First, the Proposition 65's warning thresholds are exceedingly low, particularly for reproductive toxicants, where the threshold is 1,000 times lower than the level shown in animal studies to cause no reproductive harm. These levels sometimes challenge analytical chemistry techniques and require precision that no other regulatory regime in the world requires. Second, the exposure level cannot be determined simply by measuring the concentration of the chemical in the product; it also involves an evaluation of the rate of usage or consumption of the product by average consumers, requiring data that is often unavailable and always subject to dispute by experts. The burden, expense, and unpredictability of proving a negative lead many businesses to elect to provide prophylactic warnings. The solution to the perceived problem of prophylactic warnings is not to further increase the burden of compliance on businesses. Instead, the solution should be to make it harder on private enforcers—who are overwhelmingly motivated by mercenary considerations as opposed to the public interest — to leverage the uncertainty and expense of Proposition 65 litigation to their advantage. If the agency would lower the notorious uncertainty and expense of Proposition 65 litigation, businesses will have incentives to stand behind their assessments that warnings are not required.

OEHHA suggests that its Proposal would incentivize businesses to test their products before deciding whether a warning is required. This stated objective is fundamentally at odds with how Proposition 65 was presented to voters in the official ballot pamphlet. Voters were told that Proposition 65's requirements "will not take anyone by surprise." The scope of the law was described as "apply[ing] only to businesses that *know* they are putting one of the chemicals out into the environment, and that *know* the chemical is actually on the Governor's list." OEHHA should not, and indeed cannot, advance a regulation so inconsistent with the original basis for the law it proposes to implement.

Moreover, the proposed new testing, OEHHA reasons, may present results that do not necessitate a warning. In practice, however, advances in analytical testing mean that businesses that test will likely find some level of at least one listed chemical. The issue then becomes whether businesses expend even more money to engage an expert to determine whether that level is below the safe harbor threshold. But experience teaches that the expert's evaluation will almost always rest on assumptions about the evidence a court will credit in light of ambiguities in both the science and the regulations. In other words, it depends. Therefore, even if a business is able and willing to incur these costs and demonstrate, with expert backing, that its products comply with the warning threshold, that business is far from safe. Any financially motivated private enforcer can issue a notice of violation and file a lawsuit on the basis of a single test result, even from a laboratory that (in many instances) lacks the reliability of accredited testing methods, and that filing alone results in additional expense and risk for the business.

In light of the small benefit that costly testing yields—of which, there is no guarantee—many businesses will skip testing altogether and just use the short-form warning to disclose the listed chemical that their products are most likely to contain (e.g., lead in many plant-based foods). In other words, regardless of whether the short-form warning must state a chemical's name, it will be more efficient for businesses to provide a warning, even if OEHHA adopts the Proposal.

4. OEHHA Has Better Ways to Address its Concern About Overwarning Than by Imposing Excessive and Unnecessary Costs on Businesses.

Instead of upsetting businesses' reliance interests by reversing its approach to short-form warnings, OEHHA should adopt new safe harbor levels that are based on the concentrations of listed chemicals in common products. Providing businesses with a concentration-based standard would eliminate the costly back-and-forth about the appropriate usage or consumption rates, which plays a significant role in a business's decision to warn as a prophylactic measure. This undertaking would not be novel. OEHHA already established concentration-based standards for acrylamide in some categories of food, *see* 27 Cal. Code Regs. § 25506, but this regulation affects a very small percentage of the products covered by Proposition 65 and just one listed chemical. OEHHA should undertake this process on more listed chemicals across a broader span of products.

OEHHA should also strengthen its regulations on Safe Use Determinations (SUDs). *See* 27 Cal. Code Regs. § 25204. Although OEHHA has encouraged the use of SUDs and has improved its internal procedures for consideration of SUDs to be more efficient and timely, the SUD regulations need to be reformed in several respects.

First, the SUD regulations provide that OEHHA will not undertake a SUD once an enforcement action has commenced, but businesses usually do not become aware of the need for a SUD until private enforcers target a new product category and chemical. It makes no sense for the lead agency with expertise in the application of Proposition 65 to be barred from applying that expertise in the public interest by the mere service of a 60-day notice by a private enforcer. *See id.* § 25204(b)(2).

Second, the SUD regulations provide that SUDs apply only to the requesting party and "are not intended to affect other individuals or organizations." See id. § 25204(k). Private enforcers, when referred to a SUD that applies to the specific alleged violation in every way other than the identity of the business at issue, respond by citing this regulation. It makes no sense for the agency to permit its expertise and effort to be so easily disregarded by those seeking to exploit the expense and risk of litigation.

¹ Furthermore, this regulation is not currently being invoked because public and private enforcers are preliminarily enjoined from filing new lawsuits with respect to warnings for acrylamide in food and beverage products. *CalChamber*, 529 F. Supp. 3d at 1123.

Third, several years ago, OEHHA clarified that the SUD regulations are no longer simply advisory opinions that are not binding in court and now "represent[] the state's best judgment concerning the application of the Act to the particular facts presented in the request." *See id.* § 25204(a). OEHHA intended this change to "give OEHHA's determinations presumptive effect in an enforcement proceeding," but the language does not so provide. OEHHA should revise Section 25204 so that the regulations make clear that SUDs the agency has issued have binding effect in enforcement proceedings.

The Coalition would be happy to discuss these issues with OEHHA and provide other examples of ambiguities in the regulations that provoke litigation and permit private enforcers to exploit Proposition 65 for monetary gain, thereby encouraging what the agency views as over-warning by businesses.

5. Issues and Recommendations with Chemical-Specific Short-Form Warning.

The Proposal's short-form warning text continues to create litigation risk for businesses in California. While OEHHA changed the bracketed text in its earlier proposal for the short-form warning from "[name of one or more chemicals known to cause cancer]" to "[name of chemical]," the modification does little to clarify the prior ambiguity. Without firm language in the text of the regulation, it remains unclear whether a business can avail itself of the safe harbor if it names just one chemical per major endpoint.

As written, the Proposal exacerbates litigation risks by suggesting two interpretations: (1) identify all chemicals to which the warning applies, or (2) identify just one chemical. The former defeats one of the central purposes of the short-form warning because listing all chemicals can take up so much space as to become an unreasonable burden. And where a product contains multiple chemicals for the same endpoint (i.e. two or more carcinogens), the latter interpretation invites the question, *which one?*

Without OEHHA's clear statement of what language provides businesses with a safe harbor, this new regulation simply invites private enforcers to exploit newfound ambiguity with more frivolous lawsuits. Mere suggestions in a statement of reasons that businesses need list only one chemical for each endpoint provide inadequate protections against abusive shakedown lawsuits. Therefore, if OEHHA proceeds with its Proposal, the Coalition recommends that it insert the word "exemplar," so that a warning for exposures to listed carcinogens would read "Cancer risk from exposure to [name of *exemplar* chemical] – www.P65Warnings.ca.gov." The Coalition also recommends modifying Section 25601(b) to conclude with the sentence, "Nothing in this subarticle requires any warning to identify more than one chemical for any endpoint (cancer or reproductive harm)."

6. If OEHHA Changes the Short-Form Safe Harbor Warning, Then Businesses Need at Least a 36-Month Phase-In Period and a Sell-Through Period that Applies to Pre-Printed Label Stock.

The present Proposal for Section 25603(c) provides for a two-year phase-in period and unlimited sell-through for products manufactured and labeled up to two years after the regulation is adopted. While the Coalition appreciates that the Proposal improves on its earlier proposed rulemaking, which provided for only a one-year phase-in period, this two-year timeline is still too short. A three-year phase-in period would substantially soften the impacts of this regulation, which in turn, would protect consumers who would otherwise be forced to absorb this disruptive shock in the form of higher prices. Specifically, extending this timeframe would afford companies more time to redesign and manufacture labels and packaging to the new standard, the costs of which are acutely felt by smaller businesses with lower budgets, as well as larger companies with more extensive product lines.

The Coalition also recommends that the sell-through date apply to preprinted label stock, not just products manufactured and labeled during the phase-in period. Although some companies label their products during the manufacturing process, other companies pre-order labels (often in large quantities) with plans to affix them to their products afterwards. The current Proposal ignores the costs that many business have already borne by ordering short-form labels in advance, as well as the resulting waste that would result if this inventory were made obsolete. By withholding the sell-through provision from these companies, OEHHA is in effect punishing California businesses that make investment decisions based on their careful and informed forecasting. Doing so undermines the business community's confidence in California's regulatory landscape, which could dissuade businesses from making long-term investments in the state.

7. The Proposal Must Be Clear that Court-Approved Warnings are Unaffected.

In the Proposal's Initial Statement of Reasons, OEHHA does not explicitly state whether short-form warnings provided pursuant to a consent judgment are protected. If OEHHA moves forward with its Proposal, the Coalition requests that the agency expressly state that these new warnings would not disturb the certainty afforded by present court-approved short-form warnings.

In past rulemakings, OEHHA has explained that "[t]o the extent warnings are being provided pursuant to a consent judgment, the terms of that judgment supersede the [new] regulations." Final Statement of Reasons (Sept. 1, 2016). That statement finds supports in OEHHA's regulations. See 27 Cal. Code Regs. § 2600(e) ("A person that is a party to a court-ordered settlement or final judgment establishing a warning method or content is deemed to be providing a 'clear and reasonable' warning for that exposure for purposes of this article, if the warning complies with the order or judgment."). Nevertheless, the Coalition strongly believes that a clear pronouncement

from OEHHA regarding the continued protection from a consent judgment's short-form warnings is beneficial and necessary in light of the aggressive private enforcement environment.

8. Double Warnings for Internet and Catalog Sales are Unnecessary, Unjustified, and Inconsistent with the Statute and Existing Regulations.

Finally, OEHHA should reconsider its Proposal to amend Section 25602 with respect to warnings for internet and catalog sales. As the statute plainly states, a warning "need not be provided separately to each exposed individual and may be provided by general methods[,]... provided that the warning accomplished is clear and reasonable." Cal. Health & Safety Code § 25249.11(f). The regulations state this as well. *See* Cal. Code Regs. tit. 27, § 25600(d) ("A person is not required to provide separate warnings to each exposed individual."). Thus, the Proposal's requirement that consumers of products purchased online receive *two* warnings—first at the point of sale, and second on the product's label—flouts Proposition 65's legal framework.

OEHHA provides no justification for entangling businesses in yet another warning requirement simply because a product is sold over the internet or via a catalog rather than from a shelf in a physical store. Importantly, online retailers often never possess the product; instead, they facilitate its sale while fulfillment of the order and shipping is performed by a third party. The double-warning requirement therefore creates opportunities for consumers receiving conflicting warnings, *i.e.* warnings on the website differing from the warnings affixed to the product's label, which increase the risk of private enforcement.

There are situations in which the manufacturer of a product intended to be sold online will find it more practical to provide the warning on the label of the product, even though the product will be sold outside of California, in order to ensure that consumers in California receive the warning and that its risk of Proposition 65 enforcement litigation is reduced as far as possible. There are also situations in which the manufacturer of a product intended to be sold online will be able to notify all of the online retailers of its product who offer the product for sale in California that they need to provide the Proposition 65 warning on the product description webpage. The OEHHA regulation, however, requires both of these types of manufacturers to place the warning on the label of the product — ensuring, as a practical matter, that consumers across the United States receive the California-specific warning — and to notify all online resellers of the product (many of whom may not be known to much less in communication with the manufacturer) to provide the Proposition 65 warning on the website. This is an excessive and unwarranted burden, and the only situation in which OEHHA has ever proposed that two warnings are required for each sale of a product. It will significantly increase the risk of litigation in today's aggressive enforcement environment and is not justified by any data or reasoning.

* * *

In short, several problems with the Proposal warrant OEHHA's careful reexamination of its revisions to the safe harbor regulations that became effective barely five years ago. By walking back on key safe harbor provisions that businesses have relied on, OEHHA threatens to disrupt more than just their reasonably formed expectations. OEHHA's justification for this overhaul—that the current short-form warning contributes to the problem of overwarning—is without evidence or analysis. To address the overwarning issue, OEHHA should aim its efforts toward the root causes of overwarning, instead of adopting new and onerous requirements for businesses. The Coalition therefore respectfully requests that OEHHA's Proposal be withdrawn or at least modified as suggested above.

Respectfully submitted,

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American Bakers Association

American Chemistry Council

American Cleaning Institute

American Coatings Association

American Herbal Products Association

American Lighting Association

American Sportfishing Association

American Supply Association

Art and Creative Materials Institute, Inc

Asian Food Trade Association

Association of Home Appliance Manufacturers

Auto Care Association

California Automotive Wholesalers' Association

California Business Properties Association

California League of Food Producers

California Manufacturers and Technology Association

California Retailers Association

Can Manufacturers Institute

Carlsbad Chamber of Commerce

Chemical Industry Council of California

Chemical Fabrics & Film Association

Consumer Healthcare Products Association

Council for Responsible Nutrition

Dental Trade Alliance

Diving Equipment & Marketing Association

Flexible Packaging Association

The Food Industry Association

Fragrance Creators Association

Hands on Science Partnership

ISSA

Lighter Association, Inc.

Lodi District Chamber of Commerce

MEMA, The Vehicle Suppliers Association

National Association of Music Merchants

National Confectioners Association

National Shooting Sports Foundation

Oceanside Chamber of Commerce

Outdoor Power Equipment Institute, Inc.

Outdoor Power Parts & Accessories Association

Peanut and Tree Nut Processors Association

Personal Care Products Council

Plumbing Manufacturers International

Pool and Hot Tub Alliance

Power Tool Institute

Printing United Alliance

SNAC International

Specialty Equipment Market Association

Sporting Arms and Manufacturers' Institute

The Toy Association
The Vision Council
Torrance Area Chamber of Commerce
West Ventura County Business Alliance
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