CalChamber
CALIFORNIA CHAMBER OF COMMERCE

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PREPARE TO BE INSPIRED.

P&G

PEPSICO

Amway

DOW

AUTO ALLIANCE
DRIVING INNOVATION

SHERWIN WILLIAMS.

GMA
The Association of Food, Beverage and Consumer Products Companies

TechAmerica
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TechNet

DU PONT
The miracles of science

CALIFORNIA HOSPITAL ASSOCIATION

AAFA
american apparel & footwear association

AMERICAN BEVERAGE ASSOCIATION

CALIFORNIA HOTEL & LODGING ASSOCIATION

CALIFORNIA FARM BUREAU FEDERATION

CNCDA

WD-40 COMPANY

GlobalAutomakers

CAA
California Apartment Association

WSPA

BIOCOM

PhRMA
RESEARCH PROGRESS HOPE

CSPA
Representing Household & Institutional Products

CALIFORNIA RETAILERS ASSOCIATION

California Business Properties Association

American Chemistry Council

NFIB
The Voice of Small Business.

cjac
CIVIL JUSTICE ASSOCIATION OF CALIFORNIA

cga
CALIFORNIA GROCERS ASSOCIATION
ONE VOICE SINCE 1898

CIPA

CALIFORNIA RESCUE OF FOOD PACKAGING

CIOMA

CalABC
California Automotive Business Coalition
Representing Industry to Government since 1992

Information Technology Industry Council

ORANGE COUNTY BUSINESS COUNCIL

WESTERN GROWERS
Fresh produce from our families to yours

Toy Industry Association, Inc.

ASPA
AUTOMOTIVE SPECIALTY PRODUCTS ALLIANCE

NAIOP
COMMERCIAL REAL ESTATE DEVELOPMENT ASSOCIATION
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CALIFORNIA MANUFACTURERS & TECHNOLOGY ASSOCIATION

CICC

CALIFORNIA ATTRACTIONS AND PARKS ASSOCIATION, Inc.

APARTMENT ASSOCIATION CALIFORNIA SOUTHERN CITIES, INC.

SBRPA

Personal Care Products Council

AmericanCoatings ASSOCIATION

CHPA
CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

EBRHA
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EAST BAY RENTAL HOUSING ASSOCIATION

NCRPA
Nor Cal Rental Property Association

IEA
INDUSTRIAL ENVIRONMENTAL ASSOCIATION
Promoting Industry and Protecting the Environment

cnsda

NEMA
Setting Standards for Excellence

CEA
Consumer Electronics Association

NCTO
NATIONAL COUNCIL of TEXTILE ORGANIZATIONS

AdvaMed
Advanced Medical Technology Association

WEST COAST LUMBER & BUILDING MATERIAL ASSOCIATION

BOMA California

ifra
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Styrene Information & Research Center

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AHFA
American Home Furnishings Alliance

NORTH AMERICAN HOME FURNISHINGS ASSOCIATION

CFFA
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AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

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ISSA
Advancing Clean. Driving Innovation.

spi
the plastics industry trade association

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An ISO 9001-2008 Registered Company

Council for Responsible Nutrition
The Science Behind the Supplements

International Food Additives Council

CALCIMA
California Construction and Industrial Materials Association

Travel Goods Association

California Association of Health Facilities
CAHF

STOP LAWSUIT ABUSE
California Citizens Against Lawsuit Abuse

VICA
Valley Industry & Commerce Association
Since 1949

American Cleaning Institute
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aci

Simi Valley Chamber of Commerce and Visitor Center
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San Diego Regional Chamber of Commerce

AAMA

Santa Clara
Silicon Valley Central Chamber of Commerce & Convention-Visitors Bureau

The Chamber of the Santa Barbara Region
Helping Business Succeed Since 1899

JPMA

Burton Wire & Cable

Western Wood Preservers Institute

California Furniture Manufacturers Association
100th Year Anniversary

Simplot

USHIO
Lighting—Edge Technologies

AHAM
Association of Home Appliance Manufacturers

American Frozen Food Institute

FPPI
Frozen Potato Products Institute

IFA
International Franchise Association

Franchising
Building local businesses, one opportunity at a time

SAAMI
Sporting Arms and Ammunition Manufacturers' Institute, Inc.
Since 1926

pmi
Plumbing Manufacturers International

OPEI
Outdoor Power Equipment Institute

WPHA
Western Plant Health Association

Fullerton Chamber of Commerce

Family Winemakers

International Council of Shopping Centers

Composite Panel Association

cabbi
California Association of Boutique & Breakfast Inns

MFANC
Metal Finishing Association of Northern California, Inc.

Natural Products Association

KCMA
Quality. Advocacy. Leadership.
Kitchen Cabinet Manufacturers Association

RFCi
Resilient Floor Covering Institute

USANA
Health Sciences

MFASC
Metal Finishing Association of Southern California, Inc.

WAPA
Western Agricultural Processors Association

FASA

California Cement Manufacturers Environmental Coalition

Superior Essex

PVC Pipe association

ABMA
American Brush Manufacturers Association

Art & Creative Materials Institute
Certifying Safety & Quality Since 1940

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California Cotton Ginners Association

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California Association of Firearms Retailers

November 14, 2014

Monet Vela
Office of Environmental Health Hazard Assessment
P. O. Box 4010
Sacramento, California 95812-4010

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

SUBJECT: POTENTIAL REGULATORY ACTION

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") Request for Public Participation on Potential Regulatory Actions. Our Coalition consists of nearly one hundred forty California-based and national organizations and businesses of varying sizes that, collectively, represent nearly every major business sector that will be impacted by some or all of the proposed regulatory actions should OEHHA ultimately elect to pursue them.

Many of the issues OEHHA has identified for potential regulatory action, if addressed appropriately, can help to achieve two of the Governor's proposed reforms, announced in May 2013. Specifically, while OEHHA's current regulatory undertaking related to the warning requirements appear to be aimed at achieving the Governor's calls for "improving how the public is warned about dangerous chemicals," (whether OEHHA's proposal achieves this goal is still an issue of debate), many of the proposed regulatory actions can help to reduce frivolous 'shake-down' lawsuits and strengthen the scientific basis for warning levels.

The Coalition's comments are therefore intended to help guide OEHHA as it determines whether and how to address these issues so that any future regulatory actions are in line with the Governor's proposed reforms. Specifically, our comments (1) explain whether it would be appropriate for OEHHA to address the specific issue, (2) briefly discuss the reasons for our position, and (3) provide general recommendations where appropriate. We also propose three additional issues for OEHHA's consideration that were not identified in OEHHA's Request for Public Participation.

The Coalition believes that the appropriateness of regulatory action for certain issues depends greatly on how OEHHA would ultimately address them. To this end, if OEHHA elects to address an issue that we have indicated is appropriate for regulatory action, but does so in a way that undermines the Governor's calls for reform, the Coalition reserves the right to raise objections to such efforts during the pre-regulatory and formal rulemaking processes.

OEHHA's Proposals

1. Alternative Risk Levels for Chemicals in Foods

OEHHA and the courts have previously recognized that exceptions to the statute's warning requirement and usual "no significant risk" warning trigger levels may justifiably be made when businesses that would otherwise be responsible for an exposure to a listed chemical that naturally arises in a food do not put such chemicals out into the environment or add them into foods during preparation/processing. In promulgating the Proposition 65 regulations, OEHHA further recognized that "an alternative level may be used in situations where sound considerations of public health support it" and that "[b]ecause the Act is a public health measure, the Agency believes that it was not the intent of the Act to negatively impact

activities with known significant public health benefits by requiring warnings for exposures." (Initial Statement of Reasons for 22 CCR § 12703 at 1.) It then went on to promulgate Section 25703(b) of the regulations in a manner that allowed for alternative cancer risk levels to be established for foods, including, "for example," "where chemicals in a food are produced by cooking is necessary to render the food palatable or to avoid microbial contamination," reasoning more specifically that "the public health benefits of cooking far outweigh the potential risk of cancer from the ingestion of carcinogens from cooked food." (*Id*. at 2.)

Despite a significant increase in Proposition 65 litigation concerning foods and devoting considerable attention and resources to the application of Proposition 65 to foods over the past decade, OEHHA has not 1) promulgated any alternative no significant (cancer or reproductive harm) risk levels for food, 2) given meaning and more practicable definition to the key terms in Section 25703(b), or 3) otherwise created adequate alternatives to Proposition 65's warning requirements relative to listed chemicals in foods including in order to avoid over-warning, unnecessary litigation, and consumer confusion.

The Coalition therefore encourages OEHHA to do the following with respect to alternative no significant risk levels for food:

- Create, under Section 25505 of the regulations, a straight-forward exception to the warning requirement where a listed chemical arises in a food as a naturally occurring by-product of cooking and is not otherwise added to the food;

- Otherwise, at least revise Section 25703(b)(1) of the regulations to remove the subjective terms that give rise to argument in litigation so that it applies simply "where chemicals in food are produced by cooking."

- Concurrently promulgate under Section 25703(b)(1), as a generally available safe harbor default, an alternative 1×10^{-4} cancer risk level for any listed chemicals in food that are produced by cooking.

- Under proposed Section 25607.2, concurrently authorize producers, preparers, or sellers of foods who do not elect to carry the burden of demonstrating that their food meets the alternative 1×10^{-4} cancer risk level, or who wish to warn for exposures to listed reproductive toxicants in foods, to do so solely by means of using a designated symbol with a URL for OEHHA's website's food page (where additional information could be presented).

2. Naturally Occurring Regulation

The Coalition strongly supports the entire naturally occurring regulation, which provides exemptions for food products and non-food products containing food ingredients. That said, the Coalition believes the regulation exemption for naturally occurring chemicals in food products needs to be revised in order to fulfill its original intent, as expressed by the lead agency and endorsed by the courts, since years of experience have shown parts of the regulation to be a continuing source of unexpectedly complex and expensive disputes and, hence, of little practical effect.

The original intent of the regulation was expressed by the lead agency in its Final Statement of Reasons when it adopted the current regulation:

> The Agency has determined that the adoption of these regulations is necessary in order to implement the warning requirement of the Act in a reasonable manner, and to facilitate compliance with the Act by defining key terms and making them more specific and relevant to the regulated business activities. The regulations in Article 5 define specific conditions where exposure to a listed chemical will not be deemed an "exposure" for purposes of the warning requirement.

> Chemicals which are currently subject to the requirement of warning prior to exposure include several chemicals which are naturally occurring constituents of food. The Act does not differentiate between exposure to naturally occurring chemicals and exposures to chemicals added by man. However, due to the abundance of foods which in their natural unprocessed state inherently contain low levels of carcinogens or reproductive toxicants, warning could appear on a large number of food products, and consequently, diminish the overall significance of food warnings.
>
> This regulation provides that human consumption of food containing a listed chemical does not constitute an "exposure" within the meaning of the Act to the extent that it is shown that the chemical is naturally occurring. This exemption is derived from the distinction in state and federal adulteration laws between naturally occurring substances in food and those which are added substances. (citation omitted) The laws make it easier to prove adulteration where a deleterious substance was introduced into food by man, than where a substance was naturally occurring in the food.*** The rationale for this special treatment of food is the historical desire to preserve naturally occurring foods in the American food supply, despite the presence in those foods of small amounts of potentially deleterious substances, as well as a recognition of the general safety of unprocessed foods as a matter of consumer experience (citations omitted) For these same reasons, it is reasonable and appropriate to implement the Act so that warnings are not required for naturally occurring chemicals in food.
>
> Subsection (b) provides that where human consumption of a naturally occurring chemical in a food would not cause an "exposure" pursuant to subsection (a), the same naturally occurring chemical will similarly not give rise to an "exposure" if the food is subsequently used in the production or processing of a consumer product other than food. In general, chemicals in food are more readily absorbed into the body by way of ingestion than by dermal contact or other routes. Therefore, it is reasonable to provide that where there is not an "exposure" to a naturally occurring chemical in food by the route of ingestion, there is not an "exposure" to the same chemical when the food is used as a component of a consumer product other than food.

A regulation excluding naturally occurring constituents in food from the definition of an exposure is further supported by the Court of Appeal's ruling in *Nicolle-Wagner v. Deukmejian*, 230 Cal.App.3d 652 (1991). There the court said:

> Proposition 65, and the corresponding sections of the Health and Welfare Code, are silent on the subject of naturally occurring carcinogens and reproductive toxins. We must search then, for whatever more subtle expressions of the electorate's intent may exist in the language of the statute, as well as the ballot arguments both for and against the proposition. Those sources indicate that Proposition 65 sought to regulate toxic substances which are deliberately added or put into the environment by human *** 498 activity. The controlling language of the Proposition, now Health and Welfare Code section 25249.6, provides that "no person in the course of doing business shall knowingly and intentionally expose any individual" (emphasis added), thereby suggesting that some degree of culpable human activity which results in toxins being added to the environment is required.

The court concluded that "we are persuaded, on balance, that the better view is that the electorate did not intend naturally occurring substances to be controlled by Proposition 65. Use of terms such as "knowingly and intentionally" and "putting" imply that human conduct which results in toxins being added to the environment is the activity to be controlled."

When the regulation was adopted, it was expected both to reduce the number of lawsuits and to reduce the number of warnings that are posted by food manufacturers and retailers in order to prevent lawsuits, both of which are goals of the Governor's announced reform efforts. But, due to the structure of the

regulation, ambiguities in its terms, and associated disparities in proof requirements, neither goal has been achieved as expected.

While questions concerning listed chemicals that are natural constituents of foods have been rare, the regulation has had little practical effect on reducing warnings or lawsuits in the more common situation where the food contains a chemical that was absorbed or accumulated because it is historically present in the environment in which the food is grown or raised. The issue with this part of the regulation is that, in short, it is not practical to apply.

Years of experience with the regulation bear this out. In fact, the only case in which the defendants were able to mount a successful defense based on this regulation involved one food product -- canned tuna -- that contains no other animal or plant ingredients that contribute any amount of the listed chemical at issue. That food product is quite high in value, and the industry was concentrated in three major companies, all of whom were named in the same lawsuit. It also involved a chemical (methylmercury) that had been subject to extensive study and public health review. In short, it was an unusual situation in which the economics and the science permitted the exemption to be applied even though numerous arguments arising from the structure and ambiguities in the regulation were raised to the contrary.

A similar situation arose with respect to chocolate -- another high value food commodity – that resulted in a press barrage and bounty hunter lawsuit against all the major chocolate companies. At the outset of the matter, the Attorney General's office issued a guidance letter indicating its evaluation of the evidence and its conclusion that lead in cocoa and its resulting chocolate products is naturally occurring within the meaning of the regulation. Notwithstanding the Attorney General's expressed view on the issue, because the current regulation left too much room for a contest, the case proceeded through almost two years of discovery and motion practice before plaintiff recognized that its views on the naturally occurring issue would not win the day and accepted a nuisance level payment shortly before trial. Even at that, and with no indication that anything has changed to increase the levels of lead in cocoa from known human activity, a number of Proposition 65 notices are currently pending on lead in cocoa products.

Furthermore, in the recent *Beech Nut* case involving fruit and vegetable products, although there were multiple defendants who were willing to mount the defense and established to the trial judge's satisfaction that neither they nor their growers added lead to the food products or their constituent ingredients, due to other ambiguities in the regulation and its associated proof requirements, they were still not able to establish at trial that they met the regulation's complex definition of "naturally occurring." And in the hundreds of Proposition 65 matters alleging failure to warn of lead exposures from herbal supplements, no defendant has even brought the matter to trial -- in part because the cases are filed against one company at a time; in part because most of the companies are too small to afford the substantial expense of a naturally occurring defense under the current regulation; and in part because the current regulation would require them to mount the expensive defense the tuna companies presented, but multiplied by the numerous ingredients in a given product.

In sum, because many food products are made of multiple ingredients and have complex supply chains, the naturally occurring regulation as currently drafted is not the effective tool the Agency envisioned it would be relative to limiting litigation and the number of warnings given to the public about foods they have been eating safely for dozens if not hundreds of years.

With this as background, the Coalition believes that the current regulation has not fulfilled the agency's goal in adopting it and in attempting to ensure that the law fulfills the intent of the electorate, recognized in *Nicolle-Wagner*, not to penalize companies who do not put chemicals into products or the environment. The regulation as currently written (and applied) for products containing chemicals absorbed or accumulated from soil or water requires the accused business to prove not only one negative but three negatives: (1) that the chemical did not result from any known human activity; (2) that the chemical was not avoidable by good agricultural or manufacturing practices; and (3) that there is no "currently feasible" way to lower the level. This burden is virtually insurmountable and undermines the intent of the agency in adopting the regulation while subjecting those who produce and sell food for Californians to expensive litigation.

The Coalition therefore believes that OEHHA would further the voters' and Agency's prior intent and better serve the purposes of the statute and the Governor's reform agenda by modifying the regulation significantly. The adjustments necessary to fulfill the original goals of the regulation are appropriate for further discussion with food regulators and the regulated community. We also note that, in addition to U.S. Food & Drug Administration, this is an issue on which the California Department of Food & Agriculture has extensive knowledge and experience, and we strongly recommend that OEHHA work closely with CDFA on this issue under the MOU between the two agencies.

3. Safe Use Determination Process / Interpretive Guidance

The Coalition supports the Administration's goals of reducing the number of warnings and the number of enforcement lawsuits. OEHHA has appropriately noted that a substantial portion of warnings provided to consumers and to the public are provided solely to avoid litigation. Businesses would prefer not to be confronted with the Hobson's choice of either warning or being sued. Unfortunately, that is the current reality in today's Proposition 65 climate.

Businesses have, on many occasions, conducted exposure and risk assessments of products to determine whether a warning is legally required. Even when the results of the assessments demonstrate that an exposure is unlikely to occur or is below the applicable NSRL or MADL, a business may still chose to warn. This occurs, for example, when a chemical is a current favorite of the enforcement community and likely to be noticed in the product.

If a business decides that it will not warn on the basis of its exposure and risk assessment, it may still be sued. Private enforcers rarely, if ever, abandon a 60-day notice in the face of assessments concluding that no warning is required. They know that the cost of litigation, including hiring expert witnesses, will far exceed their settlement demand.

Because of the foregoing reality, warnings and lawsuits proliferate. This reality is obviously not new information to OEHHA. Recognizing this, OEHHA has, on selected occasions, sought to provide greater certainty to businesses and public and private Proposition 65 enforcers. OEHHA has issued two safe use determinations (SUD), involving crystalline silica, one in paint and the other in cat litter. It has also issued the following interpretive guidelines (IG):

- Hand-to-mouth transfer of lead through exposure to consumer products;
- Consumption of methanol resulting from pectin that occurs naturally in fruits and vegetables;
- Chlorothalonil residues in tomato products;
- Consumption of sulfur dioxide in dried fruits.

It appears that OEHHA issued the SUDs and IGs with the purpose and intent of informing both the business and enforcement communities and to eliminate the need for warnings and to discourage lawsuits. Recently, OEHHA has stated that it is working on two other interpretive guidelines, arsenic in rice and lead in brass fixtures, presumably with the same purpose and intent.

The Coalition acknowledges OEHHA's work and urges it to increase this activity significantly in order to see a resulting reduction in warnings and lawsuits. Remarkably, the Supreme Court has issued more decisions on Proposition 65 than OEHHA has issued SUDs. This fact should raise questions as to why more SUDs have not been issued (the Supreme Court decisions dealt with different chemicals, lead and nicotine; whereas, both of the SUDs involved one chemical, crystalline silica.).

To the regulated community, the SUD process looks like a black hole. The ultimate cost is uncertain, the information that is required often appears to be infinite, the timeframe is uncertain, and often months even years pass before the business concludes that no chance for a positive outcome exists and withdraws the

request. Moreover, the language of the regulation and the safe use determinations themselves are explicit that they have no legal effect.

The SUD process is expensive. It requires the business not only to pay its own experts to develop the necessary data and other information to support its request, but also to pay OEHHA's cost. No cap exists for the cost that OEHHA may assess, and the requesting business has no basis to understand its ultimate financial exposure.

The regulation sets out what information is required in an SUD request, and theoretically, what is required for OEHHA to issue a determination. The experience of business is that the information set out in the regulation is only the beginning. It appears that OEHHA, in the exercise of extreme conservatism, seeks to eliminate all doubt before it will issue a determination. In the realm of legal evidentiary standards, OEHHA has established a standard that is more rigorous than the highest legal standard, that is, beyond a reasonable doubt. Criminals can be condemned to death under that standard, but it appears that OEHHA does not consider it sufficient to issue a SUD. In the search for an absolute, OEHHA requests more and more data, increasing the cost and prolonging the process.

Worse, the SUD process offers no certainty. There is no clear statement in the regulations about the evidentiary weight to be afforded to an SUD. The SUD establishes no presumptions, but merely represents "the state's best judgment concerning the application of the Act to the particular facts presented in the [SUD] request." Thus, at the end of this expensive and laborious process, a successful SUD does not immunize a business from an enforcement action, removing yet another potential incentive for a business to make the necessary extensive investment to pursue one. It should be no surprise that a business would decide to forego the expense and uncertainty of the SUD process and simply provide warnings.

Finally, the regulation provides that no request will be entertained if the request is the subject of a 60-day notice or of a complaint that has been filed. OEHHA states that it does not want to weigh in on either side of an enforcement action. It wants to be neutral. Often, a business doesn't know that it has an issue until it receives a 60-day notice. That is when it wants certainty. Does it have to warn for the noticed product? The truth of the matter is that science is neutral. OEHHA's determination favors neither party to the dispute. The private enforcer, like the business, should want to know whether the business is in violation of the initiative or not. The private enforcer does not, or at least should not want to pursue an action against someone who is in compliance with the law.

As noted above, OEHHA has issued more IGs than SUDs. The IG regulation is promising. It does not require the business to pay OEHHA; it includes a time frame for the issuance of a decision; and it has no prohibition about considering a request after the service of a 60-day notice or the filing of a complaint.

While only a few IGs have been released, they demonstrate a process for addressing the over warning and litigation issues. For example, OEHHA issued the IGs on sulfur dioxide in dried fruit and methanol from pectin in fruits and vegetables in a timely, effective manner. In the past, OEHHA has followed the practice of refusing to consider a request for an IG if a 60-day notice involving the same product and chemical has been served although nothing in the regulation precludes it from doing so. That practice prohibits the use of an IG when its need is most apparent. The recent statements that it is working on IGs for arsenic in rice and lead in brass fixtures indicates that OEHHA is moving away from that practice. If so, that is supported and encouraged by the Coalition.

While the examples of IGs are few, it appears also that OEHHA is using a more practical approach to the evidentiary standard for IGs than for SUDs. Certainly, the Coalition would urge OEHHA to use a preponderance of the evidence standard in issuing IGs, that is, the evidence demonstrates that a fact is more likely to be true than not.

Finally, the current effect of an IG to aid businesses to avoid litigation is uncertain. Indeed, the very definition of "interpretive guideline" offers no concrete information about what it is, or what protection, if any, it would provide to a business:

"Interpretive guideline" means a draft regulatory proposal which has been published for the information, comment, and guidance of California businesses, law enforcement and others concerned.

Characterizing an IG as a draft regulatory proposal signals clearly to a court that the IG has no legal effect. Courts are precluded from giving any weight to a draft proposal.

Both SUDs and IGs are mechanisms that are available to be used to reduce the number of warnings and lawsuits. To be effective in that cause, the regulations for both need to be improved. The immediate ideas for improving them are as follows:

- Establish a preponderance of the evidence standard of proof that businesses have to meet for OEHHA to issue both SUDs and IGs. This is a practical and realistic standard that is applicable in enforcement actions;

- Characterize both SUDs and IGs in a way that allows a court to rely on them to resolve a lawsuit through pretrial motions;

- Establish reasonable timelines for the consideration and issuance of an SUD; and

- Identify early in the SUD process the amount that OEHHA will assess the business as its cost.

Finally, the Attorney General should be persuaded to discourage the pursuit of an enforcement lawsuit when OEHHA has issued either a SUD or IG, concluding that no obligation exists to warn for that product. The Attorney General should be encouraged to amend the AG's regulations to provide that any settlement, including the award of attorney's fees, will be opposed in a case in which OEHHA has issued either a SUD or IG concluding that no obligation to warn exists for a product that is the subject of a lawsuit.

4. Regulatory Provisions on Averaging Exposures

OEHHA's request indicates that one possible concept is "Clarifying regulatory provisions on averaging exposures" with a citation to those provisions of the regulations in which the term "average" appears. The Coalition believes that OEHHA should not pursue regulatory reforms related to this concept as the current provisions of the regulations related to this issue are sufficiently clear and have been applied appropriately by the courts on a case-by-case basis to date. The Coalition also believes that, as a matter of public policy, and consistent with both OEHHA's mission and the statute, averaging should continue to be permitted wherever there is scientific justification presented for it based on the chemical at issue and regardless of whether an exposure analysis is based on a promulgated safe harbor or a full risk assessment. In fact, because it will result in overwarning, a failure to continue to allow for averaging wherever it can be scientifically justified would run contrary to the Governor's announced goals for Proposition 65 reform.

The Coalition believes there has never been any significant dispute about the scientific justification for averaging as it applies to listed carcinogens, since the effect of exposure to carcinogens is uniformly considered to occur over an extended period of time. Disputes have arisen, however, in several past cases over whether averaging over a shorter time period may be applied to reproductive toxicants and their associated safe harbor levels based on appropriate scientific justification. This issue is now pending before the First Appellate District and is therefore best addressed there or, if necessary, in the California Supreme Court. Just as it should be (and would also be in the case of a business seeking a SUD), it will turn on the particular scientific justification presented for a given chemical and associated exposure scenario.

In short, the Coalition believes the existing regulations are clear that averaging is always appropriate for carcinogens and is sometimes, but not necessarily always, appropriate for reproductive toxicants

depending on the chemical-specific scientific data available to be presented in a particular case. OEHHA should not change this basic formula or adopt some new default rule in its place.

5. Safe Harbor Levels

The Coalition appreciates OEHHA's openness to suggestions concerning priorities for the development or update of Safe Harbor levels, and notes that it has been more than a year since OEHHA has announced a new or changed safe harbor value for any chemical.

The Coalition believes that developing and updating safe harbor levels presents an opportunity for OEHHA to act on the Governor's stated desire to "end[] frivolous 'shakedown' lawsuits." A number of frivolous, "shakedown" lawsuits are pursued concerning chemicals that do not have a safe harbor value. A recent example of this phenomenon is the wide array of lawsuits threatened and brought concerning dermal exposure to DEHP, a chemical which is not readily absorbed through the skin. Another example is cocamide DEA. We request OEHHA to assign a high priority to establishing safe harbor values when doing so would head off or reduce the "frivolous 'shake down' lawsuits" about which the Governor expressed concern in May 2013.

On a related note, the Coalition requests that the actual listing of a chemical known to be present in food not be finalized either until OEHHA has adopted a safe harbor for that chemical or until OEHHA has received substantial comments from affected industries requesting that no safe harbor be adopted because of anticipated changes in scientific data or other appropriate reasons. Especially in the case of foods, OEHHA should be cautious to avoid unnecessarily disrupting existing food safety regulatory programs and food safety messaging to the public; discretion should be exercised regarding the timing of a listing so that appropriate safe harbors can be proposed prior to listing, discussed, and then announced concurrently with the listing, after an opportunity for dialogue and public comment. OEHHA has an obligation to update the Proposition 65 list once a year in light of new knowledge; that obligation does not prevent it from timing the updates to the list to accomplish this request.

6. Postnatal Development Exposures

Proposition 65 does not cover all forms of toxicity; it only covers cancer and reproductive toxicity. OEHHA's long-standing public statements concerning reproductive toxicity correctly limit reproductive toxicity to toxicity resulting from fetal exposure or toxicity to the reproductive system. There is neither a basis for nor need to change this often expressed view and, to this end, there is neither a basis for nor need to adopt regulations concerning it.

<u>Additional Proposals</u>

1. Definition of "Knowingly"

As the Coalition has stated on numerous occasions, businesses have little incentive to conduct the expensive exposure assessments necessary to determine whether or not Proposition 65 warnings are required for their products or services. That is because a Proposition 65 plaintiff may, and typically does, challenge each and every aspect of such an assessment. As businesses in the trenches of Proposition 65 enforcement know, an exposure assessment does not consistently make a plaintiff walk away from a Proposition 65 claim, no matter how well the exposure assessment was conducted.

To provide a greater incentive for businesses to conduct assessments and gain some comfort that the work and expense will offer protection from a lawsuit, the Coalition recommends that the regulatory definition of "knowingly" be revised so that a business has no knowledge of an exposure if:

- The business possesses an exposure assessment;
- The exposure assessment was conducted by a qualified scientist in accordance with relevant Proposition 65 regulations; and

- The exposure assessment concludes that no Proposition 65 warning is required.

2. Listing Process

The Coalition is concerned that the pace of new chemical listings has increased in recent years. New chemical listings present particular challenges for those who do business in California because they often require review of complex product formulations, analysis of raw material characteristics and sourcing, and -- where OEHHA is not simultaneously proposing a safe harbor level -- determination of the appropriate warning threshold for the chemical. These challenges are compounded for smaller businesses and for those whose products have shelf lives or production schedules that exceed the statutory one-year period before new listings become effective.

Three issues arise with some regularity for businesses seeking to comply with new listings.

First is the precise identification of the substance that is listed. For example, where substances are proposed for listing based on authoritative bodies' determinations, the underlying determinations do not always speak in precise terms, although the substance at issue is clearer from the context of the report and the studies on which it relies. We acknowledge that OEHHA has been receptive to suggestions for clarification of proposed listings -- a good example is "titanium dioxide (airborne, unbound particles of respirator size)" -- when such issues are raised in the listing process. But ambiguity can arise long after the substance is listed, in the course of an enforcement action, the expense and burden of which might have been avoided had the original listing been stated more precisely. Although a noticed business may at that point petition OEHHA for clarification, experience shows that the economics of the situation prevent noticed parties from undertaking that course of action, given the looming expense of litigation and the availability of attorneys fees (as well as virtually unlimited civil penalties) for prevailing enforcers. It would increase certainty and decrease litigation for OEHHA to identify more precisely the precise substances listed. Businesses should not have to hire scientific consultants to pore over detailed documents in order to figure out what the state intended to be the listed substance.

A second and related issue is the route of exposure on which a listing is based. It is well-accepted that a substance that causes an effect via one route of exposure does not necessarily cause that effect by another route. In the past, for almost all listings, OEHHA has not been precise about the route of exposure, although occasionally the listing has been stated more precisely (e.g., "formaldehyde (gas)") or the safe harbor level has been set for different routes of exposure (e.g., "by inhalation"). This lack of specificity has allowed private enforcers to proceed against businesses merely by identifying a chemical in a product and then burdening the noticed (and often small) business with establishing that the chemical does not cause the effect through the route of exposure at issue. It should be no surprise that this results in settlements, with no scientific justification, and at great expense to businesses.

Third, there often is only scant or summary documentation as to the reasoning of OEHHA or the CIC or DARTIC in listing the substance, including the studies that were relied on, studies that were disregarded as not of sufficient quality, determination of the precise substance or route of exposure, etc. This increases both the uncertainty for businesses assessing compliance and the potential areas of dispute for litigants and the courts. Indeed, some regulations require reference to the studies on which the listing is based, which may not be easily ascertained.

Consistent with principles of sound science and good government, the Coalition therefore believes OEHHA needs to adopt procedures to ensure that each listing precisely reflects the substance studied or assessed in the reports on which the listing is based, as well as the specific route of exposure for which the carcinogenic or reproductive effect has been found. For those few listings added by the State's Qualified Experts, this precise determination should be a required part of the DARTIC or CIC agenda and discussion. For the larger number of authoritative body listings, it often may be possible for OEHHA staff to make these determinations, but where there is some question, the Coalition believes OEHHA should refer the matter to the State's Qualified Experts for an advisory opinion. And perhaps most importantly, the Coalition believes that these listing determinations should be accompanied by detailed statements of

decision setting forth the reasoning of the agency or the State's Qualified Experts. In this way, there will be a clear and official record of the agency's determinations, providing greater clarity for the regulated community and for courts that must later rule in enforcement actions.

3. Notices on Food

As OEHHA knows, the last decade has seen a marked increase in private enforcement actions regarding food products. These have spawned some of the hardest fought litigation as well as some of the most ubiquitous warnings. These allegations often present important and complex issues of science and public health, not to mention challenges for California's agricultural sector. A Proposition 65 warning on a food may cause consumers to make dietary choices with unforeseen public health consequences. It may have economic impacts that affect the food supply. And it may not be required but may be given simply to resolve litigation without greater expense. The Coalition is dismayed that there is no regularized procedure for the State's food policy experts to engage on these public health and public policy issues or even to become aware of the allegations in a timely manner.

We therefore believe it would further the goals of the statute for OEHHA to modify its regulations on 60-day notices to require that, for notices involving food products or food ingredients, the noticing party must serve the notice, together with the information underlying the certificate of merit, on the California Department of Food & Agriculture. This will enable the State's food policy experts, where they believe the situation warrants, to engage in discussion with the noticing party, the noticed businesses, OEHHA, and the Attorney General's office, so that their perspective and expertise is not overlooked and instead can be considered in addressing the allegation.

Thank you for considering our comments. We welcome the opportunity to discuss these issues and others in person at OEHHA's convenience.

Sincerely,

Anthony Samson
Policy Advocate
California Chamber of Commerce

On behalf of the following organizations:

Advanced Medical Technology Association (AdvaMed)
Alliance of Automobile Manufacturers
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 Forest & Paper Association
American Frozen Food Institute
American Herbal Products Association
American Home Furnishing Alliance
American Wood Council
Amway
Apartment Association of Greater Los Angeles
Apartment Association, California Southern Cities

Association of Home Appliance Manufacturers
Automotive Specialty Products Alliance
Bestway
Biocom
Breen Color Concentrates
Building Owners and Managers Association of California
Burton Wire & Cable
California Apartment Association
California Association of Boutique & Breakfast Inns
California Association of Firearms Retailers
California Association of Health Facilities
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 Grocers Associations
California Cotton Growers Association
California Farm Bureau Federation
California Furniture Manufacturers Association
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 New Car Dealers Association
California Restaurant Association
California Retailers Association
California Travel Association
California/Nevada Soft Drink Association
Chemical Fabrics & Film Association, Inc.
Chemical Industry Council of California
Civil Justice Association of California
Coast Wire & Plastic Tec., LLC
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
Frozen Potato Products Institute
Fullerton Chamber of Commerce
Grocery Manufacturers Association
Industrial Environmental Association
Information Technology Industry Council
International Council of Shopping Centers
International Food Additives Council
International Fragrance Association, North America

International Franchise Association
Juvenile Product manufacturers Association
J.R. Simplot Company
Loes Enterprises, Inc.
Metal Finishing Association of Northern California
Metal Finishing Association of Southern California
NAIOP of California, the Commercial Real Estate Development Association
National Council of Textile Organizations
National Electrical Manufacturers Association
National Federation of Independent Businesses
National Shooting Sports Foundation
Natural Products Association
NorCal Rental Property Association
North American Home Furnishing Association
Outdoor Power Equipment Institute
Orange County Business Council
Pactiv, LLC
Parterre Floor Systems
PepsiCo
Personal Care Products Council
PhRMA
Plumbing Manufacturers International
Procter & Gamble
Redondo Beach Chamber of Commerce
Resilient Floor Covering Institute
San Diego Regional Chamber of Commerce
Santa Barbara Rental Property Association
Santa Clara Silicon Valley Central Chamber of Commerce and Convention- Visitors Bureau
Simi Valley Chamber of Commerce
Sherwin Williams
SPI: The Plastic Industry Trade Association
Sporting Arms and Ammunitions Manufacturers Institute, Inc.
Styrene Information and Research Center
Superior Essex
TechAmerica
TechNet
The Art & Creative Materials Institute
The Association of Global Automakers
The Chamber of the Santa Barbara Region
The Kitchen Cabinet Manufacturers Association
The Worldwide Cleaning Industry Association
Toy Industry Association
Travel Goods Association
Uni-Bell PVC Pipe Association
USANA Health Sciences, Inc.
USHIO America, Inc.
Valley Industry and Commerce Association
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 State Petroleum Association
Western Wood Preservers Institute

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