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INTERNATIONAL CRYSTAL FEDERATION

April 8, 2015

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Sent Electronically to: P65Public.comments@oehha.ca.gov

SUBJECT: CLEAR AND REASONABLE WARNING REGULATIONS

Dear Ms. Vela:

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 ("OEHHA") Notice of Proposed Rulemaking to Article 6 in Title 27 of the California Code of Regulations pursuant to the Safe Drinking Water and Toxic Enforcement Act ("Proposition 65"). Our Coalition consists of over one hundred seventy 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 proposed regulation.

OEHHA's January 16, 2015 Initial Statement of Reasons for the proposed revision to the Proposition 65 warning regulation ("ISOR") gives the impression that the proposed regulation would greatly benefit the business community in numerous respects. The Coalition fundamentally disagrees. Specifically, the ISOR states the following: (1) compliance with the

regulations will be relatively simple because the proposal provides "minimum elements" and thus sets a floor for what constitutes a "clear and reasonable" warning (ISOR at p.41); (2) litigation concerning the adequacy of warnings will be reduced (ISOR at p. 41); and (3) if adopted, the proposed regulations will have no economic impact whatsoever because the proposed regulation imposes no new requirements on California businesses. (ISOR at p.42.) None of these assertions is true. Contrary to its stated intent, the proposal will make Proposition 65 compliance more difficult for businesses of all sizes, will create many new avenues for increased litigation, and will have a significant economic impact on California businesses.

From a compliance perspective, the whole regulatory package, according to OEHHA, is intended to provide only "non-mandatory" and "voluntary" guidance for the methods and content of Proposition 65 warnings, leaving businesses free to warn using any means they wish as long as warnings are "clear and reasonable." (ISOR at pp. 13-14, pp.43-43.) On the other hand, the ISOR states that the proposed regulations provide "more specificity regarding the *minimum elements* for providing 'clear and reasonable' warnings for exposures . . . . (ISOR at p.41 [emphasis added].) These explicitly contradictory statements about the effect and intent of the proposed regulation are ambiguous and confusing, and they establish fertile ground for litigation regarding whether warnings not utilizing the safe harbor text or methods of transmission are "clear and reasonable" within the meaning of the statute. The regulated community cannot be asked to shoulder the burden of OEHHA's lack of clarity.[1]

From a litigation perspective, OEHHA has repeatedly stated that it does not want to further exacerbate the already problematic Proposition 65 litigation climate. To this end, OEHHA, without any substantiation, concludes that "[l]itigation concerning the adequacy of warnings should also be reduced as a result of the increased clarity provided by the proposed changes to the regulations." (ISOR at p.41.) OEHHA's conclusion is not supported. As a threshold matter, litigation or threatened litigation concerning the content of provided warnings is extremely rare. Indeed, the Coalition is only aware of a few notice letters or complaints within the past ten years that allege that warnings are inadequate, as opposed to simply being absent. The vast majority of litigation or threatened litigation instead challenges a business's decision to not provide a warning.

The proposed regulation opens up an entirely new frontier of "bad warning" enforcement actions by, for example, requiring warnings to (1) specify one or more of twelve chemicals, (2) be translated into a foreign language if any other labeling or sign about a product is provided in that language; and (3) not "dilute" or "diminish" the warning if supplemental information is provided on the warning. This component of the proposal—specifically, that it will create multiple new avenues for litigation that do not exist today—is particularly troubling because it blatantly disregards both the Coalition's previously stated concerns to this effect, as well the Governor's May 2013 call to end "frivolous 'shake-down' lawsuits."

From an economic perspective, OEHHA summarily concludes that the proposal will not have a significant statewide adverse economic impact directly affecting businesses. OEHHA reaches this conclusion based on the erroneous view that the proposal "does not impose any new requirements upon private persons or business because it primarily provides non-mandatory guidance and a voluntary safe harbor process for providing warnings already required under the

[1] OEHHA needs to make clear in the final statement of reasons ("FSOR") that any references it has made or makes to "minimum elements" or requirements refer only to what may be deemed to fall within its revised regulatory safe harbor, and do not change what courts have or may determine is necessary to effect compliance with the statute's "clear and reasonable" warning requirement itself.

Act that businesses can choose to follow." (ISOR, at pp. 42-43.) Once again, OEHHA's failure to articulate whether the "minimum elements" it references concern its proposed new safe harbor or (more broadly) the statutory warning requirement itself will lead some to conclude that all businesses must replace their existing Proposition 65 warnings, not just be prepared to defend them. Moreover, it is not consistent for OEHHA to state that change in the regulations is needed and that the change being proposed will be beneficial, but that there will be no cost because there will be no required change.

But even if this fundamental problem is addressed in a final rule, OEHHA's economic "analysis" is still inadequate because it necessarily (and incorrectly) assumes that the financial impact on business is *de minimis* because *few if any* businesses in the State of California would opt to use OEHHA's proposed warnings. If that assumption were true, there would be little if any purpose for the proposed regulations. OEHHA's assumption cannot be supported, as evidenced by the economic impact analysis prepared by Andrew Chang & Company, LLC, which demonstrates that OEHHA's proposal—when characterized accurately—will have a significant economic impact on California businesses (**Attachment 1**). Mr. Chang's economic impact analysis further underscores that a meaningful economic analysis of OEHHA's proposal—which satisfies the requirements for a Major Regulation—is a necessary and critical missing component of the rulemaking process.

In sum, notwithstanding OEHHA's statements that its proposed regulation will ease compliance costs and decrease litigation with no resulting economic impact on California business, the Coalition rejects that view. In reality, the proposal will do just the opposite. The Coalition therefore believes that the burden the proposed regulation imposes on the business community substantially outweighs any perceived benefit it may have.

Therefore, if OEHHA is not going to abandon this effort and devote itself instead to the more pressing need to better define when Proposition 65 warnings are necessary, then, at a minimum, the Coalition believes that OEHHA needs to substantially rework its draft rule and ISOR, provide a meaningful economic impact analysis, and recirculate them for another round of full public comment before proceeding to finalize any change to the existing regulation.

The remainder of this letter highlights the Coalition's concerns and explains why the proposed regulation as currently written is unacceptable.

Proposed Section 25600(a): Elimination of "Clear and Reasonable" Guidance

This subdivision provides that the newly proposed "Article 6, subarticles 1 and 2 apply when a clear and reasonable warning is required under [California Health & Safety Code] Section 25249.6." However, unlike under existing regulations, the cardinal phrase "clear and reasonable" is not given any interpretive guidance. The conclusion to be drawn from eliminating prior "clear and reasonable" guidance is that businesses cannot rely on it going forward, and that warnings satisfying the former "clear and reasonable" meaning may no longer be Proposition 65 compliant.

If the current regulation's language explaining what it means for a warning to be "clear and reasonable" is not retained, businesses will be forced to either use the new "non mandatory" safe harbor language or risk being subjected to litigation over whether alternative warnings they use, or warnings that inadvertently miss the "safe harbor" mark, are "clear and reasonable" under that now undefined standard. OEHHA's elimination of this language leaves only a vacuum to replace it, and businesses crafting their own warnings will be far more likely to be

attacked by private enforcers who take an expansive view of the statute's "clear and reasonable" requirement in order to use the expense businesses face in the litigation process as leverage to continue to extract settlements. In addition, it will waste precious state court resources, which will necessarily be taxed by a new round of senseless Proposition 65 cases.

These results are unacceptable, insofar as the ISOR states that businesses are perfectly free to create their own warnings as long as they meet California Health & Safety Code Section 25249.6's "clear and reasonable" warning requirement. (ISOR, p.1 (the "regulations . . . provide safe harbor, non-mandatory guidance on general message content and warning methods for providing consumer product, occupational and environmental exposure warnings") and n. 1 ("The term 'safe harbor' is used throughout to refer to non-mandatory guidance provided by OEHHA for the methods and content of warnings the agency has deemed to meet the 'clear and reasonable' standard required by Section 25249.6 of the Act.").

If the proposed regulation is truly intended to form a new safe harbor only and to continue to permit businesses to provide alternative warnings—as well as establish the basis for defending a non-safe harbor warning—then restoration of the existing regulation's explanation of what "clear and reasonable" means is required. For that reason, we again ask OEHHA to carry forward unaltered the current regulation's introductory language regarding the meaning of "clear and reasonable" into the newly proposed regulation.

Proposed Section 25600(b): Effective Date of Proposed Regulation

Subdivision (b) provides that the proposed warning regulations will become effective two years after adoption. The ISOR states that this "will provide businesses with a transition period to 'sell through' products that may use the old warning language." While an improvement from the September 2014 discussion draft's one year allowance, the two year effective date remains inadequate, failing to consider the realities of the marketplace and account for the numerous consumer products that circulate through the stream of commerce over the course of several years. Businesses that comply with current warning regulations and effectively transition to the proposed regulations upon adoption will be vulnerable to litigation since they will not be able to ensure that all products with the prior compliant warning language are "sold through" in time.

It is not uncommon for products to remain in the marketplace for far longer than two years after leaving a manufacturer's control.[2] Products may be warehoused by distributors or retailers until a demand arises. Some retailers specialize in selling slightly outdated or discontinued products. The marketplace is replete with examples of products that circulate between entities or sit on shelves or in storage for years before finally being purchased by a consumer.

Whether or not a product remains on the market for more than two years is not the result of a business trying to skirt regulatory requirements, but rather is a result of economic realities. The two year effective date would subject businesses to litigation due to market forces out of their control, which would thwart Governor Brown's goal of reducing frivolous litigation.

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[2] For example, certain products containing chlorinated tris have a four to five year shelf life. Accordingly, certain products may be manufactured *prior* to the effective date of the proposed regulation, yet may be purchased two or even three years *after* the proposed regulation's effective date. These products, even though they may appropriately contain warning language compliant with the regulations in effect at the time of manufacture, could nonetheless be subject to legal challenge for a deficient warning under the proposed regulation merely because the date of purchase occurred after the effective date of the proposed regulation. The proposed regulation should be revised to avoid this result.

Enterprising lawyers will be handed a new weapon for their arsenal, creating a new claim against once compliant businesses that used a permitted warning on a product, but were not able to pull product off of shelves or add a new warning before the two-year window expired. Allowing litigation against businesses for the failure to meet requirements that were not even in place at the time that the product entered the marketplace is unacceptable.

Due to these economic and practical realities, the Coalition requests that OEHHA provide an unlimited sell-through period for products already in the supply chain. This reasonable relief for manufacturers must come with some protection from litigation so that manufacturers cannot be subject to private enforcement actions if their products fall within the sell-through period. More importantly, this technical change would not pose any danger to the public because the products, whether or not they have updated warnings, will have a warning regardless and inform the public.

Accordingly, the Coalition recommends that section 25600(b) be updated to state:

> This Article will become effective two years after the date of adoption. A person may provide a warning that complies with this Article prior to its two year effective date. Any product manufactured prior to the effective date and labeled with the previously compliant safe harbor warning language will have met the requirements of a "clear and reasonable" warning under this Article, even if it remains available for sale after the effective date.

This sell-through provision will ensure that products manufactured prior to the effective date of the regulation would meet the "clear and reasonable" requirement of the law. Further, this language would avoid the consequences discussed above, which if allowed to occur, would penalize good actors for merely operating consistent with economic realities.

Proposed Section 25600(d): Supplemental Information

Subdivision (d) states: "A person may provide information to the exposed individual that is supplemental to the warning required by Section 25249.6 of the Act, such as further information about the form or nature of the exposure and ways to avoid exposure. In order to comply with this Article, supplemental information may not contradict, dilute, or diminish the warning. Supplemental information may not be substituted for the warning required by Section 25249.6."

The draft regulation does not define the key terms and concepts contained in subdivision (d), including: (1) what constitutes information that is "supplemental to the warning"; and (2) what may "contradict, dilute, or diminish the warning." As a result, the proposed enactment is unconstitutionally vague, violating the First Amendment and commercial free speech rights of affected businesses.

The ISOR attempts to provide some clarity by stating that, "As provided in Section 25601(d) [sic], a business may include additional contextual information to supplement the warning as long as it does not contradict, dilute or diminish the warning. To the extent feasible, OEHHA encourages businesses to include information such as ways to reduce exposure (e.g. washing fruit or vegetables before eating, avoiding over-browning, controlling portion size or frequency of consumption), in the warning. . . ." However, the ISOR's examples perpetuate, rather than resolve, the constitutional infirmity with respect to vagueness, and further appear to

unconstitutionally restrict content-specific speech that may truthfully and accurately supplement a warning.

For example, if "ways to reduce exposure" such as "controlling portion size or consumption frequency" are endorsed by OEHHA as sound illustrations of supplemental "contextual information" that "do[] not contradict, dilute or diminish the warning" then how would label information intended to lure customers, sell more product, and maximize consumption be treated? Food products routinely include information on packaging promoting reasons why consumers should purchase and consume the products, including emphasizing product taste; health benefits; nutritional content; reduced calories, sodium or fat; lower pricing; larger product size or free product; and brand trust and loyalty. Broadly construed, even depicting a celebrity endorser on packaging could be viewed as dilutive to a warning if the effect were to increase sales, or to associate the product with a healthy lifestyle.

Even more fundamentally, from experience defending Proposition 65 litigation, it is inevitable that private enforcers will seize on the elasticity of the terms "dilute or diminish" and that litigation will swell to give judicial context to those terms, all at considerable expense to California businesses and with no corresponding consumer benefit.

These problems can all be resolved by deleting the offending "dilute or diminish" modifiers, and reverting to the language originally proposed by OEHHA in its September 23, 2014 Discussion Draft; i.e., "In no case shall supplemental information contradict the warning provided pursuant to Section 25249.6(e)." See September 23, 2014, Section 25601(c) (last sentence). The standalone term "contradict" is much easier for businesses to understand and implement, and does not lend itself to the litigation abuses that are certain to accompany the well-intentioned, but nonetheless impermissibly mischievous, "dilute or diminish" articulation.

Not only is that result constitutionally infirm under the First Amendment, it goes far beyond Proposition 65's mandate. Proposition 65 only requires "clear and reasonable" warnings for products that expose consumers to levels of Proposition 65 chemicals that exceed designated thresholds. It does not require businesses to curtail advertising aimed at maximizing sales and consumption. Yet the intent and effect of the new proposed law would do just that.

Grandfathering

In its June 12 and October 14, 2014 comment letters to OEHHA concerning the OEHHA's pre-regulatory process proposals for revisions to the Proposition 65 warning regulations, the Coalition made extensive comments regarding the concept of "grandfathering" Proposition 65 warnings already in use, including as to those manifested in consent judgments and settlements approved by a court.

In its October 14 comments, the Coalition concurred with OEHHA that a conversion of the proposed regulatory changes concerning Proposition 65 warning requirements from a mandatory to safe harbor approach might undercut the need for a separate and detailed grandfathering provision. However, those comments also stated that the Coalition's support was contingent upon OEHHA: (1) making clear in the rulemaking record that past and future court-approved Proposition 65 warnings would always meet the statute's "clear and reasonable" warning requirement as a matter of law; (2) maintaining without modification, the general statutory criteria for "clear and reasonable" warnings currently stated in Section 25601(a) of the regulations; and (3) recognizing that courts can approve warnings as meeting the requirements of the statute in contexts where the issue is presented to them outside of approval of a

settlement (such as in a declaratory relief action or action challenging a warning approved in the context of a safe use determination).

More pointedly, to address these qualifications on the Coalition's endorsement of OEHHA not including an extensive "grandfathering" provision in a proposed rule that otherwise adopted a revised safe harbor approach, the Coalition specifically requested that the following sentence be included in the new regulation: "Nothing in this Article shall affect warnings for specific exposures that are approved by courts as compliant with the Act or require that such warnings be revised."

While OEHHA has included in its ISOR a very brief discussion of Court Approved Settlements and its rationale for not including a grandfathering provision within its proposed rule, the Coalition believes that discussion is vague, incomplete, and non-responsive to our recommendations.

OEHHA acknowledges that companies subject to a court order must comply with the court order, but OEHHA has not made clear that court approved warnings are "clear and reasonable" under the Act. As a practical matter, OEHHA's ISOR is telling business to post two non-identical warnings: the court approved warning and the new "safe harbor" warning. This will result in consumer confusion, dilute the effectiveness of either warning, and thwart the Governor's goal that OEHHA purports to advance. Unless OEHHA further addresses this issue, the probability of increased litigation, including challenges to businesses which fully implement prior court-approved warnings without first obtaining modifications of them to address the new safe harbor provisions, will be substantially increased. This is contrary to the Governor's announced goals for Proposition 65 reform and will result in unnecessary and increased burdens on both businesses and the State's courts.

Accordingly, in addition to its other comments concerning proposed Section 26000, the Coalition renews its prior call for the following sentence to be included (perhaps as subsection (f)): "Nothing in this Article shall affect warnings for specific exposures that are approved by courts as compliant with the Act or require that such warnings be revised."

A Final Statement of Reasons also needs to include a more direct, unequivocal, and affirmative statement that all court-approved Proposition 65 warnings can be relied on, by the settling parties and by non-parties to the settlement, to effectuate compliance with the statute's "clear and reasonable" requirement irrespective of the new regulation and its requirements (if it indeed still is intended to be a safe harbor when a final rule is adopted). Contrary to the suggestion in the ISOR, businesses should not need to petition OEHHA to adopt (through yet further rulemaking and expense to the taxpayers) Proposition 65 warnings previously approved by a court as meeting the statute's "clear and reasonable" requirement in order to confirm that such a warning may continue to be relied on; nor should businesses have to waste further resources in the regulatory process or in litigation to assure such a result.

Proposed Section 25600.2: Responsibility to Provide Product Exposure Warnings

Proposed Section 25600.2(d) seeks to implement Section 25249.11(f) of the Act, which directs the Agency to develop regulations to reduce the burden on retailers in providing warnings when they are not responsible for creating an exposure to a listed chemical. In particular, Proposed Section 25600.2(d)(5) would limit retailer exposure to enforcement lawsuits by allowing an opportunity to avoid those lawsuits where a foreign or exempt vendor (a vendor who has fewer

than 10 employees) supplied the product, and by defining the "actual knowledge" giving rise to a warning obligation in relation to receipt of a pre-suit notice of violation. 25600.2(d)(5)(C).

Section 25600.2(d)(5) states that a retailer is responsible for providing the warning required by Section 25249.6 in certain prescribed circumstances, one of which is when the product is supplied by a foreign or exempt vendor and the retailer has "actual knowledge" of the potential exposure. As defined in Section 25600.2(d)(5)(C), a retailer is deemed to have "actual knowledge" two business days after a retailer receives a notice served pursuant to Section 25249.7(d)(1) of the Act, thereby providing the retailer an exemption from the warning obligation if it has taken action on the notice within two business days.

The two-business-day time frame for taking action in response to a notice will be unworkable for the vast majority of the state's retailers. The following list of issues highlights numerous concerns demonstrating that it will be the exception that a retailer of any size will be able to remove products from sale or provide warnings within the two-business-day time frame.

Ensuring the Notice Gets to the Right Person(s)

Section 25903(c)(4), pertaining to the service of 60-day notices of intent to sue, requires a notice of violation to be served on the Chief Executive Officer, President, or General Counsel of a business. Typically, that person is not the individual in a retail organization responsible for assessing and responding to such a notice; the notice directed to the CEO, President or General Counsel will likely never reach that person initially, but instead must be processed by that person's administrative staff; and the notice must then be routed to the individual in the company responsible for handling the company's response to the notice. In our experience, this alone can take two or more business days.

Understanding What is at Issue in the Notice

Even when the 60-day notice finally reaches the correct individual within the retailer organization, that individual may still have difficulty understanding what product, exactly, is the subject of the notice. There are two issues here. First, the overwhelming majority of notices sent to retailers identify an "exemplar" but also a category of products (e.g., "Hand Tools with vinyl/PVC grips," including but not limited to "Wrench, SKU 12345, UPC 1 23456 78909 8"). The first issue, then, is whether the retailer is able to accurately identify the specific wrench. This problem is substantially exacerbated when the notice identifies foods, like "baking ingredients," containing a listed chemical. Not infrequently, the retailer needs more information (such as a receipt or the ticket on the product, or even a photo if the exemplar item cannot be located) in order to be able to identify the actual product and the supplier. As such, the retailer would need to reach out to the party serving the notice to request that information (which the noticing party is not required to provide under current regulations).

Second, when the notice describes a category, it is not clear whether it is the Agency's intent that proposed subsection 25600.2(d)(5)(C) would establish "actual notice" for all products within the broad category described, regardless of whether they are made of the same or similar materials (or regardless of whether the retailer has any reason to know this) or supplied by different manufacturers or suppliers. Section 25903 requires that the notice contain "the name of the consumer product or service, or the specific type of consumer product or services, that cause the violation, with sufficient specificity to inform the recipients of the nature of the items allegedly sold in violation of the law and to distinguish those products or services from others sold or offered by the alleged violator for which no violation is alleged." Courts have ruled

inconsistently on whether notices that include exemplar products but purport to provide notice over a type of product (such as "Hand Tools with vinyl/PVC grips") comply with this mandate.

Interacting with the Vendor

Retailers and their manufacturers and suppliers have a business relationship that often dictates or anticipates the handling of products. Retailers typically need to reach out to the product manufacturer or supplier (who may or may not be named in the notice) to find out whether they want the retailer to take any particular course of action with respect to the products they manufactured or supplied. The manufacturer may not want a warning to be placed on the product and be prepared to defend it, or may want the product pulled from sale in California or elsewhere. Communicating with suppliers often in and of itself takes more than two business days, and the retailer should not be put in the position of having to make a decision about whether to warn or stop sale of a product without obtaining necessary information from the supplier and affording the supplier with an opportunity to be involved in that decision.

Taking Action

If the retailer decides that it wants to avail itself of the limited warning exemption and avoid a lawsuit by subsequently providing a warning or removing the product from sale within two business days of the notice, it then needs to quickly implement this corrective action. Implementation involves several steps, depending on the size of the retail entity. For large retailers, often with several hundred stores in the state, implementation involves:

- Crafting a communication to stores;
- Potentially programming a stop-sale in the point-of-sale software system, and/or a do not ship notice at the distribution centers; and
- Programming the actual action that needs to be taken to either post a sign, sticker the identified product in all stores, or remove the product from all shelves.

Assuming the retailer has reached a decision to take affirmative action, it will typically take at least two to three business days for this process alone to effectively conclude and even that assuming that a business is able to start the process on the day it receives notice.

In light of these realities, the California business community submits that the absolute minimum time frame for a retailer to take corrective action in response to a pre-suit notice should be 10 business days. The regulation should also clarify that actual notice is limited to the "exemplar" – the product actually described in the notice, not the broader category or "specific type" of product, and that the enforcer must provide identifying information on request of the retailer, which request tolls the time period until it has been received by the retailer.

Moreover, the Agency may wish to consider the following additional actions to allow retailers to respond more effectively to notices:

- Amend section 25903 to allow companies to register an email address with the Agency for service of pre-suit notices.

- Amend section 25903 to require private enforcers to provide copies of receipts and pictures for notices served on retailers for consumer products, including food.

- Address the ambiguity in section 25903 that is created by the description in the Final Statement of Reasons for that section that allows notices to describe "spray paint," "ceramic tableware," etc. to explain that such terms do not substitute for the requirement in the proposed regulation that a notice provide "sufficient specificity to inform the recipients of the nature of the items allegedly sold in violation of the law and to distinguish those products or services from others sold or offered by the alleged violator for which no violation is alleged."

Proposed Section 25602: Chemicals Included in the Text of a Warning

In proposed Section 25602, OEHHA identifies 12 chemicals/chemical categories (sometimes referred to as the "list of 12") that must be specifically identified in a safe harbor Proposition 65 warning. This proposed section will increase frivolous litigation, in direct contradiction to OEHHA's stated goals. It will impose significant economic burdens on companies out of proportion to any public benefit. Finally, the Coalition questions OEHHA's statutory authority to elevate certain listed chemicals over others in this kind of "super-listing." For the reasons set forth below the Coalition urges OEHHA to eliminate this provision altogether.

Increased Litigation

As OEHHA knows, uncertainties pertaining to when a business must warn, combined with an aggressive enforcement climate, make it impossible to establish with scientific certainty that no exposure is occurring at levels requiring a warning. In OEHHA's own words, "determining anticipated levels of exposure to listed chemicals can be very complex." Indeed, this dynamic is precisely the reason for the so-called "overwarning" problem, by which businesses voluntarily provide a warning out of an abundance of caution—even if exposure levels do not exceed threshold levels—to shield themselves from the inevitable threat of litigation that would otherwise exist if they did not warn.

This proposed section will exacerbate this situation by creating a new category of "bad warning" enforcement actions, which will punish companies making good faith efforts to comply. The following hypothetical illustrates the point: a company whose product contains both a listed phthalate and lead determines that it should provide a warning for lead but that no exposure to the phthalate is occurring at a level requiring a warning. Thus, it provides a compliant Proposition 65 warning identifying lead only. Notwithstanding that compliant warning, that company may still be sued for failing to identify the phthalate, leaving the company to settle or engage in prolonged, expensive litigation. The only way to avoid such "bad warning" claims would be to identify all twelve chemicals, or alternatively to identify any of the twelve chemicals that the business believe *may* be present, even if they may be present at such infinitesimal levels that they do not trigger the warning requirement. This is the exact opposite outcome that OEHHA states it wishes to achieve in that it creates an entirely new sub-category of "overwarning," wherein businesses will specify chemicals in their warnings out of an abundance of caution, notwithstanding the fact that such chemicals are either not present at all or are otherwise present at infinitesimal levels such that no specification of the chemical is required by law.

Economic Burden

Proposed Section 25602 would have a significant economic impact on businesses. First, the only means by which a business may try to assure itself that need not identify a particular chemical is by conducting an exposure assessment for the chemical. Thus, the proposed regulation may effectively mandate exposure assessments in order for a business to substantiate a decision not to identify a "list of 12" chemicals. This *de facto* mandate will impose significant financial challenges in developing this highly technical scientific information, which can cost anywhere from $10,000 to $100,000 or more, depending on the product, the chemical, and whether OEHHA has established a No Significant Risk Level/Maximum Acceptable Dosage Level for the chemical.

Second, the ISOR is clear that the "list of 12" may change at any time. (ISOR at p. 22). Thus, companies must stand ready, with financial reserves in hand, to conduct yet another exposure assessment and modify their warnings based on what chemical or chemicals OEHHA may decide to add next. Worse, with the lack of any defined scientific criteria to help businesses predict what chemicals may be added in the future, businesses have no tools by which they can plan ahead, whether in product research and development efforts (e.g., to avoid the use of certain listed chemicals in product manufacture), or to conduct appropriate exposure assessments, or to develop product labels, signage, etc.

Third, higher costs also will result due to the need to increase space in a warning in order to accommodate the additional chemical identification. Such increased space comes at a cost, whether on product labels, signage, or by other methods. At a minimum, a business should not have to designate multiple chemicals under this section and should instead be permitted to use an illustrative example by referring to one of the relevant 12 chemicals by saying: "can expose you to chemicals, such as X, known to the State . . . ." The truncated on-product warning text option (proposed Section 25604(b)) is not the cure for this problem, since this option is only available for product labeling. Even then, a significant number of companies will not use the truncated warnings on product labels based on individual assessments of their market effects. Such a situation places a business in the untenable position of either paying substantial costs to accommodate the longer warning text or to risk a negative market reaction with the truncated warning text.

No Criteria for the "List of 12"

Proposed Section 25602 does not establish any criteria for identifying the "list of 12." Rather, OEHHA identifies what criteria it considered when creating the list, criteria that may well change over time without any prior notification, because nothing in the proposed regulation would bind OEHHA to any set criteria. For this reason alone, this regulation can be challenged on Constitutional due process grounds and be void for vagueness.

Further, there is no sound basis for the "criteria" that OEHHA does describe. For example, OEHHA cites "recognizability of the chemical name among the general public" as one criterion. (ISOR at p. 14.) However, OEHHA points to no study or other reference to support the identification of any of the "list of 12" on this basis. Similarly, OEHHA provides no explanation of the relevance of "recent Proposition 65 enforcement activity" as a criterion. Enforcement activity, as the regulated community well knows, is largely driven by a few individuals and their lawyers, a fact that should have no bearing in any "super-listing" of chemicals. Thus, there is no evidence in the record to support this proposed regulation.

No Statutory Authority for the "List of 12"

By identifying the "list of 12" in proposed Section 25602, OEHHA is essentially undertaking a "super chemical listing" regulatory action for which there is no statutory authority. Further, the proposed regulation is not necessary to effectuate the purpose of Proposition 65. Accordingly, OEHHA cannot lawfully promulgate this regulation. (Gov't Code § 11342.2.).

Although the ISOR states that it is not OEHHA's intent to elevate some listed chemicals above others (ISOR at 15), OEHHA's self-described criteria for the list of 12 include "widespread prevalence of the listed chemical" and "potential for significant exposure." (ISOR at p. 14.) Indeed, OEHHA devotes no less than 8 single-spaced pages in the ISOR to explain the purportedly extensive use of, exposures to, and effects of these chemicals. ISOR at 15-22. Taken altogether, OEHHA's explanations of the "list of 12" contradict OEHHA's statement that this is not a "super-listing."

Nor is the proposed regulation reasonably necessary to effectuate Proposition 65's purpose of informing individuals of exposures to chemicals. The ISOR cites no study or other references to support OEHHA's rationale.

Section 25603: Product Exposure Warnings – Method of Transmission

Warnings Prior to Purchase

Since its inception, Proposition 65 has mandated warnings for consumers prior to exposure to a listed chemical. Section 25601 of the current regulations reiterates that warnings should be timed such as to communicate their message "prior to exposure." This requirement allows businesses to employ a broad range of possible methods to warn consumers of exposures.

The proposed regulations seek to exceed this clearly established element of the law. Section 25601's "prior to exposure" language has been completely removed from the proposed regulations. It is replaced instead with the proposed language of 25603(a)(2), which would require warnings to be provided "prior to or during the purchase of the product." This is inconsistent with the statutory text and beyond the authority granted to OEHHA in enacting regulations for Proposition 65. This clearly will subject the proposed regulations to litigation if adopted in its current form.

That the proposed regulations seek to impose a new regime of "prior to purchase" warnings is highlighted by section 25603(b), which requires warnings to be prominently displayed prior to the purchase of a product online. Further, this requirement appears to be implied for product labels as well, as the new regulations exclude references for warnings "prior to exposure."

OEHHA has failed to clearly delineate how this narrower approach is authorized by the law or why it is necessary. In fact, contrary to the proposal itself, the ISOR continues to use the statutorily supported "prior to exposure" standard throughout its explanations. Once again, the regulated community cannot be called upon to shoulder the burden of OEHHA's lack of clarity on this point.

Further, OEHHA's proposed approach would invalidate several effective warning methods now employed by businesses. Currently, businesses provide warnings using a variety of methods that warn consumers prior to exposure, but potentially post-purchase. Such methods include user manuals, use and care guides, warnings on internal packaging, and on product packaging for products bought over the internet. These warning methods would now be subject to

challenge under the proposed regulations, while doing little to improve consumers' access to information, reduce frivolous litigation, or introduce predictability and clarity to businesses. Lastly, implementing warnings that are provided "prior to purchase" will be unduly expensive, particularly for small businesses.

Warning Via Electronic Devices

Beyond 25603(a)(2)'s unauthorized shift in the required timing of warnings, it suffers from a host of other problems which render it unworkable for business and subject to legal challenge. As described in the Initial Statement of Reasons, 25603(a)(2) is intended as a "catch-all" provision, encompassing an array of devices and tools that may be employed to provide consumers with a warning. However, such devices may only be employed in a manner that does not require the purchaser to "seek out the warning."

There is no described threshold for what actions a purchaser must have to take in order to be considered "seeking out a warning." The ISOR lists several methods that may be suitable for providing a warning, including "electronic shopping carts, QR Codes, smart phone applications, barcode scanners, self-checkout registers, pop-ups on Internet websites and any other electronic device that can immediately provide the consumer with the required warning." However, several of these devices would likely require a purchaser to take proactive steps with the device in order to access the warning. For example, QR Codes would require a consumer to scan the code embedded on the product with a camera-equipped smart phone to access the warning.[3] Likewise, barcode scanners would require a consumer to scan a product prior to purchase.

One would assume that OEHHA intends for these devices to be sufficient methods of providing a warning. However, the ISOR also states that the provision should not be read as allowing business to rely on such devices, if a consumer must "seek out the warning." Through this vague guidance, the subsection and the ISOR, leaves unanswered the question: at what point is a purchaser being required to "seek out a warning"? Due to this lack of clarity about what methods are permitted, many businesses are unlikely to provide warnings under this subsection, even if it may be the most effective method. This vagueness is fodder for frivolous lawsuits and creates uncertainty for businesses, especially given the fact that the proposed regulations considerably limit the available methods of warning.

Internet Purchases

The proposed "prior to purchase" requirements will especially impose substantial economic and compliance burdens on internet retailers. Section 25603(b) appears to require warnings to be given prior to an internet purchase, even if the product has proper labels that have been included by a manufacturer.

It is unclear how this requirement is meant to harmonize with the proposed allocation of responsibility under section 25600.2(b), which purportedly seeks to minimize the burden on retail sellers. Under that section, it would appear that a retailer has no stated responsibility to warn if the manufacturer affixes a warning label to the product. In such a scenario, retailers are only responsible for warnings if they "covered, obscured or altered a warning label" – absent

[3] For US EPA FIFRA-registered products, US EPA has cautioned that any information accessible by a QR code on a label would have to be reviewed and approved by EPA and the state in which it will be sold because it points to content that "accompanies" the label which could cause further complications and delays in registering products.

this, retailers seem to have no obligations. Section 25603(b), on the other hand, imposes an affirmative burden to warn on internet retailers, regardless of whether a warning has been provided on the product label by the manufacturer. As a result, the proposed regulations are inconsistent.

Requiring such a warning to be provided in every instance for every covered product is a massive burden to put on internet retailers of any size. Large internet marketplaces selling a massive volume of products from a variety of manufacturers will be prime targets for frivolous lawsuits, as a failure to provide a "prominently displayed" warning on the site will be enough to trigger a suit against the retailer. On-product labeling, apparently, will be inadequate to protect the seller.

This lack of protection will be equally crippling to small retail sites, as they may lack the economic or staff resources to constantly update the coding on their website to comport with their current inventory. The simple mistake of failing to check a product label to see if the manufacturer included a warning, thereby requiring the retailer to include a warning on their website, could trigger costly litigation.

Multiple Languages

Section 25603(d) also generally suffers from vagueness, does not give proper guidance to businesses on how to comply, and thus will directly lead to more lawsuits.

First, the subsection does not indicate what amount of another language needs to be present on a label to trigger a warning in that language. It is not difficult to foresee an aggressive plaintiff finding an otherwise compliant label with one or two non-English words and bringing suit. For example, consumer products may be branded with a single common non-English word (e.g., "hola beautiful", "blue and belle," "ciao comfort," etc.). These popular non-English words are common in the American lexicon.

Second, while the proposed regulations give detailed and precise requirements for the language to be employed in the English-language warnings, they do not give an indication of how these warnings are to be properly translated. As the safe-harbor warnings have been replaced by these provisions, businesses do not have guidance on the content that must be included in the non-English warnings. Allegedly improperly translated warnings may further prompt suits. Defending such a suit will require engaging linguistic experts to prevail, making a forced settlement inevitable.

Third, the foreign language proposal does not take space limitations into account. At the very least, the foreign language requirement should, where triggered in the consumer product context (as distinct from the environmental exposure contact), be limited to the provision of only one language in addition to English with the additional language being the one most likely to be understood by consumers of that product in California (i.e., Spanish in most cases, except where the product is targeted predominately for use by a different ethnic subpopulation). In addition, given tri-lingual NAFTA labeling requirements, there is little sense or upside to requiring Proposition 65 warnings to be printed in French given that very few people in California even speak it. Further, because of space limitations and the heightened need for an importance of nuance and context, there should, at the very least, be an exemption in the multiple languages requirement for food labels.

Fourth, this provision also appears to create greater burdens on retailers, against the goals of section 65200.2. 65200.2(d)(5) states that retailers will be held responsible for warning requirements when a manufacturer, producer, packager, importer or distributor of a product cannot be compelled to comply, because they are foreign persons, and if the retailer has actual knowledge of the product exposure. Therefore, retailers selling foreign goods, with labeling in other languages, may be required to provide extra warning labels in the other language.

With these practical and legal issues in mind, it should be noted that during the March 25 public hearing on the proposed regulation, OEHHA stated that it intends to include translated warnings on its proposed website. OEHHA can eliminate the problems the Coalition has identified with respect to the foreign language requirement by including translated warnings on its website in multiple languages in lieu of requiring businesses to provide them whenever another language is present on a label. This would reduce unnecessary burdens on the regulated community, ensure that businesses aren't targeted with frivolous litigation with respect to this aspect of the proposal, and further satisfy OEHHA's stated objective of ensuring that non-English speaking members of the public have access to information about chemical exposures in their primary language.

Alternatively, if OEHHA remains inclined to require businesses to provide warnings in multiple languages on labels, it would only make sense for the foreign language requirement to be triggered if other *health-related* warnings for a product are given in multiple languages, not based solely on the mere use of multiple languages on a label in other regards. Even then, OEHHA should limit the requirement to one additional language.

Owner's Manual

The issue of whether a warning can be placed in an owner's manual to satisfy a manufacturer's labeling obligation under Proposition 65 is not clearly addressed in the proposal and may not even be allowed. The term "Label" is defined in the proposal as "affixed to a product or its immediate container or wrapper." The term "Labeling," however, is defined to include a "communication that accompanies a product." In the proposed regulations, the section on the methods of transmitting a warning includes "A label on the product that includes all the elements specified in Section 25604." (See §25603(3)) It does not include the term "labeling" in this subparagraph, as is the case in the current regulation. The current regulation states that a warning may be provided "on a product's label or other labeling." The terms "Label" and "Labeling" in the current regulation have the same general definitions as in the proposed regulation in that "Labeling" includes communication accompanying a product and "Label" does not. To ensure that the current policy of providing warnings in the owner's manual where other warnings and information are contained, such as for electric safety and drinking water safety, does not change, we strongly recommend the following revisions to the regulation before it is finalized:

Suggested additions to Section 25603(a)(3) in underline –

> A label on the product <u>or other labeling</u> that includes all the elements specified in Section 25604.

General Concerns

Section 25603, in general, highlights an issue endemic to the proposed regulation as a whole: OEHHA fails to acknowledge the inherent difficulty across the entire products supply chain in

limiting, controlling, and distinguishing which products ultimately are sold in California, as opposed to elsewhere. Markets are more global than ever and web-based sales continue to increase, making ascertaining the final point of sale for a product extremely difficult or impossible in the real world business context. OEHHA's proposed regulations effectively regulate national commerce, placing onerous (and unconstitutional) requirements on any business which worries that their product may somehow end up on the shelves in California without their knowledge, consent or intent. Rather than producing a more stream-lined and effective Proposition 65 warning program for both California consumers and world businesses alike, the proposed regulations instead expand Proposition 65's reach, imposing an unacceptably confusing and broad scheme on to businesses worldwide, while doing little to promote Governor Brown's sought after reforms.

Proposed Section 25604: Product Exposure Warning – Content

This section provides the elements that, if contained in a warning and delivered pursuant to the methods in section 25603, meet the requirements for Proposition 65. The proposed language in this section presents several concerns.

American National Standards Institute (ANSI) Symbol

First, to comply with this section, a Proposition 65 warning would need to include a symbol consisting of a black exclamation point in a yellow equilateral triangle with a bold black outline. It is unclear why any symbol should be included with a Proposition 65 warning, especially one that has been used for other purposes and will not be meaningful to the receiver of the warning. Specifically, this very symbol is associated with more significant or acute hazards than those that fall within Proposition 65's reach, such as choking or allergic reaction risks.
Borrowing the ANSI symbol and paring it with a "WARNING" in all capital letters will inadvertently and perversely increase consumer confusion. Its widespread appearance on products such as earrings, headphones, and garden hoses will seriously dilute, by overwarning, the ANSI Z535 committee's careful standardization work since 1979 to "promote a single, uniform graphic system used for communicating safety and accident prevention and information." (ANSI Z535.4-2011, Foreword, page vii.) The use of this symbol and "WARNING" is clearly intended for potential accident situations where death or a serious potential injury is possible. (ANSI Z535.4-2011, clause E4.3, page 31.)

Accordingly, it would be more consistent with the statute and make more sense to use within a symbol a "P65" or "65" that associates with the basis for why the warning is being given and provides a cure to using the URL to go to the website where more explanatory and contextual information will be available.

From a practical standpoint, the proposed requirements for the color scheme of the symbol (yellow with a bold black outline) will be problematic for businesses placing the warning on their products depending on their packaging and color scheme. Businesses that have established and used product packaging that are known to their consumers should not have to undertake a packaging modification simply for the purpose of adding the yellow and black triangle symbol, particularly given that consumers will not know what the symbol represents. The proposal is unduly onerous (because printing costs may escalate with the number of separate colors being used or the number of pieces/parts of labeling to which they may have to be applied) and, because the color yellow may itself non-verbally signal a more significant or acute level of risk than that for which the warning (which could be based only a small detectable amount and/or due to a 1,000 fold safety factor) is being given.

Truncated Warning "Option"

The proposed truncated warning in 25604(b)(2)(A) likely will not be utilized and thus does not provide a meaningful option for businesses to provide an abbreviated warning. That proposed subsection allows a business to use the symbol, the word " WARNING" in all capital letters, and the relevant health endpoint (e.g., the word "Cancer"), with a reference to the Proposition 65 URL. It is difficult to imagine that any business would provide such a misleading and confusing warning on its products. The truncated warning would give virtually no information to the consumer and would put the obligation on the consumer to investigate further to understand the reference to "WARNING Cancer." This is especially problematic since the truncated warning would imply that the product causes cancer, even though it does not do so. This would be misleading and most consumers would simply abandon a purchase of the product rather than go investigate what the words "WARNING Cancer" is really intended to convey.

Proposed Section 25605: Environmental Exposure Warnings – Methods of Transmission

Proposed Section 25605 contains elements that, if not improved, will create significant financial costs to businesses and increase the risk of unnecessary enforcement actions.

Subsection (a)(1) describes signage to be used to transmit the warning. Under this subsection, warnings transmitted via signs must be "provided in a conspicuous manner and under such conditions as to make it likely to be read, seen and understood by an ordinary individual in the course of normal daily activity...." Yet, proposed Section 2600.1(j) already defines "sign" in virtually the identical way. The ISOR does not explain how that definition and subsection(a)(1) interact. This apparent duplication is confusing, making it difficult for a business to understand exactly what is required and, worse, rendering it a target for exploitation via bounty hunter lawsuits.

The requirement to provide warnings in other languages imposes significant burdens on business and makes them vulnerable to lawsuits. Subsection (a)(3)(C), for example, may require a business to canvass a particular area to make the factual determinations necessary to determine whether a warning in another language must be given. Such investigation would require significant resources; even so, it may not reveal information that could trigger a second language warning requirement (e.g., whether a foreign language newspaper is being circulated to the affected area).

Difficulties also arise with subsection (a)(2)'s reference to "language ordinarily used by the business." That language perfectly sets up a dispute of fact, to be litigated by the parties, about what language is "ordinarily" used. This requirement should be eliminated.

Finally, the Coalition again questions why the proposal would eliminate as an option the posting of signs in a manner described in Title 3, California Code of Regulations, Section 6776(d). That section sets forth the requirements for a property operator to provide signs about pesticides that have been applied on the property. The reference to Section 6776(d), which is found in the current safe harbor environmental warning regulations, is not a mere duplication of the occupational exposure warning regulations. The reference was specifically intended to establish another means for businesses to transmit warnings, particularly for unfenced outside areas. As the Health & Welfare Agency stated in the Final Statement of Reasons for adopting this provision in the current regulations:

> One commentator recommended that the regulation expressly permit signs on the business perimeter. (Exh. 21,p. 20.) The Agency adopted this suggestion in part by referring in the regulation to the posting requirement of section 6776(e)(1) of title 3 of the California Code of Regulations. That section provides for the posting of entrances, and every 600 feet where a facility is unfenced and adjacent to a right-of-way. This should cover, but is not limited to, most agricultural operations, ***where the entire posted location presents a potential for exposure*** and the purpose of the posting is to keep people out of the field. Adopting the same approach may not be appropriate for fenced sites, such as industrial plants, where the exposure occurs at a discrete location inside the facility but it is intended that people will enter the premises.

(1989 Revised Final Statement of Reasons, 22 California Code of Regulations, Division 2, Section 12601 - Clear and Reasonable Warning, at p. 43 (emphasis added).) Accordingly, the Coalition urges OHEHA to retain this option for environmental exposure warnings.

Proposed Section 25205: Lead Agency Website

Section 25205 is a standalone but related regulation that proposes that OEHHA will develop and maintain a website to provide information to the public to supplement and explain the basis for the Proposition 65 warnings provided by businesses.

Significantly, in addition to allowing OEHHA to compile its own information on the website for public consumption, the proposed website regulations, under Section 25205 subdivision (b), empower OEHHA to *require* manufacturers, producers, importers and distributors of products bearing a Proposition 65 warning to provide the agency with a plethora of complicated and highly technical information regarding their warnings. (Section 25205(b) ["The manufacturer, producer, distributor, or importer of a product . . . must provide the following information."].) Such information may include the identities of the chemicals in the product for which a warning is being given, the location or components of a product in which such chemicals are present, the concentration of those chemicals, and "any other information the lead agency deems necessary."

Proposition 65 does not empower OEHHA to require manufacturers, producers, importers and distributors to provide it with any supplemental information. Specifically, Proposition 65 requires a person in the course of doing business to provide a "clear and reasonable" warning before knowingly and intentionally exposing individuals to Proposition 65-listed chemicals. Under this provision, OEHHA has the statutory authority to promulgate regulations with respect to what warnings may look like and say to ensure that they meet the "clear and reasonable" requirement of the law. Indeed, OEHHA is exercising this very authority under the current warning proposal.

No provision in Proposition 65, however, provides OEHHA with authority to require that businesses provide it with supplemental information of any sort beyond that which is already provided in a warning. Perhaps recognizing this restriction, the warning regulation proposal itself expressly *permits*, but appropriately does not *require*, businesses to provide consumers with supplemental information in their warnings. (Section 25600(d) ["A person may provide information to the exposed individual that is supplemental to the warning required by Section 25249.6 of the Act, such as further information about the form or nature of the exposure and ways to avoid exposure."].) If OEHHA wishes to give businesses the option to provide such supplemental information to OEHHA for the purpose of posting it on its website, then Section 25600(d) can expressly permit businesses to do so. With that modification, providing

supplemental information to the exposed individual and/or OEHHA would be permissive only, and thus Section 25600(d) as revised would be sufficient to address this issue without the need for subsection (b) of the website regulation.

In addition to lacking statutory authority to demand information from businesses, the website proposal is unclear and unreasonable. OEHHA's Initial Statement of Reasons for the website regulation ("Website ISOR") states that, in demanding this information from businesses, OEHHA intends to "collect existing, publicly available information and make it accessible to those who may have questions when they see a Proposition 65 warning." (Website ISOR, at p. 3.) Yet, the ISOR later states that the information OEHHA seeks to collect from businesses is "not always publicly available." (Website ISOR, at p.6.)

This contradiction must be resolved. For example, businesses may have information developed by their legal representatives, including working through consultants, that is not publicly available because it is protected work-product. The proposed regulation does not specifically address work-product considerations. Instead, it creates a procedure by which businesses can designate requested information as "confidential" subject to OEHHA's review of the information and concurrence in the designation. That process is inadequate to protect work-product. Accordingly, the regulation should be revised to clearly state that work-product does not have to be provided.

OEHHA also fails to take into consideration the financial resources that businesses would be required to expend separate and apart from gathering and providing the information OEHHA seeks to collect. Specifically, businesses would have to expend resources monitoring the website to ensure that OEHHA is not posting information submitted by other persons that is inaccurate, misrepresents their products or that otherwise misleads the public. If this were to occur, businesses would be forced to bear the economic burden of taking administrative or legal steps to correct the wrong or misleading information.

Finally, under Section 25205(c), if OEHHA determines the information that a business claims is confidential must be released to the public, OEHHA will notify the business only 15 days prior to disclosure in order to provide the business with the opportunity to submit additional justification for the claim or to contest OEHHA's determination in an appropriate proceeding. While the Coalition very much agrees with the concept of providing businesses with the opportunity to submit additional justification or contest OEHHA's determination, the proposed 15-day timeframe is insufficient because it imposes an unrealistically short timeframe for businesses to respond. Specifically, many mid-to-large size companies will simply not be able to respond in such a short timeframe; in fact, it would likely take 15 days just for OEHHA's notification to be presented to the appropriate individuals within the affected business. Accordingly, if proposed Section 25205(b) is retained, then a reasonable lead time of at least 90 days must be provided in order to allow sufficient time for businesses to provide a reasoned and adequate response.

I. CONCLUSION

Thank you for considering our comments. We appreciate the opportunity to participate in this very important regulatory process.

Sincerely,

Anthony Samson
Policy Advocate
The California Chamber of Commerce

On behalf of the following organizations:

Advanced Medical Technology Association (AdvaMed)
Agricultural Council of California
Alliance of Automobile Manufacturers
Allwire, Inc.
Alpha Gary
American Apparel & Footwear Association
American Architectural Manufacturers Association
American Beverage Association
American Brush Manufacturers Association
American Chemistry Council
American Cleaning Institute
American Coatings Association
American Composites Manufacturers Association
American Fiber Manufacturers Association
American Forest & Paper Association
American Frozen Food Institute
American Herbal Products Association
American Home Furnishing Alliance
American Wood Council
Amway
APA – The Engineered Wood Association
Apartment Association of Greater Los Angeles
Apartment Association of Orange County
Apartment Association, California Southern Cities
Association of Home Appliance Manufacturers
AXIALL LLC
Automotive Specialty Products Alliance
BayBio
Belden
Berk-Tek
Bestway
Betco Corporation
Bicycle Product Suppliers Association
Biocom
Biotechnology Industry Organization
Brawley Chamber of Commerce
Breen Color Concentrates
Building Owners and Managers Association of California
Burton Wire & Cable
California Apartment Association
California Asphalt Pavement Association

California Association of Boutique & Breakfast Inns
California Association of Firearms Retailers
California Association of Health Facilities
California Association of REALTORS®
California Attractions and Parks Association
California Automotive Business Coalition
California Business Properties Association
California Cement Manufacturers Environmental Coalition
California Citizens Against Lawsuit Abuse
California Construction and Industrial Materials Association
California Cotton Ginners Association
California Cotton Growers Association
California Farm Bureau Federation
California Furniture Manufacturers Association
California Healthcare Institute
California Hospital Association
California Hotel & Lodging Association
California Independent Oil Marketers Association
California Independent Petroleum Association
California League of Food Processors
California Manufacturers and Technology Association
California Metals Coalition
California/Nevada Soft Drink Association
California New Car Dealers Association
California Paint Council
California Restaurant Association
California Retailers Association
California Self Storage Association
California Travel Association
Can Manufacturers Institute
Chambers of Commerce Alliance Ventura and Santa Barbara Counties
Chemical Fabrics & Film Association, Inc.
Chemical Industry Council of California
Civil Justice Association of California
Coast Wire & Plastic Tec., LLC
Communications Cable and Connectivity Association
Composite Panel Association
Consumer Electronics Association
Consumer Healthcare Products Association
Consumer Specialty Products Association
Council for Responsible Nutrition
Dow Chemical Company
DuPont
East Bay Rental Housing Association
Family Winemakers of California
Fashion Accessories Shippers Association
Federal Plastics Corporation
Flexible Vinyl Alliance
Footwear Distributors & Retailers of America
Frozen Potato Products Institute
Fullerton Chamber of Commerce

Greater Bakersfield Chamber of Commerce
Grocery Manufacturers Association
Hardwood Plywood Veneer Association
Independent Lubricant Manufacturers Association
Industrial Environmental Association
Information Technology Industry Council
International Crystal Federation
International Franchise Association
International Council of Shopping Centers
International Fragrance Association, North America
IPC – Association Connecting Electronics Industries
J.R. Simplot Company
Juvenile Products Manufacturers Association
Loes Enterprises, Inc.
Lonseal, Inc.
Metal Finishing Association of Northern California
Metal Finishing Association of Southern California
Mexichem
Motor & Equipment Manufacturers Association
NAIOP of California, the Commercial Real Estate Development Association
National Association of Chemical Distributors
National Council of Textile Organizations
National Electrical Manufacturers Association
National Federation of Independent Businesses
National Lumber and Building Material Dealers Association
National Shooting Sports Foundation
Natural Products Association
NorCal Rental Property Association
North American Home Furnishing Association
North Valley Property Owners
OCZ Storage Solutions
Orange County Business Council
Outdoor Power Equipment Institute
Pactiv Corporation
Parterre Flooring Systems
Personal Care Products Council
PhRMA
Plumbing Manufacturers International
Polyurethane Manufacturers Association
Procter & Gamble
Rancho Cordova Chamber of Commerce
Redondo Beach Chamber of Commerce
Resilient Floor Covering Institute
San Diego Regional Chamber of Commerce
Santa Barbara Rental Property Association
Searles Valley Minerals
Sentinel Connector System
Sika Corporation
Simi Valley Chamber of Commerce
Specialty Equipment Market Association
SPI: The Plastic Industry Trade Association

SPRI, Inc.
Southwest California Legislative Council
Styrene Information and Research Center
Superior Essex
TechAmerica
TechNet
The Adhesive and Sealant Council
The Art and Creative Materials Institute
The Association of Global Automakers
The Kitchen Cabinet Manufacturers Association
The Chamber of the Santa Barbara Region
The Vinyl Institute
The Worldwide Cleaning Industry Association
Toy Industry Association
Travel Goods Association
Treated Wood Council
USANA Health Sciences, Inc.
USHIO America, Inc.
Visalia Chamber of Commerce
WD-40 Company
West Coast Lumber & Building Materials Association
Western Agricultural Processors Association
Western Growers Association
Western Plant Health Association
Western Propane Gas Association
Western State Petroleum Association
Western Wood Preservers Institute
Window & Door Manufacturers Association
Writing Instrument Manufacturers Association

cc: Matt Rodriguez, Secretary, CalEPA
George Alexeeff, Director, OEHHA
Allan Hirsch, Chief Deputy Director, OEHHA
Carol Monahan-Cummings, Chief Counsel, OEHHA
Mario Fernandez, Counsel, OEHHA
Gina Solomon, Deputy Secretary for Science and Health, CalEPA
Tara Dias-Andress, Deputy Secretary for Legislative Affairs, CalEPA
The Honorable Luis Alejo, Chair, Assembly ESTM Committee
The Honorable Bob Wiekowski, Chair, Senate Environmental Quality Committee
Nancy McFadden, Executive Secretary, Office of the Governor
Dana Williamson, Cabinet Secretary, Office of the Governor
Ken Alex, Senior Policy Advisor, Office of the Governor
Cliff Rechtschaffen, Senior Policy Advisor, Office of the Governor
Kish Rajan, Director, Governor's Office of Business and Economic Development
Poonum Patel, Deputy Director, Governor's Office of Business and Economic Development

AS:mm

Attachment

ATTACHMENT 1

"The Business Cost of Proposed Changes to Article 6 of Proposition 65"
Andrew Chang & Co., LLC
April 8, 2015

CalChamber
CALIFORNIA CHAMBER OF COMMERCE

The Business Cost of Proposed Changes to Article 6 of Proposition 65

April 8, 2015

ANDREW CHANG & CO, LLC

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California Chamber of Commerce (CalChamber) is a nonprofit business association with over 13,000 members, both individual and corporate, representing virtually every economic interest in the state. CalChamber members include several of the largest businesses in California, but 75 percent of its members are small businesses with 100 or fewer employees. CalChamber acts on behalf of the business community to improve the state's economic and employment climate by representing business on a broad range of legislative, regulatory and legal issues.

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The professionals at Andrew Chang & Company work with our clients to achieve tangible results by combining our best-in-class research and analyses with unique insights into public policy and business and government strategy and operations. Using advanced economic, statistical and business administration techniques, we provide strategy and operations consulting to Fortune 1000 firms and provide policy, economic, fiscal and operations consulting for public sector agencies and non-profit organizations to improve operations.

The Business Cost of Proposed Changes to Article 6 of Proposition 65
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The Business Cost of Proposed Changes to Article 6 of Proposition 65
(Key Findings)

- Proposed regulations require significantly more specificity in warnings:
  - Include the name of one or more of the 12 chemicals identified by OEHHA on the warning if present and above safe harbor levels
  - Include a URL of OEHHA maintained Lead Agency website on all warnings
  - If requested by OEHHA, submit technical information regarding the exposure to OEHHA
  - Include specified language for certain industries such as dental care, furniture and amusement parks
  - Include a color symbol with a yellow triangle and an exclamation point on certain product or public entry signs
  - Provide additional warnings in all languages used on other signage in the affected area

- Increased required specificity opens businesses to potential new litigation regarding the contents of warnings:
  - Proposed regulations create new avenues of litigation regarding the contents of warnings, whereas businesses that provide a warning under the current regulations are generally protected from litigation
  - Proposed regulations eliminate the oft-relied upon guidance regarding what constitutes a "clear and reasonable" warning, thereby potentially removing businesses' ability to provide warnings other than those specified by OEHHA
  - Added language forbids businesses from providing supplemental information that may contradict, dilute or diminish the warning without providing specific definitions of these words
  - New translation requirements expose businesses to content-based litigation over whether translation was required and/or whether the translated language is adequate

- Twelve-year additional costs resulting from proposed changes range from $410 million to $818 million in our low and high estimate; cost drivers include:
  - Administration costs for replacing and installing new product and facility signs
  - Increased testing costs for requirement to list 12 identified chemicals by name
  - Litigation costs for new 'content-based' litigation, whereas current regulations substantially protect most business that post a warning from litigation

- Compliance rates could decrease from the current estimated rate of 87 percent to 81 percent or as low as 45 percent as a result of proposed regulations. This is due to:
  - Decreased risk mitigation resulting from increased content-based litigation
  - Increased cost of compliance resulting from administration costs and increased number of tests needed

The Business Cost of Proposed Changes to Article 6 of Proposition 65
(Executive Summary)

Voters passed Proposition 65, The Safe Drinking Water and Toxic Enforcement Act, in 1986 with the goal of protecting Californians from exposure to chemicals known to the State of California to cause cancer or reproductive toxicity. Specifically, Proposition 65 requires California businesses with ten or more employees to provide a clear and reasonable warning before knowingly and intentionally exposing individuals to chemicals known to cause cancer and/or reproductive toxicity. The California Office of Environmental Health Hazard Assessment (OEHHA) proposes to repeal and replace the current Article 6 regulations concerning clear and reasonable warnings. The proposed Article 6 requires greatly increased specificity in warnings and will effectively require the vast majority of businesses to replace their existing warnings with new, more specific warnings that meet the criteria set forth in the proposed regulation. Further, certain requirements contained in the proposed regulation will require businesses to undertake substantial financial investments relating to testing which, in turn, will constitute a substantial cost to businesses as compared to the status quo. Despite these wide ranging requirements, OEHHA's economic impact assessment concludes that the proposed regulations would have "no significant economic impact."[1]

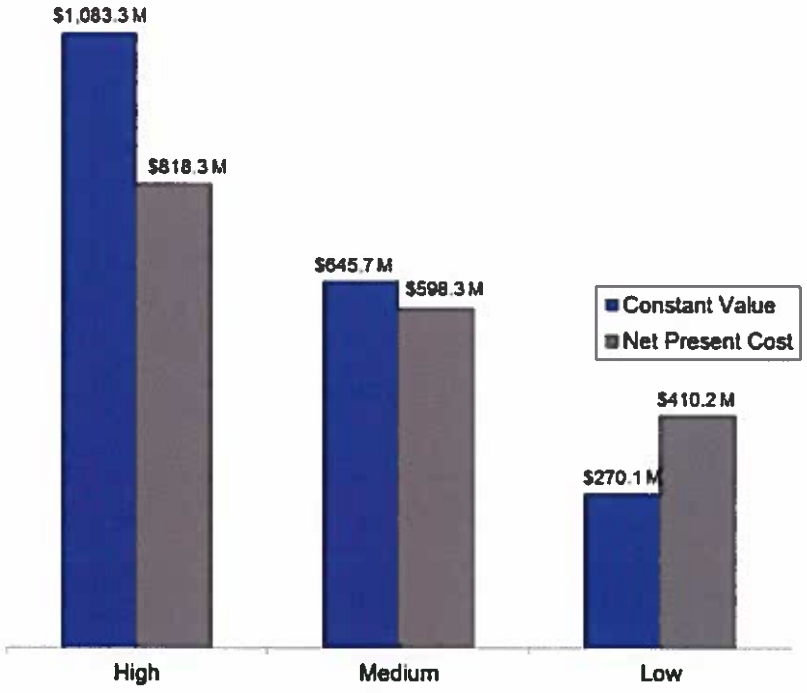
Andrew Chang & Company (ACC) was retained by the California Chamber of Commerce to conduct an independent economic impact assessment of the proposed changes to Article 6 to support more informative public discussion regarding the proposed regulations. To conduct this assessment, we performed a comparative analysis of the current and proposed Article 6 and reviewed current literature and data regarding the costs to businesses from the existing regulation, as well as potential cost components under the proposed regulation. We constructed a fiscal model to estimate the rate at which businesses would comply with regulations, given

[1] "Initial Statement of Reasons," *Office of Environmental Health Hazard Assessment*. January 16, 2015. p. 43.

specific cost and risk profiles. We then developed three scenarios to encapsulate the regulation's range of potential impact to businesses.

The three scenarios (as shown below in Figure 1.0) produce twelve-year costs ranging from $270 million to $1.1 billion, depending on the scenario. In net-present value terms, costs range from $410 million to $818 million, utilizing a five percent discount range. These changes are primarily driven by increased testing costs and increased risk of content-based litigation. Content-based litigation is actual or threatened litigation relating to the adequacy of a provided warning. In all scenarios, the proposed regulation drives significant up-front costs due to new compliance requirements. The proposed regulations are also expected to increase litigation costs both in the short and long runs.

Figure 1.0
12-Year Total Costs



Though there are some uncertainties in regards to the implementation of the proposed regulations, this analysis reveals the significant impact the newly proposed Article 6 will have on

businesses even under optimistic circumstances. Under the California Code of Regulations, a Standardized Regulatory Impact Assessment for Major Regulations must be submitted for any proposed rulemaking in which the expected impact is greater than $50 million in the first year of full enactment, as determined by the enacting department. OEHHA's current one-page Economic Impact Assessment that concludes there will be "no significant economic impact" is deficient due to the flawed assumption that there will be no new cost.[2] In all scenarios of our economic analysis, up-front costs significantly exceed $50 million annually, clearly pointing to the need for more in-depth assessment of the impact of the proposed regulation in the form of a Standardized Regulatory Impact Assessment for Major Regulations for its proposed rulemaking.

[2] Initial Statement of Reasons, p. 43.

1. Approach

Our study was completed in three key phases. First, we began with a comparative content analysis and literature review of both the current Proposition 65 regulations regarding "clear and reasonable" warnings and the newly proposed regulations. Second, we conducted a thorough review of existing literature, focusing on the current cost to businesses incurred due to Proposition 65 as well as cost components that could be incurred as a result of the proposed changes. Third, we developed an econometric model to estimate the range of potential fiscal impacts of the proposed regulations to California businesses.

The first phase focused on the content of the current and proposed Article 6 regulations and the existing literature concerning the two. We reviewed academic research, government reports and industry analyses to accurately assess and catalogue the changes in the regulation. Our review found that whereas current regulations allow for a more generic warning, the proposed regulation significantly increases the amount of detail required for compliant warnings. The proposed regulation further eliminates the guidance pertaining to what constitutes "clear and reasonable." Businesses often rely on this guidance to provide warnings separate and apart from those provided by the Office of Environmental Health Hazard Assessment (OEHHA), but which nonetheless meet the "clear and reasonable" requirement of the law. The results of this phase are detailed in section two.

In the second phase, we analyzed current literature and government records pertaining to the cost Proposition 65 has imposed on businesses to date and the potential cost drivers resulting from the proposed regulations. Our estimate of costs incurred to date is based on annual settlement summaries from the California Office of the Attorney General (OAG) as well as transcripts from a House Hearing in Washington DC and academic literature. These sources detail a clear litigation cost resulting from Proposition 65 but provide little insight as to the compliance costs necessary to avoid litigation. Our assessment of potential cost drivers due to

the proposed regulation led us to focus on three key areas: administration, testing and litigation. Our review included literature focused on State, national and international policies to help us develop the most well-informed price range for both administration and testing costs for similar changes. Finally, our review yielded no research or study concerning the potential increase in litigation; however, public comments made regarding the proposed rulemaking and interviews of subject matter experts indicates increased litigation is highly likely. The findings of this review are detailed in section three.

In the third phase of our analysis, we developed, reviewed and refined our econometric model. Given the existence of some uncertainty, we calculated how much businesses would be willing to spend in order to reduce their risk of litigation. Our model assumes businesses will make the rational decision to pay to comply with the regulation, so long as the cost of compliance is equal to or less than the amount of risk they are able to mitigate. From this baseline, we estimated the cost of the proposed regulation by modeling the impact of changes to two key variables: the amount of risk mitigated by complying with the law and the average number of tests needed per business to comply. A detailed description of the model is provided in section four and the findings are detailed in section five.

2. Review of Current and Proposed Article 6 Regulations

To begin our analysis, we conducted a review to identify pertinent differences between the current and proposed regulations. These changes form the basis for assessing the fiscal impact of the proposed regulation.

Under current law, when listed chemicals are found to be present at levels above the safe harbor levels established by OEHHA, businesses are required to provide a "clear and reasonable" warning. Section 25601 explains, "[w]henever a clear and reasonable warning is required ... the method employed to transmit the warning must be reasonably calculated, considering the alternative methods available under the circumstances, to make the message available to the individual prior to exposure. The message must clearly communicate that the chemical in question is known to the state to cause cancer, or birth defects or other reproductive harm." This regulation provides specific wording to be used in some instances, such as "WARNING: This product contains a chemical known to the State of California to cause cancer" and six other variations.[3] Currently, the regulation leaves additional specificity to the businesses.

Proposed Article 6 regulations seek to alter areas that allow discretion and add significant specificity in the "clear and reasonable" requirements. As OEHHA stated in their Initial Statement of Reasons, "the existing safe harbor warnings lack the specificity necessary to ensure that the public receives useful information about potential exposures. Further ... [i]t is [necessary] to update the regulations to take advantage of current and future approaches to providing important health-related information to the public." To this extent, the proposed regulations make several additions as listed below in Table 1.0.

[3] For different required texts in current regulations, see Section 25604(a)(1), 25604(2), 25606(a)(1), 25606(a)(2), 25608.1(a), 25608.1(b), and 25608.3(e)(1).

Table 1.0

Changes to Current Regulations

Requirements	Current Regulation	Proposed Changes
Post a warning for the public if there is a chemical present that is known to cause cancer or reproductive harm	☑	☑
Include the name of any of the 12 chemicals identified by OEHHA on the warning if they are also present and above safe harbor levels[4]	☐	☑
Include a URL of OEHHA maintained Lead Agency website on all warnings[5]	☐	☑
If requested by OEHHA, submit technical information regarding the exposure to OEHHA [6]	☐	☑
Include specified language for certain industries, such as dental care, furniture and amusement parks[7]	☐	☑
Include a color symbol with a yellow triangle and an exclamation point on certain product or public entry signs[8]	☐	☑
Provide warnings in the same language or languages as any other label, labeling or sign accompanying a product[9]	☐	☑

These changes would require that all current warnings be replaced in a two-year time period beginning after adoption of the regulations.[10] OEHHA has acknowledged and subsequently confirmed in its "Initial Statement of Reasons" that businesses can choose to use the old safe harbor warnings for the two year delayed effective date period but would be required to have

[4] See Section 25602(a).

[5] See Section 25604(a)(2); all subsequent "Content" sections of Title 27 contain the same requirement.

[6] See Section 25205(b); current text states businesses "must provide the following information, when reasonably available, upon the lead agency's request.

[7] See Sections 25608.8 through 25608.27.

[8] See Sections 25604(a)(1), 25606(a)(1), 25608.11(a)(1), 25608.13(a)(2)(A), 25608.15(a)(1), 25608.17(a)(1), 25608.19(a)(1), 25608.21(a)(1), 25608.23(b), 25608.25(a)(1) and 25608.27(a)(1).

[9] See Sections 25603(d), 25605(a)(1) and (2)(C), 25608.1(b), 25608.3(b), 25608.5(b), 25608.18(b), 25608.20(b), 25608.22(b), and 25608.24(c).

[10] See Section 25600(a) & (b).

new signs by the end of those two years.[11] However, OEHHA provides a conflicting narrative later in its "Initial Statement of Reasons" when it states that "Subarticle 2 provides non-mandatory, safe harbor guidance..."[12] This claim is relatively unsubstantiated by the related regulatory text: "Nothing in this section shall be construed to preclude a person from providing a warning using content or methods other than those specified in this Article that nevertheless complies with Section 25249.6 of the Act."[13] These conflicting narratives, if left unaddressed, may lead to confusion in the business community and controversial litigation. We interpret the intention of this piece to be permissive on paper but mandatory in practice, as businesses that choose to treat Subarticle 2 as non-mandatory will be doing so without the guidance regarding what constitutes a "clear and reasonable" warning that OEHHA has elected to eliminate in its proposed regulation. We therefore interpret all parts of the proposed regulation as mandatory in our economic analysis.

Additionally, the requirement to include the name of any or all of the 12 identified chemicals when present above safe harbor levels also has significant potential impacts because of issues with competing test results and the potential for frequent additions to the list. OEHHA has responded in its "Initial Statement of Reasons" by stating that "the addition or removal of a listed chemical from this section will require the adoption of an amended regulation and can only occur after a formal regulatory process that includes a public notice, hearing and opportunity to comment."[14] These updates, regardless of whether they go through a formal regulatory process, will require many businesses to conduct yet a new round of testing to determine if their products and/or facilities contain that chemical at a level that would require specification in the warning.

[11] Initial Statement of Reasons, p. 5.
[12] Initial Statement of Reasons, p. 13.
[13] See Section 25601(a).
[14] Initial Statement of Reasons, p. 22.

Additionally, as noted in the CalChamber Coalition's April 8 comment letter on this aspect of the proposal, the following hypothetical illustrates a scenario that is likely to occur: a company whose product contains both a listed phthalate and lead determines that it should provide a warning for lead but that no exposure to the phthalate is occurring at a level requiring a warning. Thus, it provides a compliant Proposition 65 warning identifying lead only. Notwithstanding that compliant warning, that company may still be sued for failing to identify the phthalate, leaving the company to settle or engage in prolonged, expensive litigation.

Additionally, while a key goal of the regulation is to increase specificity, several key definitions are removed or omitted. The definition of "clear and reasonable" warnings, which is included in the current regulation, is absent from the proposed regulation. In addition, section 25600(d) states that "supplemental information may not contradict, dilute, or diminish the warning," however, it provides no guidance as to what this means and therefore leaves businesses vulnerable to attack when providing what is, in their opinion, lawful supplemental information.

3. Evaluating Costs of Regulations

Our second phase focused on determining cost drivers that impact the total amount businesses pay as a result of Proposition 65. We used this research to determine the current level of spending and to inform the design of our econometric model. Our research focused on litigation costs, compliance costs (which include testing and administration) and other factors (including reformulation and lost business).

Current Litigation Costs

The cost of litigation consistently remains the most cited cost of Proposition 65, driving the push for reform. Since adoption, we estimate that Proposition 65 litigation settlements have cost businesses over half a billion dollars. This total consists of the estimated settlement cost before 2000 of $325 million[15] and the recorded settlement cost since 2000 of $240 million. In fact, the Attorney General's 2013 Annual Summary of Proposition 65 Settlements noted that there were a total of 352 in-court settlements in 2013. Total payments associated with the 352 settlements amounted to $17,409,756. Of that total, only one-tenth went to the State of California, and the remainder went to the private enforcement community. Specifically, 11 percent went to OEHHA, 12 percent went indirectly to private-enforcer plaintiffs as a payment in lieu of penalty, 3.6 percent went directly to private-enforcer plaintiffs, and, remarkably, 74 percent went directly to the private enforcers' lawyers as attorneys' fees and costs.

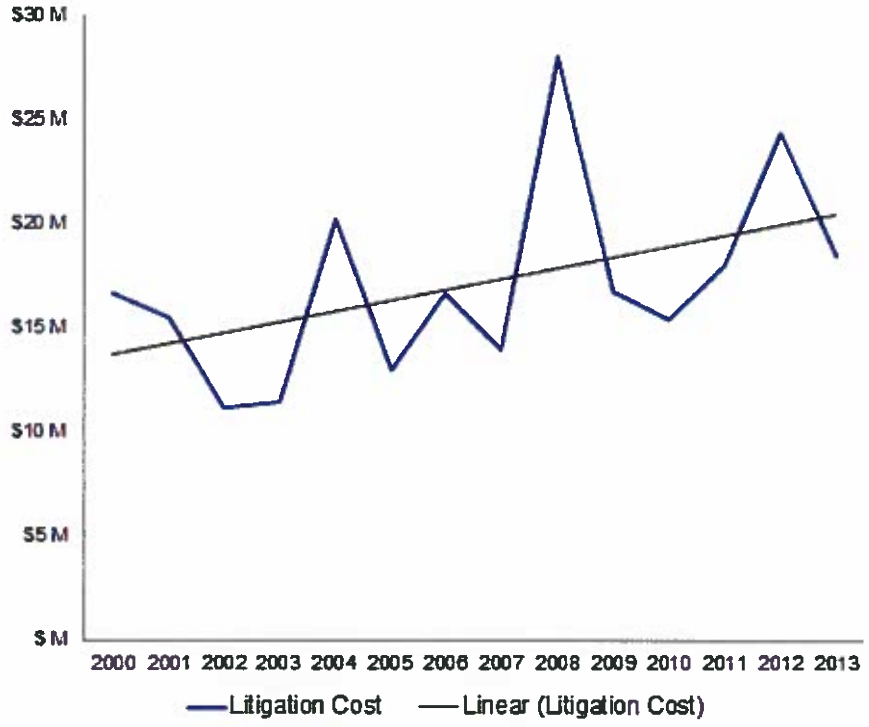
Our figure remains a conservative estimate, however, as recorded settlement costs only include the settlement fees, i.e. the civil penalty, the plaintiff attorney fee and other fees – which are often awarded to the plaintiff.[16] It does not include the very small number of cases that go to trial, or, more critically, the defense, consulting and testing costs associated with responding to

[15] House Committee on Small Business.
[16] Marlow, M.L., "Too Much (Questionable) Information?" Cato Institute, Winter 2013-2014, p. 28.

complaints, whether the case is settled, tried or dropped. These costs could conceivably be enough to more than double the cost of litigation.

Figure 1.1

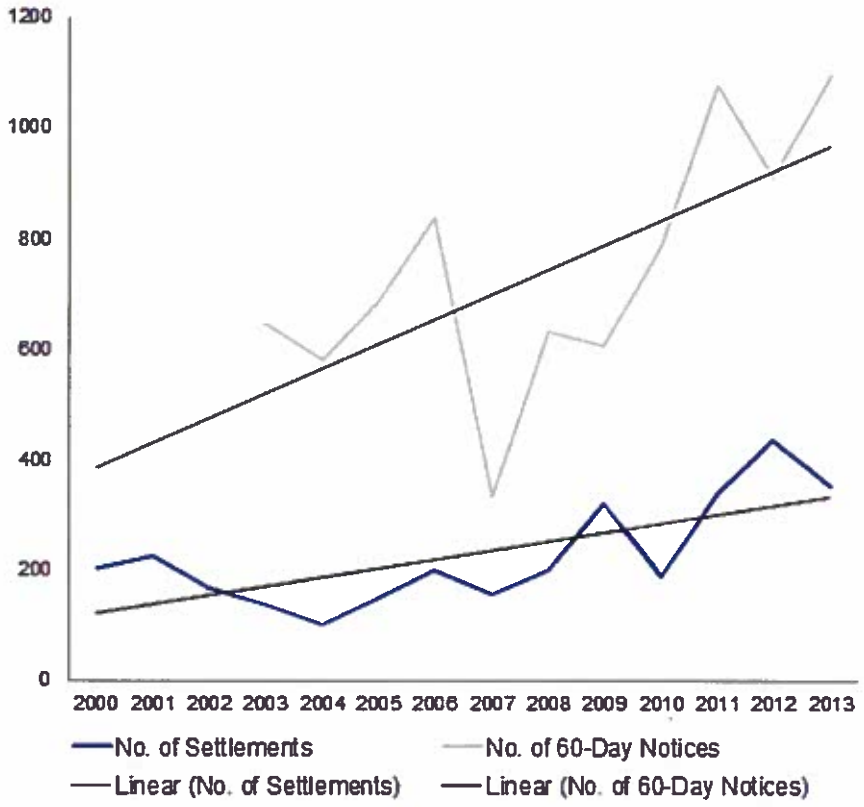
Settlement Costs by Year



An analysis of the OAG settlement data reveals the amount of litigation has grown consistently over time. The number of settlements has a 3.94 compounded annual growth rate (CAGR) with an even larger 4.89 CAGR increase in 60-Day Notices. (See Appendix A – Literature Review: Litigation Costs for a breakdown of annual settlements and payments).

Figure 1.2

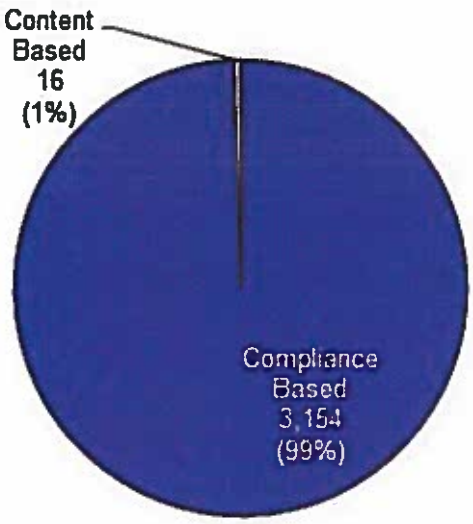
No. of 60-Day Notices and Settlements by Year



Over 99 percent of settlements since 2000 have resulted from compliance-based litigation, meaning a business failed to post a warning. The remainder has been content-based litigation, meaning a warning was in fact provided but was nonetheless challenged as not being "clear and reasonable." To calculate this number, we analyzed the listed injunctive relief for each settlement since 2000 to determine whether the settlement involved the lack of a warning or improper content of the warning. (See Appendix A – Literature Review: Content Based Litigation). As displayed in figure 1.3, businesses that post a warning face almost no fear of litigation under the current regulation.

Figure 1.3

Total Settlements Since 2000



The cost of litigation is by far the most recorded, analyzed and criticized cost of Proposition 65. Proposition 65 expressly incentivizes individual pursuits by entitling private enforcers to 25 percent of the penalty collected for a successful enforcement, in addition to legal fees and additional expenses incurred, which are separately available under California's "private attorney general law." This provision "offered a profit incentive for lawsuits to enforce the measure ... balanced against a very low risk."[17] While plaintiffs filing a 60-Day notice face a very low risk under current regulations, defendants receiving the notice face a much higher risk and "must prove that any exposure to a listed chemical is 1000 times lower than the 'no observable effect' level."[18]

Current Compliance Costs

In today's climate, the vast majority of litigation or threatened litigation involves challenges to a business's decision not to provide a warning. Before they post a warning, however,

[17] Caso, A.T., "Bounty Hunters and the Public Interest: A Study of California Proposition 65." *Engage*, Vol. 13, No. 1. March 2012, p. 31.

[18] Caso, p. 31.

businesses are expected to take steps to determine whether or not a warning is required to comply with Proposition 65. These costs receive less attention than the cost of litigation, but nonetheless appear to be significant. No data currently exists on compliance costs, or even the rate of compliance. As it pertains to compliance more generally, OEHHA itself has noted that "[d]etermining anticipated levels of exposure to listed chemicals can be very complex."[19] As noted by the Cato Institute with respect to costs, "[a]ssessing the costs of Proposition 65 is a complex task because no one compliance strategy works for all businesses. Business owners must determine whether to post warning labels, stop production, reformulate, and/or ignore Proposition 65. Choosing the appropriate course of action involves many complex questions that involve research, legal costs, and tastes for risk."[20] Research from a prominent law firm further concluded that "[v]ery few businesses have this information or conduct tests of every product they sell, and developing this type of information could be extremely costly."[21]

Little evidence exists to estimate the cost of testing and the cost of relabeling due to Proposition 65. Our research found only two estimates, provided by small business owners in testimony before Congress, spending an average of $312 and $445 per unit on testing and relabeling as a result of Proposition 65.[22] While our research did produce the number of firms and establishments subject to Proposition 65 (those with ten or more employees), there is no data on the number of firms with warnings, the number of firms who have conducted tests or the average costs of compliance including testing, consulting and purchasing and installing the proper warning.

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[19] http://www.oehha.org/prop65/p65faq.html

[20] Marlow, pp. 26-27.

[21] Feeley, M., et. al. "Proposition 65 'Reform': Consumer Protection Stimulation?" Latham & Watkins, No. 1677. April 2014, p. 3.

[22] House Committee on Small Business. Totals as found in the transcript were adjusted for inflation and divided by the number of products as found in the transcript to provide an average price per label change.

As a proxy for this data, we reviewed research on compliance rates of other California environmental, health and safety laws. A 2008 National Resource Defense Council (NRDC) report tracked compliance rates of businesses and organizations under six of California's critical environmental, health and safety laws: water pollution; hazardous waste management; drinking water; air pollution; agricultural pesticide use; and workplace safety and health. This research reported the proportion of compliant and non-compliant businesses in each program. Our approach selected the median of the six rates (87 percent) as a baseline for Proposition 65 current compliance rates. We feel this is a strong estimate because all of the environmental regulations included achieved compliance rates within a relatively narrow band, ranging from 81 percent to 95 percent.

Table 1.1

Compliance Rates

California Regulatory Program	Proportion of Identified Violations (Non Compliance Rate)	High Range of Non Compliance Rate	Low Range of Non Compliance Rate	Statewide Average Compliance Rate
Water Pollution	8%	36%	12%	92%
Hazardous Waste Management	5%	N/A	N/A	95%
Drinking Water	11%	62%	0%	89%
Air Pollution	15%	67%	0%	85%
Agricultural Pesticide Use	19%	76%	0%	81%
Workplace Safety and Health	55%	76%	14%	45%

Compliance Cost Drivers

To inform the development of our model, our analysis of the proposed regulation suggests five key cost components:

- Administration – includes the cost of new warnings and the labor for installation for all current facility and products signs
- Testing – includes the cost of additional tests necessary to comply with the new regulation
- Litigation – includes the potential change in the amount of compliance litigation, driven by any change in compliance rates and content litigation, due to additional requirements and decreased specificity in the proposed regulation
- Reformulation – includes the cost of reformulating products to remove listed toxins
- Lost Business – includes the cost to business resulting from either increased cost to the consumer or loss of consumer faith resulting from new warning s

In order to ensure a conservative approach, we only account for Administration, Testing and Litigation costs.

To determine potential administration costs, we reviewed three providers of Proposition 65 signs and recorded their price range and variable factors of cost. We then estimated a low and a high range of labor cost for research and installation. See Table 1.2 below for more details.

Table 1.2

Cost of Warnings

Source	Methodology	Key Findings
http://www.compliancesigns.com/Chem-Bio-CA-PROP-65-Area.shtml	▪ Analyzed all signs sold from source ▪ Limited results to signs that were at least 5"x5" in size ▪ Recorded the highest and lowest price range found ▪ Noted variations in size and material that might drive differences in price	▪ Range of $13.00 to $62.00 per sign ▪ Size variations included 10"x10", 15"x15", 24"x24" and 30"x30" ▪ Material variations included brass, aluminum and vinyl
http://www.mysafetysign.com/prop-65-signs?engine=adwords&keyword=sign+proposition+65&gclid=COC6hNiHycMCFVKPfgod6AIAuw	▪ Analyzed all signs sold from source ▪ Limited results to signs that were at least 5"x5" in size ▪ Recorded the highest and lowest price range found ▪ Noted variations in size and material that might drive differences in price	▪ Range of $5.85 to $28.45 per sign ▪ Size variations included 5"x5", 5"x7", 7"x10", 10"x10", 10"x14" and 12"x18"
http://www.safetysign.com/california-prop-65-signs?atrkid=V1ADW389C9EEA-6525904740-k-proposition%2065%20warning%20sign-33587378700-p-g-m-1o1&gclid=CL6R5taHycMCFYhbfgodvSUAXw	▪ Analyzed all signs sold from source ▪ Limited results to signs that were at least 5"x5" in size ▪ Recorded the highest and lowest price range found ▪ Noted variations in size and material that might drive differences in price	▪ Range of $10.95 to $22.00 per sign ▪ Size variations included 5"x5" and 10"x10" ▪ Material variations included plastic, aluminum and vinyl

Our next step was to estimate potential relabeling costs. We conducted a review of national and international academic, private and government literature. Our review suggested a broad range of potential costs and is detailed in table 1.3.

Table 1.3

Cost of Changing Labels

Study	Scope	Key Findings
Chapoupka, F.J., et. al. "An evaluation of the FDA's analysis of the costs and benefits of the graphic warning label regulation." *BMJ*, December 2014.	▪ Analyzes FDA's 2009 economic impact analysis of requiring graphic warning labels (GWLs) on cigarette packaging	▪ Combined costs between $319.5 and $518.4 million for one-time fixed costs of implementing the new labels and $6.6 to $7.1 million in annual implementation and enforcement
"Cost Schedule for Food Labelling Changes." *PricewaterhouseCoopers (PwC)*, April 2014.	▪ Prepared for the Australian Department of Health, the report estimates the costs incurred by food companies to changing food and beverage labelling as a result of regulatory and non-regulatory changes	▪ Cost per stock-keeping unit between $821 AUD ($642) and $12,295 AUD ($9,616)
"Developing a Framework for Assessing the Costs of Labelling Changes in the UK." *Campden Technology Ltd*, May 2010.	▪ In-depth investigation of direct and indirect costs associated with changing labels on a wide range of food and drink types	▪ Cost per stock-keeping unit between 265 Euros ($302) and 12,000 Euros ($13,684) per single label change
"Economic Evaluation of Health Canada's Proposal to Amend the Tobacco Product Information Regulations." *Industrial Economics, Inc.*, December 2009.	▪ Analysis of the potential effects of new proposed regulations of tobacco products and labels	▪ Cost per label change between $9.3 million and $10.7 million per year
"Modification of the Hazard Communication Standard (HCS) to conform with the United Nations' (UN) Globally Harmonized System of Classification and Labeling of Chemicals (GHS): Questions and Answers." *Occupational Safety and Health Administration*, Last Accessed February 2015.	▪ Overview of key features in the United State's adoption of the United Nation's hazard communication system Globally Harmonized System of Classifications and Labeling of Chemicals (GHS)	▪ Classifying chemical hazards in accordance with the GHS criteria and revising safety data sheets and labels will cost $22.5 million a year
"Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products." *Federal Register*, November 2013.	▪ Analyzes proposed regulation by the Food and Drug Administration to change labeling content and approval process	▪ The net annual social cost for changing labels for drug labels will cost between $4,237 and $25,852 ▪ Over 20 years the net present value will be from $63,000 to $384,6000 at a three percent discount rate and from $44.9 thousand to $273.9 thousand at a seven percent discount rate

While the proposed regulation does not explicitly require additional testing, fulfilling its requirements would implicitly require new and/or additional testing. Under the current regulation, businesses are required to provide a warning if there is an exposure to any listed chemical above certain levels. Once a business has determined that a warning is necessary, either from testing or other means, no additional testing is necessary. Under the new regulation, which requires specific chemicals to be listed if they exist at levels requiring a warning, businesses

would need specific tests for any pertinent chemicals rather than providing a more generic warning that does not specify particular chemicals.

To determine testing costs, we reviewed comparative testing prices from the REACH Programs implemented by the European Union (EU) and China and an analysis from the Environmental Protection Agency concerning testing data for high production volume (HPV) chemicals (see Table 1.4 below). This review produced an incredibly wide range of potential costs due to the complexity of testing and the many separate costs it may involve. By way of example, any given test includes: selecting the specific item to be tested; the specific chemical to be tested for; hiring a consultant to assess the test results; selecting the most accurate exposure scenario; creating appropriate models to assess exposure levels regarding particular item and chemical; comparing exposure levels to OEHHA exposure levels and their exposure models; and determining whether or not a sign is needed. The intricacy of this process makes estimating a specific testing cost per business challenging, however, the wide range discovered speaks to the often costly choices businesses face when choosing if and how to conduct various tests.

Table 1.4

Cost of Testing

Study	Scope	Key Findings
Fleischer, M., "Testing Costs and Testing Capacity According to the REACH Requirements." *Journal of Business Chemistry*, Vol. 4, Issue 3, September 2007.	▪ Analyzes the prices for laboratory testing services and testing capacity in nine major European countries ▪ Data gathered through survey of 28 independent and corporate laboratories in the second half of 2004	▪ Minimum and maximum price was found to be 800 Euros ($912) to 80,000 Euros ($91,224) for any one test per chemical
"HPV Chemical Hazard Data Availability." *Environmental Protection Agency*, April 1998, Updated August 2010.	▪ EPA analysis of the 3,000 plus high production volume (HPV) chemicals that the US imports or produces	▪ The basic set of test data costs roughly $200,000 per chemical
"New Chemical Substance Notification in China – China REACH." *Chemical Inspection & Regulation Service*, April 2014.	▪ High-level overview of China's REACH program, implemented on January 19, 2010 and similar to EU REACH	▪ Testing fee accounts for "a large portion of the total costs" and typically costs several hundred thousand RMB to obtain a full set of data (at least $32,000)

While this review provided a wide range of potential prices, there remained several uncertainties, including:

- What portion of businesses has already completed testing of some kind?
- What portion would have to conduct more testing?
- What types of testing would be necessary?
- How many of those tests would each business conduct to achieve compliance?

In addition to administration and testing, our literature review suggested that compliant businesses may still face increased litigation as a result of proposed changes to Proposition 65, as the enforcement community could accuse businesses of failing to identify any one of the 12 specific chemicals identified by OEHHA, even though the businesses' testing concluded that specification of the chemical was not required.[23]

Within our model, we assume that the average cost of both compliance and content litigation settlements will equal the inflation-adjusted average cost of settlements to date. In order to estimate additional defense fees, we assume defense fees equal plaintiff fees. While the high cost of attorney fees are controversial, defense fees are estimated to be as high or higher due to the burden of proof and the need for expert testimony and testing. We assume settlements will increase by the annual rate of growth recorded since 2000.

Summary of Costs

In accounting for the cost of the current and proposed regulations, our analysis produced the following:

- Detailed number and cost of settlements since 2000
- Recorded and expected growth of number and cost of settlements
- High portion of attorney fees within settlements

[23] Feeley, p. 4.

- Number of businesses and establishments with ten or more employees
- Estimated compliance rate of businesses currently
- Estimated cost range per business for Administration costs due to new regulations
- Estimated cost range per business for Testing costs due to new regulations
- Estimated cost per content based settlement due to new regulations

However, significant uncertainties remained in our analysis:

- The risk of content-based litigation
- The number of businesses in need of tests
- The number of tests needed per business

We mitigated the uncertainties by using a scenario based analysis of driving factors.

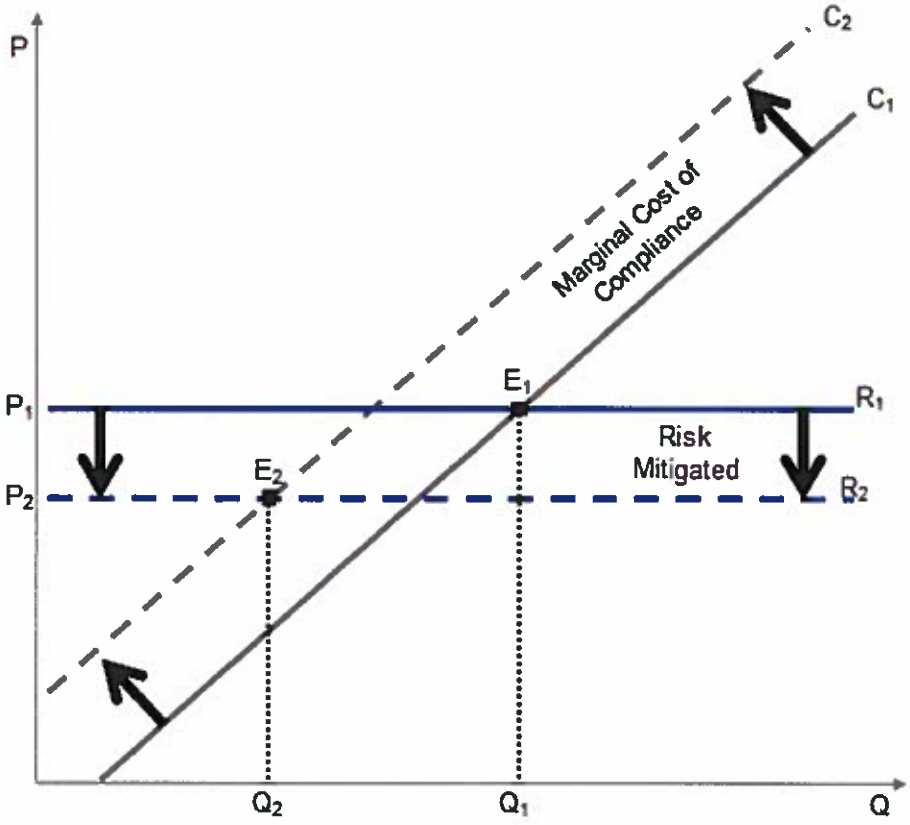
4. Modeling Methodology

In order to account for the various uncertainties, our model assumed a current equilibrium between the cost of compliance and the corresponding amount of risk mitigated. The approach is based on standard economic theory, assuming that businesses are rational actors that will spend as much as is needed on compliance, so long as it is less than the cost of non-compliance. In this case, the cost of compliance includes testing and administration, while the amount of risk mitigated is equal to the average defense and settlement spending per non-compliant business (99 percent of settlements) minus the average defense and settlement spending per compliant business (one percent of settlements). Because the great majority of businesses are compliant and compliant businesses face virtually no threat of lawsuit, under current law, compliance mitigates a large amount of risk.

This concept is represented in figure 1.4 where the current marginal cost of compliance (C1 curve) intersects with the current risk mitigated (R1 curve) at the intersection point (E1). Our comparative analysis of the current and proposed regulations as well as the review of current literature suggests that changes to Article 6 will increase the cost of compliance (C2 curve) due to additional testing costs and decrease the risk mitigated (R2 curve) due to increased risk of content lawsuits faced by compliant businesses, thus leading to a lower equilibrium (intersection point E2) and a fewer number of compliant businesses.

Figure 1.4

Illustrative Graph of Model



With this approach, we utilized the research gathered to construct an econometric model to estimate the potential costs of proposed changes (see Figure 1.5 below). We focus on two primary impacts from the proposed regulation: the increased risk of content litigation and the need for additional testing due to the requirement to include any of the 12 chemicals identified by OEHHA.

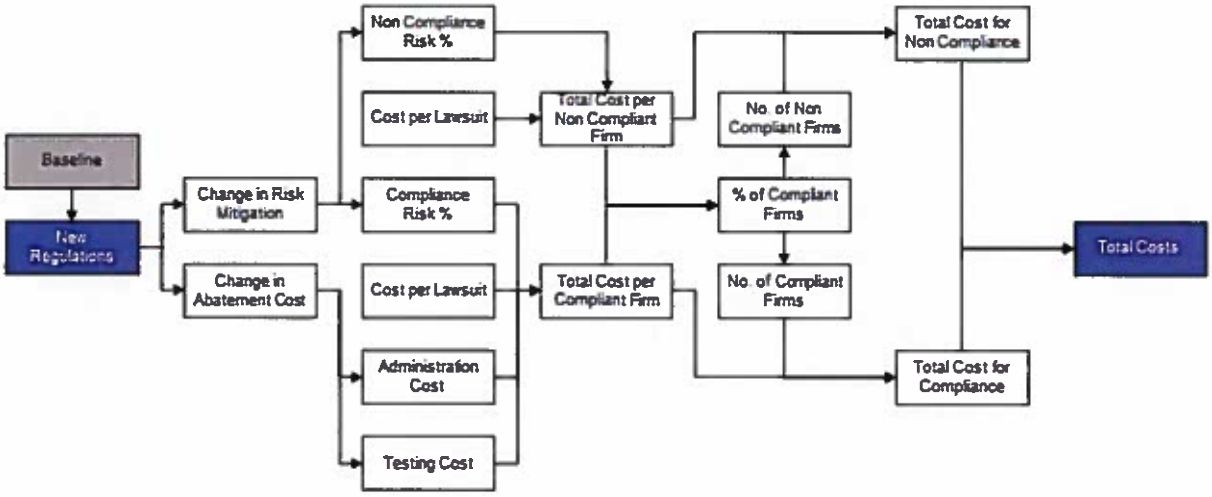
The first several steps are used to estimate the cost for compliant and non-compliant firms. The average cost for compliant firms is more complicated, as it includes both the cost of compliance and the risk of content lawsuits they face, despite their investment in testing and warnings. The average cost of compliant firms is equal to their spending on testing and administration plus the product of their risk of a content lawsuit and the average cost per

lawsuit. The average cost for non-compliant firms is much simpler, since they do not spend on administration or testing; only facing the risk of compliance lawsuits. The average cost of non-compliant firms is the product of the risk of compliance suit and the average cost per lawsuit.

Based on these estimates, the model calculates an equilibrium percentage of firms that will have the financial incentive to comply. It then applies the average cost for each type of firm calculates the total cost in the scenario. We estimated costs in the baseline (current law) scenario and three alternative scenarios, representing a range of plausible costs.

Figure 1.5

Model Flowchart

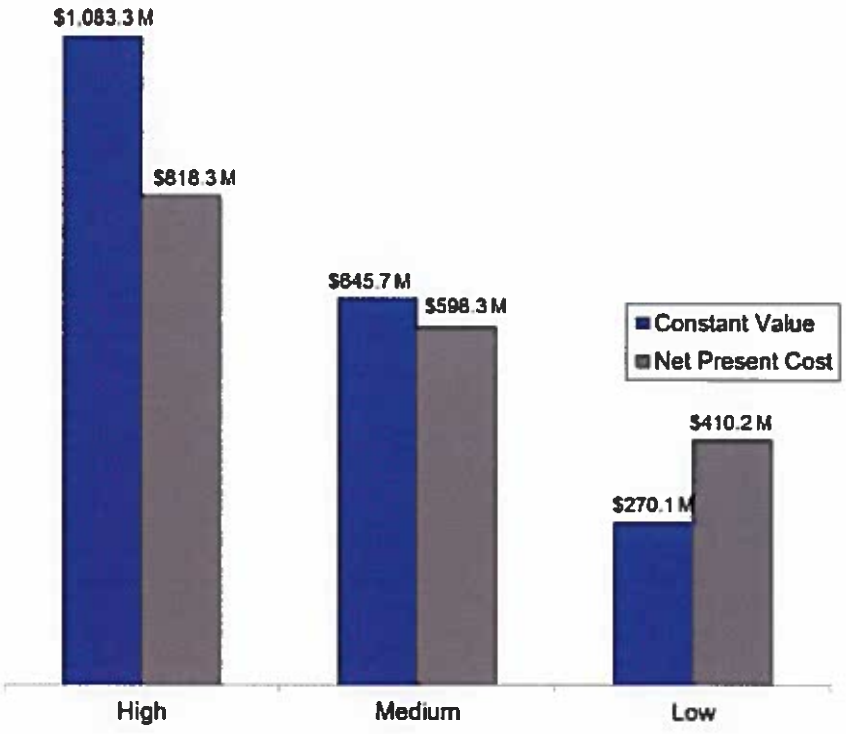


5. Findings

Our findings are based on a baseline (current law) scenario and three alternative scenarios, modeling a range of potential assumed increases in testing and content lawsuits. These scenarios are detailed below.

These scenarios show that the proposed changes to Proposition 65 could cost businesses between $270 million and $1.1 billion (constant value). Using a five percent discount rate we estimate these costs are between $410 million and $818 million net present costs.

Figure 5.0
Total Increased Costs



The relationship between constant value and net present cost impacts may appear counterintuitive, because net present costs typically are lower than constant value costs. Our model calculates that all scenarios will face significant up-front costs for testing and

administration due to new compliance requirements. In many cases, however, these compliance costs are not "new" costs but instead are moving forward costs that the businesses would need to spend later to maintain compliance. As a result, compliant firms save money on compliance in subsequent years. In all cases, however, litigation appears likely to increase.

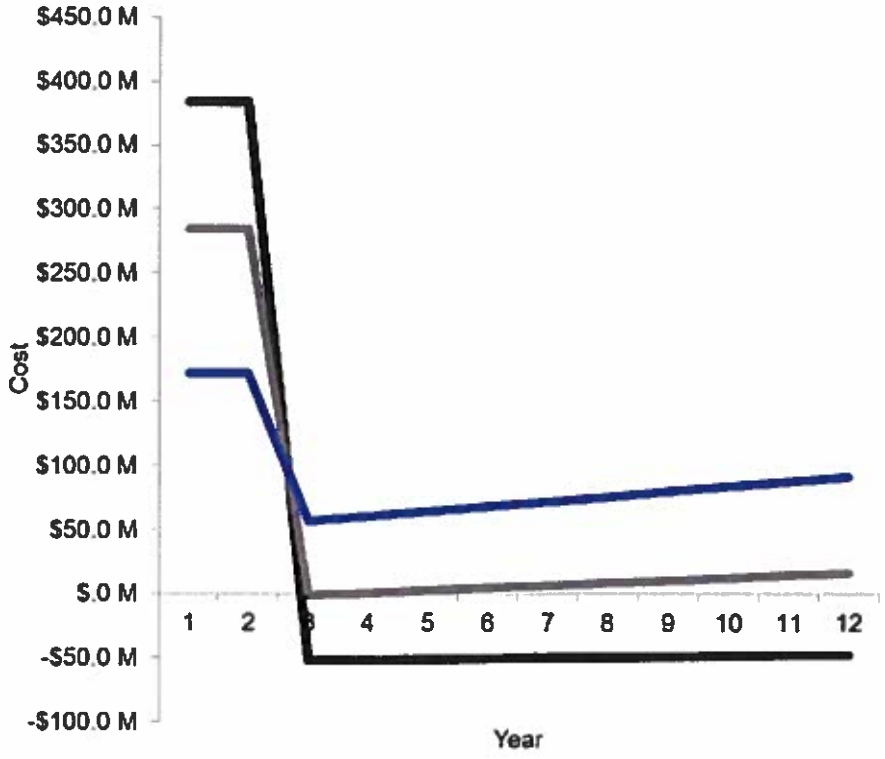
Our low estimate assumes a small increase in testing costs (estimated average of 0.5 additional tests needed) but no changes in content lawsuits (equal to current risk of 0.0007 percent). This leads to modestly lower compliance rates but substantial up-front costs to comply with the new regulations. Additionally, there is a small increase in litigation but this is offset by annual savings due to compliance costs that were paid up front.

Our medium estimate assumes a moderate increase in testing costs (estimated average of 1.0 additional tests needed) and increased risk of content lawsuits (estimated 0.053 percent risk, half of the high estimate). This leads to moderately lower compliance rates, decreasing the number of businesses that pay up-front compliance costs but increasing ongoing litigation.

Our high estimate assumes a large increase in testing costs (estimated average of 2.0 additional tests needed) and substantial risk of content lawsuits (estimated 0.107 percent risk, this estimate would yield two-thirds as many content lawsuits as there are currently compliance lawsuits, holding compliance rate constant). This scenario yields much lower compliance rates, decreasing the number of businesses that pay up-front compliance costs but substantially increasing ongoing litigation.

Figure 1.6

Annual Total Cost



This range of results is driven by two varying inputs: the risk of content litigation and the average number of additional tests needed. As seen below in Table 1.5, we assume a range of inputs for each of these inputs to determine a range of possible outcomes. We consider all estimates of these two inputs holistically conservative for three reasons:

- Our high estimate of content litigation risk (0.11 percent) is roughly one fifth of current compliance litigation risk (0.55 percent)[24]
- Our high estimate for the average number of additional tests needed per firm (2.0) would only cover one sixth of the tests needed to assure whether or not all 12 of the identified chemicals were present above the safe harbor levels

[24] Non-compliance risk of litigation is calculated by dividing the number of non-compliance litigation by the number of non-compliant businesses. For the number of non-compliant businesses see Table 1.1.

- All estimates of our testing costs assume the lowest cost per test found in the research ($912 per test)

Table 1.5

Components of Total Cost

Model Components	Baseline Estimate	High Estimate	Mid-Estimate	Low Estimate
Assumption – Risk of Content Litigation	Baseline	High risk of content lawsuits – 0.11%	Moderate risk – 0.05%	Low risk – 0.0007%
Assumption – No. of Additional Tests	Baseline	2 tests per firm	1 test per firm	0.5 tests per firm
Assumption – Administration Costs	Spread evenly over 10 yeas	Lump sum over 2 years	Lump sum over 2 years	Lump sum over 2 years
Compliance Rate	87%	45%	66%	81%
Cost of Abatement	$459.9 M	$335.6 M	$554.4 M	$748.2 M
Cost of Content Litigation	$2.4 M	$145.6 M	$107.8 M	$2.0 M
Cost of Non-Compliance Litigation	$244.7 M	$1,044.2 M	$643.3 M	$367.1 M
Cost of Regulations	NA	$818.3 M	$598.3 M	$410.2 M
Total	$707.1 M	$1,525.4 M	$1,305.3 M	$1,117.3 M

As Table 1.5 reveals, the risk of content litigation and average number of additional tests needed has an inverse relationship with the compliance rate. As the compliance rate drops, the total cost of abatement decreases but litigation costs increase significantly. For annual estimates see Table 1.6 below.

Table 1.6

Annual Costs

Scenario	Year											
	1	2	3	4	5	6	7	8	9	10	11	12
Baseline (Total)	$0.0 M	$0.0 M	$100.2 M	$101.4 M	$102.5 M	$103.7 M	$104.9 M	$106.1 M	$107.2 M	$108.4 M	$109.6 M	$110.7 M
Baseline (Net Present)	$0.0 M	$0.0 M	$90.2 M	$86.2 M	$82.0 M	$77.8 M	$73.4 M	$68.9 M	$64.3 M	$59.6 M	$54.8 M	$49.8 M
Low (Total)	$383.7 M	$383.7 M	$47.9 M	$49.6 M	$51.4 M	$53.1 M	$54.9 M	$56.6 M	$58.4 M	$60.1 M	$61.8 M	$63.6 M
Low (Net Present)	$383.7 M	$364.5 M	$43.1 M	$42.2 M	$41.1 M	$39.8 M	$38.4 M	$36.8 M	$35.0 M	$33.1 M	$30.9 M	$28.6 M
Medium (Total)	$284.3 M	$284.3 M	$99.0 M	$102.1 M	$105.3 M	$108.4 M	$111.6 M	$114.8 M	$117.9 M	$121.1 M	$124.2 M	$127.4 M
Medium (Net Present)	$284.3 M	$270.1 M	$89.1 M	$86.8 M	$84.2 M	$81.3 M	$78.1 M	$74.6 M	$70.7 M	$66.6 M	$62.1 M	$57.3 M
High (Total)	$172.1 M	$172.1 M	$156.5 M	$161.5 M	$166.6 M	$171.7 M	$176.8 M	$181.9 M	$187.0 M	$192.1 M	$197.2 M	$202.3 M
High (Net Present)	$172.1 M	$163.5 M	$140.8 M	$137.3 M	$133.3 M	$128.8 M	$123.8 M	$118.3 M	$112.2 M	$105.7 M	$98.6 M	$91.0 M

6. Conclusion

Changes to Proposition 65 could cost businesses from $410 million to $818 million in the first ten years. The highest cost would be the result of up-front compliance costs, ranging from $336 million to $748 million. Ongoing litigation costs would increase in all scenarios, due to a lower compliance rate because of the higher cost of compliance and the potential for increased risk of content lawsuits.

While some uncertainties remain, our scenario-based economic model highlights the potential cost these regulations could incur, based on conservative cost estimates. In all scenarios, the results run counter to OEHHA's one-page analysis, which concluded there would be no economic impact whatsoever. The potential for high costs and the outlined uncertainties speak to the need for greater research and discussion regarding any changes to Proposition 65 and Article 6.

Appendix A: Literature Review

Proposition 65

Study	Scope	Key Findings
Caso, A.T., "Bounty Hunters and the Public Interest: A Study of California Proposition 65." *Engage*, Vol. 13, No. 1. March 2012.	▪ Analyzes the history of Proposition 65 and the bounty hunter litigation since 1986 ▪ Utilizes settlement summaries from the Office of the Attorney General	▪ The bounty hunter provision offered in Proposition 65 is off-balance against a very low risk ▪ In order to prevail against a failure-to-warn charge, business owners must prove that exposure to a listed chemical is 1000 times lower than the "no observable effect" level ▪ The majority of fees paid in settlements go to attorney fees ▪ No analysis has been made of the types of challenges made by plaintiffs or the value those charges added to public health
Feeley, M., et. al. "Proposition 65 'Reform': Consumer Protection Stimulation?" *Latham & Watkins*, No. 1677. April 2014.	▪ Analyzes the proposed changes to Article 6 regulations	▪ Very few businesses have testing data or conduct tests of every product they sell as such data is very costly to acquire ▪ Requirement to include the 12 chemicals identified by OEHHA exposes businesses to substantial new litigation risks and additional testing costs
House Committee on Small Business, Hearing On Proposition 65's Effect On Small Business, HR Rep. No. 106-38 at 43 (October 28, 1999), available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=106_house_hearings&docid=f:61647.pdf.	▪ Transcript of Committee meeting and testimony	▪ Estimated litigation costs for Proposition 65 from its beginning to 1999 are estimated at over $325 million ▪ The burden of proof for these lawsuits have fallen on the accused rather than the plaintiff ▪ All small business testimony support Proposition 65 but oppose the hostile "bounty hunter" litigation that has met them since
Marlow, M.L., "Too Much (Questionable) Information?" *Cato Institute*, Winter 2013-2014, pp. 20-28.	▪ Analyzes cancer statistics collected by the Surveillance, Epidemiology, and End Results (SEER) Program of the National Cancer Institute since 1973 ▪ Focus specifically on data from San Francisco-Oakland area and control groups Seattle-Puget Sound registry, Atlanta and Detroit	▪ Little evidence indicated that Proposition 65 exerted a positive and statistically significant effect on cancer incidence gaps for all sexes ▪ Study supported by previous research that found explicit warnings do not clearly alter purchases or consumption ▪ Proposition 65 may incentivize firms to wait for other firms to test products in order to "free-ride" on those benefits without incurring costs ▪ Settlement costs potentially significantly underestimate total cost as they do not include legal and expert witness costs of defendants or court costs for cases that went to trial ▪ To date, few studies address the efficacy of Proposition 65 ▪ To date there have been no comprehensive studies of the frequency of reformulations or whether public health has improved as a result of the law
Sanford, A. & Walsh, WJ. "California Proposition 65: Confusion, Disbelief and Unanticipated Costs." *Pepper Hamilton LLP*. March 2008	▪ Analyzes Proposition 65 and its complications and costly litigation	▪ The science behind litigation is referred to as "outright junk science" at times yet defendants are forced to prove their innocence ▪ Settlement costs do not include "untold millions spent to defend these lawsuits, to implement product changes and to recall products, as well as lost sales, and loss of goodwill" ▪ There is no clear set of tests or requirements to determine compliance

Administration Costs: New Signs

Source	Methodology	Key Findings
http://www.compliancesigns.com/Chem-Bio-CA-PROP-65-Area.shtml	▪ Analyzed all signs sold from source ▪ Limited results to signs that were at least 5"x5" in size ▪ Recorded the highest and lowest price range found ▪ Noted variations in size and material that might drive differences in price	▪ Range of $13.00 to $62.00 per sign ▪ Size variations included 10"x10", 15"x15", 24"x24" and 30"x30" ▪ Material variations included brass, aluminum and vinyl
http://www.mysafetysign.com/prop-65-signs?engine=adwords&keyword=sign+proposition+65&gclid=COC6hNiHycMCFVKPfgod6AlAuw	▪ Analyzed all signs sold from source ▪ Limited results to signs that were at least 5"x5" in size ▪ Recorded the highest and lowest price range found ▪ Noted variations in size and material that might drive differences in price	▪ Range of $5.85 to $28.45 per sign ▪ Size variations included 5"x5", 5"x7", 7"x10", 10"x10", 10"x14" and 12"x18"
http://www.safetysign.com/california-prop-65-signs?atrkid=V1ADW389C9EEA-6525904740-k-proposition%2065%20warning%20sign-33587378700-p-g-m-1o1&gclid=CL6R5taHycMCFYhbfgodvSUAXw	▪ Analyzed all signs sold from source ▪ Limited results to signs that were at least 5"x5" in size ▪ Recorded the highest and lowest price range found ▪ Noted variations in size and material that might drive differences in price	▪ Range of $10.95 to $22.00 per sign ▪ Size variations included 5"x5" and 10"x10" ▪ Material variations included plastic, aluminum and vinyl

Administration Costs – Cost of Changing Labels

Study	Scope	Key Findings
Chapoupka, F.J., et. al. "An evaluation of the FDA's analysis of the costs and benefits of the graphic warning label regulation." *BMJ*, December 2014.	▪ Analyzes FDA's 2009 economic impact analysis of requiring graphic warning labels (GWLs) on cigarette packaging ▪ Specifically examines the FDA's estimated cost benefit analysis of GWLs	▪ FDA's report substantially underestimated the benefits and overestimated the cost ▪ Final new estimates of combined costs ranged from $319.5 to $518.4 million for one-time fixed costs of implementing the new labels and $6.6 to $7.1 million in annual implementation and enforcement
"Cost Schedule for Food Labelling Changes." *PricewaterhouseCoopers (PwC)*, April 2014.	▪ Prepared for the Australian Department of Health, the report estimates the costs incurred by food companies to changing food and beverage labelling as a result of regulatory and non-regulatory changes	▪ Cost per stock-keeping unit between $821 AUD ($642) and $12,295 AUD ($9,616) ▪ Factors include severity of change required and the type of product
"Developing a Framework for Assessing the Costs of Labelling Changes in the UK." *Campden Technology Ltd*, May 2010.	▪ The Department for Environment, Food and Rural Affairs commissioned Campden BRI to carry out an in-depth investigation of direct and indirect costs associated with different aspects of changing labels on a wide range of food and drink types	▪ Cost per stock-keeping unit between 265 Euros ($302) and 12,000 Euros ($13,684) per single label change ▪ Average total cost of 3,260 Euros ($3,718) per single stock keeping unit for a single label change
"Economic Evaluation of Health Canada's Proposal to Amend the Tobacco Product Information Regulations." *Industrial Economics, Inc.*, December 2009.	▪ Analysis of the potential effects of new proposed regulations of tobacco products and labels	▪ Changing labels on tobacco products will cost between $9.3 million and $10.7 million per year ▪ Over ten years the net present value will be between $62.4 million and $71.7 million at an eight percent discount rate
"Modification of the Hazard Communication Standard (HCS) to conform with the United Nations' (UN) Globally Harmonized System of Classification and Labeling of Chemicals (GHS): Questions and Answers." *Occupational Safety and Health Administration*, Last Accessed February 2015.	▪ Overview of key features in the United State's adoption of the United Nation's hazard communication system Globally Harmonized System of Classifications and Labeling of Chemicals (GHS)	▪ Classifying chemical hazards in accordance with the GHS criteria and revising safety data sheets and labels will cost $22.5 million a year
"Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products." *Federal Register*, November 2013.	▪ Analyzes proposed regulation by the Food and Drug Administration to change labeling content and approval process	▪ The net annual social cost for changing labels for drug labels will cost between $4,237 and $25,852 ▪ Over 20 years the net present value will be from $63,000 to $384,6000 at a three percent discount rate and from $44.9 thousand to $273.9 thousand at a seven percent discount rate
U.S. Congress, Office of Technology Assessment, *A New Technological Era for American Agriculture, OTA-F474* (Washington, DC: U.S. Government Printing Office, August 1992).	▪ Analyzes advancing technologies for agriculture and their potential impacts on production, agribusiness, management, food quality and environmental safety	▪ Implementing a label change can be expensive for the food industry, including administrative, analytical, marketing, printing, inventory and product reformulation costs

Testing Costs

Study	Scope	Key Findings
Fleischer, M., "Testing Costs and Testing Capacity According to the REACH Requirements." *Journal of Business Chemistry*, Vol. 4, Issue 3, September 2007.	• Analyzes the prices for laboratory testing services and testing capacity in nine major European countries • Data gathered through survey of 28 independent and corporate laboratories in the second half of 2004	• Minimum and maximum price was found to be 800 Euros ($912) to 80,000 Euros ($91,224) for any one test per chemical
"HPV Chemical Hazard Data Availability." *Environmental Protection Agency*, April 1998, Updated August 2010.	• EPA analysis of the 3,000 plus high production volume (HPV) chemicals that the US imports or produces	• 43% of HPVs have no testing data on basic toxicity and only seven percent have a full set of basic test data • The basic set of test data costs about $200,000 per chemical
"New Chemical Substance Notification in China – China REACH." *Chemical Inspection & Regulation Service*, April 2014.	• High-level overview of China's REACH program, implemented on January 19, 2010 and similar to EU REACH	• Testing fee accounts for "a large portion of the total costs" and typically costs several hundred thousand RMB to obtain a full set of data (at least $32,000)

Compliance Rates

California Regulatory Program	Proportion of Identified Violations (Non Compliance Rate)	High Range of Non Compliance Rate	Low Range of Non Compliance Rate	Statewide Average Compliance Rate
Water Pollution	8%	36%	12%	92%
Hazardous Waste Management	5%	N/A	N/A	95%
Drinking Water	11%	62%	0%	89%
Air Pollution	15%	67%	0%	85%
Agricultural Pesticide Use	19%	76%	0%	81%
Workplace Safety and Health	55%	76%	14%	45%

Notes

- Source: Wall, M.E., Rotkin-Ellman, M, and Soloman, G. "An Uneven Shield: The Record of Enforcement and Violations Under California's Environmental, Health, and Workplace Safety Laws." *NRDC Report*, October 2008.
- This report tracked compliance rates of businesses and organizations under six of California's critical environmental, health and workplace safety laws over a multi-year period
- The data above includes the statewide averages of violations (non-compliance rate) and the high and low range of violations on a local or county level. The compliance rate is found by subtracting the non-compliance rate from one
- This research is the most analogous with Proposition 65, as it includes similar laws within California and tracks business and organizations' compliance with the law. OEHHA does not track compliance rates and no Proposition 65 specific data exists on the topic
- Our method assumes an 87 percent compliance rate as it is the median of the reported compliance rates. The median is preferable and more conservative than the average, as Workplace Safety and Health seems an outlier and would skew the utilized compliance rate

Litigation Costs

Year	No. of 60-Day Notices	No. of Settlements	Total Payments	Civil Penalties	Percent of Total	Attorney Fees	Percent of Total	Other	Percent of Total
2013	1,094	352	$16,635,063	$1,287,176	7.74%	$10,830,483	65.11%	$4,517,433	27.16%
2012	911	437	$15,521,847	$1,154,983	7.44%	$8,746,832	56.35%	$5,620,032	36.21%
2011	1,077	338	$11,160,280	$1,674,081	15.00%	$5,969,749	53.49%	$3,517,389	31.52%
2010	788	187	$11,440,810	$1,250,262	10.93%	$7,480,831	65.39%	$3,046,918	26.63%
2009	606	321	$20,197,521	$2,441,302	12.09%	$16,634,525	82.36%	$1,145,352	5.67%
2008	632	199	$13,040,964	$1,961,060	15.04%	$7,955,685	61.01%	$3,124,220	23.96%
2007	332	156	$16,608,077	$3,759,888	22.64%	$10,041,243	60.46%	$2,806,946	16.90%
2006	837	199	$13,992,870	$2,760,957	19.73%	$7,962,017	56.90%	$3,269,896	23.37%
2005	686	148	$28,030,640	$5,292,244	18.88%	$16,687,659	59.53%	$6,053,010	21.59%
2004	580	101	$16,739,803	$1,930,749	11.53%	$10,353,528	61.85%	$4,434,269	26.49%
2003	647	137	$15,415,338	$1,836,442	11.91%	$8,834,932	57.31%	$4,716,553	30.60%
2002	N/A	166	$17,956,517	$2,486,689	13.85%	$13,166,258	73.32%	$2,292,491	12.77%
2001	N/A	224	$24,327,338	$4,415,899	18.15%	$16,809,966	69.10%	$3,101,473	12.75%
2000	N/A	205	$18,504,203	$2,848,538	15.39%	$13,531,600	73.13%	$2,124,065	11.48%
Total	**8190**	**3170**	**$239,571,271**	**$35,100,271**	**14.31%**	**$155,005,307**	**63.95%**	**$49,770,045**	**21.93%**
CAGR	**4.89%**	**3.94%**	**0.76%**	**5.84%**	**N/A**	**1.60%**	**N/A**	**-5.25%**	**N/A**

NOTES: This information is available through the California Office of the Attorney General. Totals have been adjusted for inflation per the California Price Index for 2016. Compounded Annual Interest Rates (CAGR) and Percentage Rates are calculated by Andrew Chang & Company. The number of 60-Day Notices from 2000-02 was not available due to a technical error in the OAG database. OAG has acknowledged the error and it working to fix it but has yet to do so.

Content Based Litigation

Date	Injunctive Relief	Plaintiff	Defendant	Settlement
3/14/2012	Reduce dosage on product label	Environmental Research Center, Inc	Amazon Herb Company	$35,531
7/2/2010	Conspicuous warnings	Consumer Advocacy Group	The Kittrich Corporation	$29,425
10/1/2010	New precautionary and use instructions	Consumer Advocacy Group	Green Light Company	$56,587
12/21/2010	Revised cautionary statement	Consumer Advocacy Group	Sawyer Products, Inc.	$28,293
5/9/2007	Enhanced warnings	California Women's Law Center	Tahitian Noni International, Inc.	$59,648
5/9/2007	Enhanced warnings	California Women's Law Center	Drugstore.com	$11,812
5/9/2007	Enhanced warnings	California Women's Law Center	Women Living Naturally, Inc.	$4,725
5/9/2007	Enhanced warnings	California Women's Law Center	Pure Essence Laboratories, Inc	$47,246
4/11/2006	Enhanced warnings	California Women's Law Center	Maximum Living, Inc.	$7,564
4/11/2006	Enhanced warnings	California Women's Law Center	Madison Pharmacy; Women's Health America	$7,369
5/8/2006	Enhanced warnings	California Women's Law Center	Matol Botanical International, Ltd.	$40,681
5/31/2006	Enhanced warnings	California Women's Law Center	Vitamin Shoppe Industries, Inc.	$4,441
9/26/2002	New warnings on nicotine products	Paul Dowhal	Perrigo Company	$37,949
4/24/2001	Enlarge warnings already given	Mateel Environmental Justice Foundation	Wine Enthusiast	$0
3/28/2000	Memorialize pre-existing "idling" policy	As You Sow	Consolidated Freightways	$66,113
1/14/2000	Additional product warning materials	As You Sow	Oatey Company	$44,075

NOTES: This information is available through the California Office of the Attorney General. Above settlement cases were selected based on an in-house analysis determining the settlement was content based (meaning litigation was due to the content of a pre-existing warning) rather than compliance based (meaning there was no warning at the time of litigation).

Reformulation Costs

Study	Product	Low	Mid	High
EU Ministry of Defence. (2010). Guidance to the Use of Cadmium Alternatives in the Protective Coating of Defence Equipment. *Ministry of Defence, Defence Standard 03-36.*	Cadmium Replacement	1	4	10
Fernandez, L. and Keller, A.A. (2000). Cost–benefit analysis of methyl tert-butyl ether and alternative gasoline formulations. *Environmental and Science Policy.*	MTBE Replacement (Ethanol)	0.21	1.78	9.63
Fernandez, L. and Keller, A.A. (2000). Cost–benefit analysis of methyl tert-butyl ether and alternative gasoline formulations. *Environmental and Science Policy.*	MTBE Replacement (Non Oxygenated)	0.22	0.47	1.70
Lohse, J. et al (2003). Substitution of Hazardous Chemicals in Products and Processes.	Metal parts cleaning		2.25*	
Lohse, J. et al (2003). Substitution of Hazardous Chemicals in Products and Processes.	Cleaning of facades		2.25*	
Lohse, J. et al (2003). Substitution of Hazardous Chemicals in Products and Processes.	Textiles cleaning in laundries		2.25*	
Lohse, J. et al (2003). Substitution of Hazardous Chemicals in Products and Processes.	Marine anti-fouling coatings	2		6
Lohse, J. et al (2003). Substitution of Hazardous Chemicals in Products and Processes.	Wood Preservation	1		1
Lohse, J. et al (2003). Substitution of Hazardous Chemicals in Products and Processes.	Flame Retardant in Circuit Boards		4*	
Lohse, J. et al (2003). Substitution of Hazardous Chemicals in Products and Processes.	Lubricant in Inland Water	2		3
Lohse, J. et al (2003). Substitution of Hazardous Chemicals in Products and Processes.	Mould Release Agents		2	
Lohse, J. et al (2003). Substitution of Hazardous Chemicals in Products and Processes.	Rechargeable Batteries		2.25*	
Lohse, J. et al (2003). Substitution of Hazardous Chemicals in Products and Processes.	Phthalates in Toys		2.25*	
Legg, K.O., et al (1996). The Replacement of Chrome in Electroplating. *Surface and Coatings Technology.*	Chrome Plating	1		1.5
Ozturk, E., et al (2008). A chemical substitution study for a wet processing textile mill in Turkey. *Journal of Cleaner Production.*	Textiles	1		1
Panel on Policy Implications of Greenhouse Warming. (1992) *Policy Implications of Greenhouse Warming: Mitigation, Adaptation, and the Science Base. National Academy of Sciences, National Academy of Engineering, Institute of Medicine.*	(HCFCs) and (HFCs) for CFCs	2	3	
van't Erve, T.J., et al (2010). Trimethylsilyldiazomethane: A safe non-explosive, cost effective and less-toxic reagent for phenol derivatization in GC applications. *Environment International.*	TMS-DM for DM		0.74	

NOTES: These studies provided a low, medium and high range of factorial cost increase due to reformulation.

Appendix B: Public Comment

Group	Summary
American Apparel & Footwear Association (AAFA)	▪ Changes to "clear and reasonable" warning regulations will increase litigation and impose high compliance cost to businesses ▪ Compliance will involve a very lengthy and expensive process, including testing the product at a lab and providing documentation as to how the product will be used and handled. The lab then has to develop specific a specific transference test for that item, then determines a testing cost for that specific test. Then results are sent to a toxicologist who will translate transference information into numbers that can be compared to the standard. The toxicologist will also conduct risk assessments to provide information to the level of exposure. Then, businesses will be able to determine if the product is compliant ▪ OEHHA has not provided sound scientific rational for requiring the specific list of 12 chemicals to be listed ▪ Changes to the warning signs without education to the public will result in confusion
AdvMed et al	▪ Language of "will be exposed" will lead to litigation, as companies will then be compelled to be able to prove that any exposure level a person is allegedly subjected to would be below that which would trigger a warning ▪ Changes to "clear and reasonable" warning regulations would exacerbate the prevalence of unnecessary and expensive litigation
American Herbal Products Association (AHPA)	▪ Requirements of the website place high levels of responsibility and financial strain on businesses ▪ Changes to the warning signs may produce confusion and unnecessary redundancy
Alliance for Natural Health	▪ Attorneys will still profit most from related litigation ▪ Supplemental companies are unfairly targeted by current and proposed regulation ▪ OEHHA has only established safe harbor levels for about half of all chemicals listed, making litigation more likely ▪ There is no established standard for testing
Auto-Alliance Automakers	▪ Some suggested warning label requirements are unreasonably burdensome and should not apply to some complex durable goods ▪ New regulations and requirements are vague and impractical to implement, specifically the 12 identified chemicals due to the onerous testing process
American Cancer Society	▪ Existing warnings fail to provide enough information to know the potential risk ▪ Add more specificity to the list including more named chemicals, the exposure level and tailored warnings for schools
American Chemistry Council	▪ Proposed regulatory scheme will serve largely to increase consumer, accelerate product reformulation without justification and increase bounty hunter litigation and adverse effects on small businesses
American Coatings Association	▪ Additional warning requirements will instead duplicate federal and state law, create confusion in the marketplace and give rise to exorbitant compliance and litigation costs

Group	Summary
Business + Institutional Furniture Manufacturers Association (BIFMA)	• New regulations requiring information on every product would be a large burden on manufactures • It is difficult to identify original chemical composure or the manufacture of recycled materials
CalChamber Coalition	• New regulations will open an entirely new frontier of litigation, as most current litigation is related to the lack of a sign, but added specificity will allow for new litigation related to content • Litigation will also increase because of the very ambiguity of the regulatory language • High costs of testing dissuade many businesses from testing products themselves
California Apartment Association	• New regulations are "difficult, if not impossible" for a property manager or owner or manager to evaluate every property and the variety of products in that property • There are currently, at least 73,000 metal and plastic warning sings produced by CAA posted at their properties
California Healthcare Institute	• Proposed changes would expose manufacturers to frivolous lawsuits, impose duplicative regulations on labeling, impose requirements that would conflict with federal law, delay access to medical treatment, confuse patients and deter the use of beneficial products
California Healthy Nail Salon Collaborative	• Identifying specific chemicals in warnings will provide workers and consumers a crucial tool
California Hospital Association	• Proposed "clear and reasonable" warning regulations, as drafted, will actually lead to more frivolous Prop 65 lawsuits
California Medical Association	• The creation of a new section for prescription medical devices is warranted, and closely aligns with current FDA regulations
California New Car Dealers Association	• Proposed changes are unnecessarily punitive to industries that are currently compliant to Proposition 65 • Proposed changes are overly prescriptive and needlessly burdensome on franchised dealers • Language of "will expose" is potentially false and misleading
California Parks and Attraction Association	• Signs posted throughout the premises of parks would detract from the themes and result only in redundant and unnecessary warnings, threatening to diminish parks' positive economic impact
California Retailers Association	• Regulations should clarify that the responsibility of compliance falls on suppliers and new provisions should be added to eliminate the ongoing abusive litigation routinely brought against retailers
California Council For Environmental and Economic Balance	• Proposed regulations would cause a significant increase in frivolous litigation without improving the quality of public and workplace warnings • Proposed regulations do nothing to address abusive and inconsistent lawsuits

Group	Summary
Center for Environmental Health	• Proposed regulation will make important information clearer, easier for Californians to understand and protect Californian's health better than the current regulations
Californians for a Healthy & Green Economy (CHANGE)	• New regulations will make warnings more informative, more useful and more consistent with the purpose of the statute • Grandfathering provision is too broad and overreaching
CHPA	• New regulations would increase manufacturer compliance costs, inconsistent and excess warnings, increase opportunities for frivolous litigation and will likely result in increased consumer confusion
Clean Water Action	• Added requirements to identify specific chemicals, provide warnings in other languages and language of "will expose you to" will better support the purpose of Proposition 65
Council for Responsible Nutrition	• Proposed changes will confuse consumers and create more opportunities for litigation
Consumer Specialty Products Association	• Proposed changes will induce further consumer confusion, more litigation and significant price increases on affected products
Law Offices of David Rowe	• OEHHA's warning website risks potential chaos, excessive burden on small businesses and widespread abuse by sophisticated businesses • Improved warnings are long needed and the correct step
Defoamer Industry Trade Association	• Proposal conflicts with other federal and national labeling requirements • New regulations will lead to needless litigation where exposure to listed chemicals is theoretical and not actual
Environmental Law Foundation	• New regulations will increase clarity, remove ambiguity and make Proposition 65 more effective
Environmental Research Center	• Proposed amendments are a significant opportunity to further protect California consumers from dangerous chemicals known to cause cancer and reproductive toxicity
FoodAg Coalition	• New regulations will confuse the consumer, particularly with respect to food • New regulations will increase unnecessary and unjustified litigation and will give the public false and fearful impressions
Frozen Potato Product Institute	• Proposed changes would create inconsistent requirements and warnings contrary to many court-approved settlements • More information would increase consumer confusion and alarm rather than provide meaningful warnings
Global Organization for EPA and DHA	• If the 12 identified chemicals must be listed, there should be a specification regarding inorganic arsenic compounds

Group	Summary
Grocer Manufacturers Association	• Draft proposal would increase litigation exposure to a food company that is providing warnings for not having provided warnings consistent with the more onerous regulations
Independent Lubricant Manufacturers Association (ILMA)	• Some new regulations will be excessively burdensome to businesses • Listing identified chemicals will not improve understanding of the risks associated with such low exposure levels • Regulations conflict with federal labeling laws, and methodology for testing is unclear
Industrial Environmental Association	• New regulations will create more opportunities for shake-down lawsuits, create significant compliance costs for businesses and will confuse the public regarding the risk of exposure
Information Technology Industry Council	• An OEHHA maintained website is not the best method for collecting web-based information • Businesses that provide a warning to avoid costly exposure assessments would be targeted with this proposal
Klamath Environmental Law Center	• Added specificity in warning sign language is necessary and will better protect California consumers and employees
Lexington Law Group	• New language will provide more information for consumers and flexibility for businesses • Grandfathering policy is too broad and unjustified
NAIMA	• Changes to regulations will cost businesses millions of dollars and only consume the consumer • New regulations are redundant or contradictory to many other federal and state regulations • New labels do not provide any information on actual risk or level of exposure
National Products Association	• The proposal in its current form is unworkable and will not achieve the goals outlined by either the Governor or OEHHA, specifically improving scientific evidence for warnings and decreasing shake-down lawsuits
NMMA	• New regulations would confuse consumers and place an excessive burden on businesses • Additional requirements will spur new lawsuits and legal claims
Oatey Company	• Proposed language is contradictory to other state and federal regulations and, in some instances, scientifically incorrect
PhRMA	• Proposed website requires too much information with too many updates to be feasible • Proposed language is alarmist in nature and not necessarily correct
Phylmar Group	• OEHHA has not demonstrated the necessity of the potential amendments • Proposed amendments will not decrease litigation and may create new sources of it • Increase information will cause confusion and unnecessary worry

Group	Summary
Plumbing Manufacturers International	• Proposals would enact complex, significant revisions as well as new requirements that would encourage additional lawsuits and place burdensome obligations on manufactures, retailers and others
Riddell Williams	• Website requirements violate the California public's Fourth Amendment rights under the U.S. and State Constitutions to be free from unreasonable searches and seizures by government officials
Rubber Manufacturers Association	• OEHHA has not provided any scientific criteria for the amendments and many changes in language are inaccurate • Website requirements do not protect confidential business information
Simplot Plant Sciences	• More stringent acrylamide warning labels on potato products are unnecessary and not warranted due to advances in the industry
Truck and Engine Manufacturers Association	• OEHHA should exempt diesel engine exhaust due to the impracticality of warning on all instances of exposure and past legal cases that have found the same
Western States Petroleum Association	• Proposed regulations would increase uncertainty for businesses and the public, result in more confusing and cumbersome warnings, fail to provide the public with useful information and ultimately increase litigation