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August 27, 2018

*Via electronic submission to  
<https://oehha.ca.gov/comments>*

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

Re: Proposed Adoption of New Section Under Article 7: No Significant Risk Levels  
Section 25704: Exposures to Listed Chemicals in Coffee Posing No Significant Risk

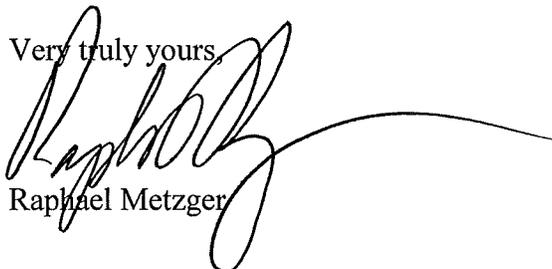
## CERT SUBMISSION NO. 19

Dear Ms. Vela:

Enclosed herewith is the document that is being submitted on behalf of our client, the Council for Education and Research on Toxics (CERT): Legal Brief of the Council for Education and Research on Toxics ("CERT") in Opposition to the Proposed New Regulation

Kindly include CERT's Legal Brief regarding the proposed new regulation in the record for this rulemaking proceeding.

Very truly yours,



Raphael Metzger

RM:ip  
encls: as specified

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Attorneys for Interested Party  
COUNCIL FOR EDUCATION AND  
RESEARCH ON TOXICS a California  
public benefit corporation ("CERT")

**CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY**  
**OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT**

IN RE PROPOSED ADOPTION OF NEW )  
SECTION UNDER ARTICLE 7: NO )  
SIGNIFICANT RISK LEVELS: SECTION )  
25704: EXPOSURES TO LISTED )  
CHEMICALS IN COFFEE POSING NO )  
SIGNIFICANT RISK )  
\_\_\_\_\_ )

**LEGAL BRIEF OF THE COUNCIL FOR  
EDUCATION AND RESEARCH ON  
TOXICS ("CERT") IN OPPOSITION TO  
THE PROPOSED NEW REGULATION**

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**I. BACKGROUND**

**A. PRELIMINARY STATEMENT AND SUMMARY OF ARGUMENT**

This Brief, submitted by the Council for Education and Research on Toxics in opposition to the proposed regulation, explains that the proposed regulation is unlawful, because it exceeds OEHHA’s regulatory authority. This Brief makes four points:

First, the regulation is unlawful because it would contravene the intent of the Voters, who in adopting Proposition 65, specifically intended that the Initiative apply to carcinogens in coffee.

Second, the regulation is contrary to the existing scientific data regarding acrylamide, including OEHHA’s own determination that the No Significant Risk Level (NSRL) for acrylamide is *exceeded* for all coffee drinkers. Thus, the proposed regulation is contrary to the scientific evidence.

Third, the proposed regulation is unlawful, because it creates categorical exemptions for heat-formed carcinogens in coffee, in the absence of any quantitative cancer risk assessments. The regulation is therefore not consistent with and conflicts with Proposition 65, rather than implementing and furthering the purpose and goals of the Act. *Morris v. Williams* (1967) 67 Cal.2d 733, 748 [“no regulation adopted is valid or effective unless consistent and not in conflict with the statute.”], quoting Gov’t Code § 11374, now § 11342.2 [“Whenever by the express or implied terms of any statute a state agency has authority to adopt regulations to implement, interpret, make specific or otherwise carry out the provisions of the statute, no regulation adopted is valid or effective unless consistent and not in conflict with the statute and reasonably necessary to effectuate the purpose of the statute.”]

Fourth, the proposed regulation violates the Settlement Agreement in the *Duke II* case, pursuant to which OEHHA and the Governor agreed, on December 23, 1992, “that any provision which is adopted after the date of this agreement to define the term ‘no significant risk’ of the Act for any food, drug, cosmetic or medical device product . . . shall be based upon specific numeric standards for the chemical, as evidenced by the rulemaking file” and that “[s]uch levels shall be consistent with and conform to sections 12703 and 12721 of title 22 of the California Code of Regulations [now 27 C.C.R. §§ 25703 and 25721].”

**B. CERT’S INTEREST IN THE PROPOSED REGULATION**

The Council for Education and Research on Toxics (CERT) is a California public benefit corporation, whose charitable purposes are education and research regarding toxic substances. CERT is unique among public benefit corporations because all of its officers and directors provide their services to the organization *pro bono*, so CERT can devote all of its resources to its charitable goals. Most of CERT’s funds are distributed in the form of research grants regarding toxic substances. The overwhelming majority of these grants are issued to researchers at University of California campuses. CERT also funds scientific conferences and provides funds so students can attend such conferences.

A major focus of CERT’s efforts has been to reduce dietary exposure to the carcinogen acrylamide and to inform Californians of the carcinogenic hazard of this heat-formed carcinogen that is prevalent in the human diet. CERT filed the first case to enforce Proposition 65 regarding acrylamide in french fries in 2002. The California Attorney subsequently intervened in that case and CERT co-litigated that case with the California Attorney General. In addition, CERT’s counsel co-litigated a case filed by the California Attorney General regarding acrylamide in potato chip. Those cases were both successful and conferred substantial benefits to California consumers. In the former case, french fry manufacturers agreed to provide legally required cancer hazard warnings and in the latter case, potato chip manufacturers reduced acrylamide levels in potato chips in lieu of warning - the best result for public health. In 2010, CERT commenced what is undoubtedly the largest Proposition 65 case against the coffee industry regarding acrylamide in coffee. After eight years of litigation, CERT has prevailed in that case and has already settled that case with about 10 of the 90 defendants. CERT’s goal in that case is to encourage coffee producers to substantially reduce acrylamide levels in coffee, obviating the need for Proposition 65 cancer hazard warnings for coffee sold in California. As CERT will show in its scientific submissions, many technologies are available to reduce acrylamide in coffee while maintaining flavor, some of which can be implemented easily and at minimal cost.

Thus, CERT has a substantial interest in the proposed regulation and, having focused its research and efforts on acrylamide and other heat-formed contaminants in food for the past 16 years, CERT has much scientific information to submit to OEHHA regarding the proposed regulation.

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**C. OEHHA’S AUTHORITY TO ADOPT REGULATIONS IS SPECIFIED BY STATUTE AND IS ALSO EXPRESSLY LIMITED BY STATUTE**

Health and Safety Code § 25249.12(a) states: “The Governor shall designate a lead agency and other agencies that may be required to implement this chapter, including this section. Each agency so designated may adopt and modify regulations, standards, and permits as necessary to conform with and implement this chapter and to further its purposes.” Thus, in adopting Proposition 65, the People delegated limited authority to governmental agencies designated by the Governor to implement the Initiative. Notably, the People delegated authority to OEHHA to adopt regulations “as necessary to conform with and implement” Proposition 65 “and to its purposes.”

Government Code § 11342.1 states: “Except as provided in Section 11342.4, nothing in this chapter confers authority upon or augments the authority of any state agency to adopt, administer, or enforce any regulation. Each regulation adopted, to be effective, shall be within the scope of authority conferred and in accordance with standards prescribed by other provisions of law.”

Additionally, Government Code § 11342.2 states: “Whenever by the express or implied terms of any statute a state agency has authority to adopt regulations to implement, interpret, make specific or otherwise carry out the provisions of the statute, no regulation adopted is valid or effective unless consistent and not in conflict with the statute and reasonably necessary to effectuate the purpose of the statute.”

The effect of these statutes is that although the People, in adopting Proposition 65, delegated authority to implement the Initiative to such agencies that the Governor designates to do so, the authority of OEHHA as an agency designated by the Governor to implement Proposition 65 is limited to regulatory action that is “necessary to conform with and implement” Proposition 65 [Health and Safety Code § 25249.12(a)]; that is “within the scope of authority conferred and in accordance with standards prescribed by” that section [Government Code § 11342.1]; and that is “consistent and not in conflict with” Proposition 65 “and reasonably necessary to effectuate the purpose of the statute.” [Government Code § 11342.2].

As will be explained, adopting the proposed regulation would exceed OEHHA’s authority and would therefor violate these statutes.

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**D. IT IS WELL ESTABLISHED THAT AGENCIES MAY NOT ADOPT REGULATIONS THAT ARE CONTRARY TO OR CONFLICT WITH STATUTES**

“Even apart from the[] statutory limits [of Government Code §§ 11342.1 and 11342.2], it is well established that the rulemaking power of an administrative agency does not permit the agency to exceed the scope of authority conferred on the agency by the Legislature.” *Bearden v. U.S. Borax, Inc.* (2006) 138 Cal.App.4th 429, 436, citing *California Employment Commission v. Kovacevich* (1946) 27 Cal.2d 546; accord, *Agnew v. State Board of Equalization* (1999) 21 Cal.4th 310, 321.

“A ministerial officer may not . . . under the guise of a rule or regulation vary or enlarge the terms of a legislative enactment or compel that to be done which lies without the scope of the statute and which cannot be said to be reasonably necessary or appropriate to subserving or promoting the interests and purposes of the statute.” *Agnew v. State Board of Equalization* (1999) 21 Cal.4th 310, 321, citing *First Industrial Loan Co. v. Daugherty* (1945) 26 Cal.2d 545, 550.

“[A] regulation which impairs the scope of a statute must be declared void.” *Agnew v. State Board of Equalization* (1999) 21 Cal.4th 310, 321, citing *Assn. For Retarded Citizens v. Dept. of Developmental Services* (1985) 38 Cal.3d 384, 391; *Morris v. Williams* (1967) 67 Cal.2d 733, 748.

“[A]n agency does not have discretion to promulgate regulations that are inconsistent with the governing statute, alter or amend the statute, or enlarge its scope.” *California School Boards Association v. State Board of Education* (2010) 191 Cal.App.4th 530, 544. “No matter how altruistic its motives, an administrative agency has no discretion to promulgate a regulation that is inconsistent with the governing statutes.” *Terhune v. Superior Court* (1998) 65 Cal.App.4th 864, 873, citing *Agricultural Labor Relations Board v. Superior Court* (1976) 16 Cal.3d 392, 419..

“The administrative agency must confine itself to reasonable interpretation in adopting regulations for administration of its governing statute; if it goes beyond that, the legislative area has been invaded and the regulation counts for nought.” *Los Angeles County v. State Department of Public Health* (1958) 158 Cal.App.2d 425, 437.

“[A]gency interpretations, whether expressed in a regulation or less formal statement, are nothing more than legal opinions freighted with a diminished power to bind.” *Slocum v. State Board of Equalization* (2005) 134 Cal.App.4th 969, 974.

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**E. RELEVANT STATUTES AND REGULATIONS**

California Health & Safety Code § 25249.6 states: “No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10.”

California Health & Safety Code § 25249.7(k) states as follows:

(k) Any person who serves a notice of alleged violation pursuant to paragraph (1) of subdivision (d) for an exposure identified in subparagraph (A), (B), (C), or (D) or paragraph 1 . . . shall not file an action for that exposure against the alleged violator, or recover from the alleged violator in a settlement any payment in lieu of penalties or any reimbursement for costs and attorney’s fees, if all of the following conditions have been met:

(1) The notice given pursuant to paragraph (1) of subdivision (d) was served on or after the effective date of the act amending this section during the 2013-14 Regular Session and alleges that the alleged violator failed to provide clear and reasonable warning as required under Section 25249.6 regarding one or more of the following, and no other violation:

. . .

(B) An exposure to a chemical known to the state to cause cancer or reproductive toxicity in a food or beverage prepared and sold on the alleged violator’s premises primarily intended for immediate consumption on or off premises, to the extent of both of the following:

- (i) The chemical was not intentionally added.
- (ii) The chemical was formed by cooking or similar

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preparation of food or beverage components necessary to render the food or beverage palatable or to avoid microbiological contamination.

California Health & Safety Code § 25249.10(c) states: “Section 25249.6 shall not apply to any of the following: . . . (c) An exposure for which the person responsible can show that the exposure poses no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer, and that the exposure will have no observable effect assuming exposure at one thousand (1000) times the level in question for substances known to the state to cause reproductive toxicity, based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of such chemical pursuant to subdivision (a) of Section 25249.8. In any action brought to enforce Section 25249.6, the burden of showing that an exposure meets the criteria of this subdivision shall be on the defendant.”

27 California Code of Regulations § 25703 states as follows:

**§ 25703. Quantitative Risk Assessment.**

(a) A quantitative risk assessment which conforms to this section shall be deemed to determine the level of exposure to a listed chemical which, assuming daily exposure at that level, poses no significant risk. The assessment shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for listing the chemical as known to the state to cause cancer. In the absence of principles or assumptions scientifically more appropriate, based upon the available data, the following default principles and assumptions shall apply in any such assessment:

(1) Animal bioassay studies for quantitative risk assessment shall meet generally accepted scientific principles, including the thoroughness of experimental protocol, the degree to which dosing resembles the expected manner of human exposure, the temporal exposure pattern, the duration of study, the purity of test material, the number and size of exposed groups, the route of exposure, and the extent of tumor occurrence.

(2) The quality and suitability of available epidemiologic data shall be appraised to determine whether the study is appropriate as the basis of a quantitative risk assessment, considering such factors as the selection of the exposed and reference groups, reliable ascertainment of exposure, and completeness of follow-up. Biases and confounding factors shall be identified and quantified.

(3) Risk analysis shall be based on the most sensitive study deemed to be of sufficient quality.

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(4) The results obtained for the most sensitive study deemed to be of sufficient quality shall be applicable to all routes of exposure for which the results are relevant.

(5) The absence of a carcinogenic threshold dose shall be assumed and no-threshold models shall be utilized. A linearized multistage model for extrapolation from high to low doses, with the upper 95 percent confidence limit of the linear term expressing the upper bound of potency shall be utilized. Time-to-tumor models may be appropriate where data are available on the time of appearance of individual tumors, and particularly when survival is poor due to competing toxicity.

(6) Human cancer potency shall be derived from data on human or animal cancer potency. Potency shall be expressed in reciprocal milligrams of chemical per kilogram of bodyweight per day. Interspecies conversion of animal cancer potency to human cancer potency shall be determined by multiplying by a scaling factor equivalent to the ratio of human to animal bodyweight, taken to the one-fourth power.

(7) When available data are of such quality that physiologic, pharmacokinetic and metabolic considerations can be taken into account with confidence, they may be used in the risk assessment for inter-species, inter-dose, and inter-route extrapolations.

(8) When the cancer risk applies to the general population, human body weight of 70 kilograms shall be assumed. When the cancer risk applies to a certain subpopulation, the following assumptions shall be made, as appropriate:

<i>Subpopulation</i>	<i>Kilograms of Body Weight</i>
Man (18+ years of age)	70
Woman (18+ years of age)	58
Woman with conceptus	58
Adolescent (11-18 years of age)	40
Child (2-10 years of age)	20
Infant (0-2 years of age)	10

(b) For chemicals assessed in accordance with this section, the risk level which represents no significant risk shall be one which is calculated to result in one excess case of cancer in an exposed population of 100,000, assuming lifetime exposure at the level in question, except where sound considerations of public health support an alternative level, as, for example:

(1) where chemicals in food are produced by cooking necessary to render the food palatable or to avoid microbiological contamination; or

(2) where chlorine disinfection in compliance with all applicable state and federal safety standards is necessary to comply with sanitation requirements; or

(3) where a clean-up and resulting discharge is ordered and supervised by an appropriate governmental agency or court of competent jurisdiction.

**F. THE PROPOSED REGULATION**

According to the Notice published on OEHHA’s website, the proposed regulation would “add a new section to Article 7 of Title 27 of the California Code of Regulations, section 25704, stating that exposures to Proposition 65 listed chemicals in coffee that are produced as part of and inherent in the processes of roasting coffee beans and brewing coffee pose no significant risk of cancer.”

The proposed text for the new regulation would state: “Exposures to listed chemicals in coffee created by and inherent in the processes of roasting coffee beans or brewing coffee do not pose a significant risk of cancer.” Thus, the proposed regulation purports to declare, by administrative fiat, that an entire class of unidentified listed chemicals that are formed in the process of roasting coffee beans or brewing coffee, does not pose a significant risk of cancer.

The proposed regulation is similar to former 22 C.C.R. § 12713, which purported to provide categorical exemptions from the warning requirement of Proposition 65 for all exposures to foods, drugs, and cosmetics that complied with existing state and federal laws, whether or not No Significant Risk Levels for exposure to listed carcinogens in such foods, drugs, and cosmetics were exceeded. That regulation was challenged by a coalition of environmental and labor organizations claiming that it was inconsistent with and conflicted with Proposition 65, and it was held, by Judge Ronald R. Robie of the Sacramento Superior Court (now Associate Justice of the Third Appellate District) to be void and unenforceable. Judge Robie explained that “[b]y adopting § 12713 of the regulations and failing to provide a definition based upon a specific exposure to a particular listed chemical, the state has created a categorical exemption from the warning law . . . without specific regard to the chemicals involved.” Judge Robie concluded: “The . . . regulation (although intended to implement § 25249.10), cannot be squared with and is not consistent with that section and § 25249.6. It, therefore, is invalid on its face.” The Agency appealed Judge Robie’s ruling, but ultimately concluded that Judge Robie was correct, whereupon it agreed to repeal the invalid regulation.

The regulation that OEHHA now proposes suffers from the same defect as former 22 C.C.R. § 12713, because it purports to create a categorical exemption for exposures to listed chemicals from exposure to foods (i.e., all coffee beverages) in the absence of quantitative risk assessments demonstrating that No Significant Risk Levels for any such listed chemicals are not exceeded.

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**II. FIRST POINT - IN ADOPTING PROPOSITION 65, THE VOTERS EXPRESSED THEIR INTENT THAT THE INITIATIVE WOULD APPLY TO CARCINOGENS IN COFFEE**

The views of an Act’s authors are indicia of Voters’ intent that is considered in construing initiatives. *AFL-CIO v. Deukmejian* (1989) 212 Cal.App.3d 425, 436 n.4 (trial court took judicial notice of pre-election materials including newspaper articles, editorials, and interest-group articles in interpreting Proposition 65); *Carlos v. Superior Court* (1983) 35 Cal.3d 131, 144 n. 12 (quoting “[a]n article by ... one of the authors of the argument in favor of Proposition 7, [which] confirms this explanation of the [ballot argument and which was published] in the *Los Angeles Times*,” *People v. Tanner* (1979) 24 Cal.3d 514, 546, n. 5 (Newman, J., concurring) (noting views of the bill’s author reported in the *Los Angeles Times*); *American Tobacco Co. v. Superior Court* (1989) 208 Cal. App.3d 480, 487 (discerning intent from views stated in “numerous contemporaneous news accounts”).

In campaigning for Proposition 65, Carl Pope, Political Director of the Sierra Club and one of Proposition 65's co-authors, often used decaffeinated coffee containing methylene chloride as an example of a food that would require a cancer warning. Thus, an article titled “Consumers Tackle Toxics” by Paul Rauber published in *Consumers Cooperative of Berkeley, Inc.* explained that Proposition 65 “offers consumers tough new protections against the cancer ... causing chemicals ... which appear in every-day products from decaffeinated coffee to gasoline.”

Likewise, a brochure handed out throughout California during the campaign by the principal opposition group, Californians Against the Toxics Initiative, entitled “No on 65,” stated: “Even supporters of Proposition 65 admit that it would affect a wide range of everyday household products, including apple juice, shampoo and *decaffeinated coffee*. (Emphasis added). Decaffeination is performed as part of the process of roasting coffee beans. Methylene chloride, a listed carcinogen, has long been used to decaffeinate coffee.

Since pre-election materials of both proponents and opponents of Proposition 65 stated that it would apply to decaffeinated coffee (a roasted coffee product), it is clear that the Voters intended Proposition 65 to apply to carcinogens in coffee. Accordingly, the proposed regulation, which would exempt various unspecified listed carcinogens in coffee from Proposition 65 would contravene the intent of the Voters and would therefore be invalid. *Morris v. Williams* (1967) 67 Cal.2d 733, 748.

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**III. SECOND POINT - THE PROPOSAL MAKES RETROACTIVE PROVISIONS OF THE ACT THAT THE LEGISLATURE SPECIFIED ARE NOT TO BE RETROACTIVE**

In 2013 the California Legislature amended Proposition 65, pursuant to Assembly Bill 227, by adding subdivision (k) to Health and Safety Code §25249.7. This amendment prospectively exempted exposures to heat-formed carcinogens in coffee sold at retail stores for immediate consumption.

In amending the Act regarding ready-to-drink coffee, the Legislature clearly expressed its intent that the exemption for heat-formed carcinogens in ready-to-drink coffee not apply retroactively, by providing that “[a]ny person who serves a notice of alleged violation . . . shall not file an action for that exposure against the alleged violator, or recover from the alleged violator in a settlement any payment in lieu of penalties or any reimbursement for costs and attorney’s fees, if . . . the notice . . . was served on or after the effective date of the act amending this section during the 2013-14 Regular Session ....”

Thus, the Legislature expressed its intent that the amendments effected by Assembly Bill No. 227 would only apply *prospectively* and would *not have any retroactive application*. Indeed, it was because the amendment would not apply retroactively to past violations or any pending lawsuits that Assembly Bill No. 227 was essentially unopposed and was able to muster the votes of two-thirds of the members of the Senate and the Assembly, which super-majority of legislators is legally required to amend the Safe Drinking Water and Toxic Enforcement Act (Proposition 65).

The amendments effected by Assembly Bill No. 227 were specifically intended to apply prospectively to retail sales of ready-to-drink coffee, because (1) ready-to-drink coffee contains acrylamide, which is a chemical that is known to the State to cause cancer and reproductive toxicity, (2) acrylamide is present in brewed coffee because it is formed when coffee beans are roasted and acrylamide in roasted coffee beans dissolves in water when roasted coffee grounds are brewed, (3) ready-to-drink coffee is sold in coffee shops and restaurants, (4) ready-to-drink coffee is primarily intended for immediate consumption on or off retail premises, (5) acrylamide is not intentionally added to ready-to-drink coffee by retail coffee sellers, (6) acrylamide is formed by roasting coffee beans - a means of “cooking” “beverage components”; (7) roasting coffee beans is “necessary to render [coffee] palatable”; and (8) roasting coffee beans reduces “microbiological contamination” by thermally reducing levels of microorganisms that are present in raw coffee beans, including mycotoxins.

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Indeed, the language which now appears in subdivision (k) of Health & Safety Code § 25249.7 was drafted specifically to apply to heat-formed carcinogens in coffee, as ready-to-drink coffee is the only beverage that satisfies the statutory criteria.

The proposed regulation does not state whether OEHHHA intends the regulation to have only prospective effect or whether OEHHHA also intends the regulation to have retroactive effect.

“In construing statutes, there is a presumption against retroactive application unless the Legislature plainly has directed otherwise by means of ‘express language of retroactivity *or* . . . other sources [that] provide a clear and unavoidable implication that the Legislature intended retroactive application.” *Quarry v. Doe I* (2012) 53 Cal.4th 945, 955.

“Generally, the same rules of construction and interpretation which apply to statutes govern the construction and interpretation of administrative regulations.” *As You Sow v. Conbraco Industries* (2005) 135 Cal.App.4th 431, 459; quoting, *Union of American Physicians & Dentists v. Kizer* (1990) 223 Cal.App.3d 490, 504-505.

In amending Health & Safety Code § 25249.7 in 2013 to add subsection (k), exempting exposure to heat-formed carcinogens in coffee sold for immediate consumption (ready-to-drink coffee) from the warning requirement of Proposition 65, the Legislature clearly expressed its intent that the amendment would only apply prospectively and that it would have no retroactive application. Thus, the intent of the Legislature that the exemption only be accorded prospective effect is clear indeed.

In proposing its new regulation that would exempt all heat-formed carcinogens in coffee, OEHHHA has not expressly stated whether the proposed regulation is to be applied retroactively or not. The proposed regulation must therefore be presumed to apply only prospectively unless “other sources provide a clear and unavoidable implication” to the contrary. *Quarry, supra*. It does, however, appear that OEHHHA may intend its regulatory proposal to have retroactive effect, because the following language on page 5 of the Initial Statement of Reasons for the proposed regulation states:

“OEHHHA understands that this proposed regulation, if adopted, may cause businesses to ask courts to modify consent judgments or to seek reconsideration of court rulings and may result in businesses that are voluntarily providing warnings to choose not to do so.”

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However, OEHHA may not, by administrative regulation, make retroactive that which the Legislature, in amending Health & Safety Code § 25249.7 in 2013, decreed would not be retroactive!

Government Code § 11342.2 states: “Whenever by the express or implied terms of any statute a state agency has authority to adopt regulations to implement, interpret, make specific or otherwise carry out the provisions of the statute, no regulation adopted is valid or effective unless consistent and not in conflict with the statute and reasonably necessary to effectuate the purpose of the statute.”

“Even apart from the statutory limits, it is well established that the rulemaking power of an administrative agency does not permit the agency to exceed the scope of authority conferred on the agency by the Legislature.” *Bearden v. U.S. Borax, Inc.* (2006) 138 Cal.App.4th 429, 436; accord, *Agnew v. State Board of Equalization* (1999) 21 Cal.4th 310, 321.

“A ministerial officer may not . . . under the guise of a rule or regulation vary or enlarge the terms of a legislative enactment or compel that to be done which lies without the scope of the statute and which cannot be said to be reasonably necessary or appropriate to subserving or promoting the interests and purposes of the statute.” *Agnew v. State Board of Equalization* (1999) 21 Cal.4th 310, 321, citing *First Industrial Loan Co. v. Daugherty* (1945) 26 Cal.2d 545, 550.

“[A]n agency does not have discretion to promulgate regulations that are inconsistent with the governing statute, alter or amend the statute, or enlarge its scope.” *California School Boards Association v. State Board of Education* (2010) 191 Cal.App.4th 530, 544. “No matter how altruistic its motives, an administrative agency has no discretion to promulgate a regulation that is inconsistent with the governing statutes.” *Terhune v. Superior Court* (1998) 65 Cal.App.4th 864, 873, citing *Agricultural Labor Relations Board v. Superior Court* (1976) 16 Cal.3d 392, 419.

Since the Legislature amended Proposition 65 in 2013 by exempting Proposition 65 violations for exposures to heat-formed carcinogens in ready-to-drink coffee from the warning requirement of the Act, but since the Legislature clearly expressed its intent that the exemption only apply prospectively, the proposed regulation, by which OEHHA would accord a retroactive application to such exposures and violations, is inconsistent with and conflicts with the Legislature’s non-retroactive intent.

Since the regulation conflicts with the Legislature’s intent that the exemption for ready-to-drink coffee not be retroactive, it is unlawful and void. *Morris v. Williams* (1967) 67 Cal.2d 733, 748.

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To justify its action which contravenes the intent of the Legislature, Plaintiff suspects that OEHHA will attempt to argue that the proposed regulation has no retroactive effect because it merely “clarifies” existing law. Indeed, throughout the Notice of Proposed Rulemaking and the Initial Statement of Reasons, OEHHA repeatedly declares that the proposed regulation “simply clarifies that Proposition 65 listed chemicals in coffee pose no significant cancer risk.”

“A statute that merely *clarifies*, rather than changes, existing law does not operate retrospectively even if applied to transactions predating its enactment” “because the true meaning of the statute remains the same.” *McClung v. Employment Development Dept.* (2004) 34 Cal.4th 467-471. However, “[a] declaration that a statutory amendment merely clarified the law ‘cannot be given an obviously absurd effect, and the court cannot accept the Legislative statement that an unmistakable change in the statute is nothing more than a clarification and restatement of its original terms.’” *Id.* at 473. Indeed, “courts will not infer that the Legislature intended only to clarify the law unless the nature of the amendment clearly demonstrates that this is the case or the Legislature itself states in a particular amendment that its intent was to be declaratory of existing law.” *Medina v. Board of Retirement* (2003) 112 Cal.App.4th 864, 869-870.

Here, the Legislature has not claimed that the proposed regulation is merely declaratory of existing law, nor has OEHHA stated this in the Initial Statement of Reason for the proposed regulation. Moreover, it appears that OEHHA intends the proposed regulation to have retroactive effect, because OEHHA contemplates that consent judgments would be vacated and Proposition 65 warnings removed. In any event, the proposed regulation does not merely clarify existing law, because Health & Safety Code §25249.7(k) expressly creates a non-retroactive exemption for heat-formed carcinogens in coffee. Since the proposed regulation would apparently exempt heat-formed carcinogens in coffee retroactively, the proposed regulation does not merely “clarify” existing law, but rather purports to change the law, by making retroactive that which the Legislature decreed would only be prospective.

In conclusion, the proposed regulation cannot be interpreted to merely “clarify” existing law in order to avoid any issue of impermissible retroactive application, but rather must be acknowledged to change the law. Indeed, the proposed regulation squarely contradicts the Act by making retroactive that which the Legislature decreed would not be retroactive. Accordingly, the regulation is unlawful.

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**IV. THIRD POINT - PURSUANT TO 27 C.C.R. § 25703, CARCINOGENS IN COFFEE CANNOT BE DEEMED TO POSE NO SIGNIFICANT RISK UNLESS A QUANTITATIVE RISK ASSESSMENT SHOWS THAT THEIR NSRLS ARE NOT EXCEEDED**

“Generally, the rules that govern interpretation of statutes also govern interpretation of administrative regulations.” *Berkeley Hillside Preservation v. City of Berkeley* (2015) 60 Cal.4th 1086, 1097; *Hoitt v. Department of Rehabilitation* (2012) 207 Cal.App.4th 513, 523; *Price v. Starbucks Corporation* (2011) 192 Cal.App.4th 1136, 1145; *Guzman v. County of Monterey* (2009) 46 Cal.4th 887, 898; *California Drive-in Restaurant Assn. v. Clark* (1943) 22 Cal.2d 287, 292. “Our primary aim is to ascertain the intent of the administrative agency that issued the regulation.” *Hoitt v. Department of Rehabilitation, supra*, at p. 523; *Manriquez v. Gourley* (2003) 105 Cal.App.4th 1227, 1235.

An administrative regulation that provides an exemption to Proposition 65 must be narrowly construed so as not to “frustrate the purpose of the statute which it implements.” *Mateel Environmental Justice Foundation v. Edmund A. Gray Co.* (2004) 115 Cal.App.4th 8, 24, citing *People ex rel. Lungren v. Superior Court* (1996) 14 Cal.4th 294, 324 [as a “remedial statute,” Proposition 65 must be “construed broadly to accomplish [its] protective purpose.”].

“[I]t is well established that . . . section headings may properly be considered in determining legislative intent, and are entitled to considerable weight.” *People v. Hull* (1991) 1 Cal.4th 266, 272; accord *In re Carr* (2<sup>nd</sup> Dist. 1998) 65 Cal.App.4th 1525, 1530; *Bowland v. Municipal Court* (1976) 18 Cal.3d 479, 489; *People v. Navarro* (1972) 7 Cal.3d 248, 273.

Based on this principle of statutory interpretation, in determining the intent of 27 C.C.R. § 25703, “considerable weight” must be accorded to the heading “Quantitative Risk Assessment.”

“The chosen words of the regulation are the most reliable indicator of intent.” *Price v. Starbucks Corporation* (2011) 192 Cal.App.4th 1136, 1145; see also, *California School Employees Assn. v. Governing Board* (1994) 8 Cal.4th 333, 338.

Subsection (a), states: “A quantitative risk assessment which conforms to this section shall be deemed to determine the level of exposure to a listed chemical which, assuming daily exposure at that level, poses no significant risk. . . .” Subsection (b) states that “[f]or chemicals assessed in accordance with this section, the risk level which represents no significant risk shall be one which is calculated to result in one excess case of cancer in an exposed population of 100,000 . . .”

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Although Subsection (b) refers to “chemicals in food [that] are produced by cooking,” it “does not state that a quantitative risk assessment is not required for carcinogens in cooked foods. Thus, subsection 9b) cannot be construed as an exception to the quantitative risk assessment requirement.” *CERT v. Starbucks*, No. BC435759: Statement of Decision After Trial (Phase II), p. 15.

The Final Statement of Reasons for this section states: “Prior to this regulatory action, interested parties . . . requested that the Agency prevent the potential of liability under the Act as a result of the cooking of food. A petition from thirteen food, drug, cosmetic and medical device organizations requested that the Agency provide that exposure to chemicals which result from cooking pose no significant risk. [Citation.] *This proposal was not adopted, however, because the Agency could not be certain that all exposures which result from all manner of cooking in fact pose no significant risk.*” Final Statement of Reasons, 22 C.C.R. § 12703, at p. 5.<sup>1</sup>

Accordingly, to be exempt from Proposition 65’s warning requirement, a quantitative risk assessment that complies with the requirements of the regulation must demonstrate that the No Significant Risk Level for exposure to the carcinogen is not exceeded. “The Act does not allow any categorical exemption from liability for failure to warn except based upon a specific numerical value (i.e., a level of a listed chemical) that is calculated by means of a quantitative cancer risk assessment conducted in accordance with the Act.” *CERT v. Starbucks*, No. BC435759: Statement of Decision After Trial (Phase II), p. 16

“Proposition 65 provides an express exemption from liability for chemicals that occur naturally in food. However, such exemption does not apply to carcinogens that are formed during the cooking process of natural food.” *CERT v. Starbucks*, No. BC435759: Statement of Decision After Trial (Phase II), p. 16; 27 C.C.R. § 25501(a) - Exposure to a Naturally Occurring Chemical in a Food.

Although the Agency found, in adopting 27 C.C.R. § 25703, that it “*could not be certain that all exposures which result from all manner of cooking in fact pose no significant risk,*” Final Statement of Reasons, C.C.R. § 12703, at p. 5, it now proposes adopting a regulation that “exposure to listed chemicals in coffee created by . . . roasting coffee beans . . . do not pose a significant risk of cancer.”

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The only way that these contradictory assertions of the Agency could be reconciled is if, since the adoption of 27 C.C.R. § 25703, OEHHA conducted quantitative risk assessments for *all* listed carcinogens formed in roasting coffee beans and quantitatively determined that the No Significant Risk Level for each such chemical is not exceeded among coffee drinkers. However, nothing in the Initial Statement of Reasons for the proposed regulation indicates that OEHHA undertook quantitative risk assessments for every listed carcinogen that is formed in roasting coffee beans, or that OEHHA even attempted to identify every listed carcinogen that is formed in roasting coffee beans. OEHHA has certainly not published quantitative risk assessments for all listed carcinogens that are formed in roasting coffee beans, and it is likely OEHHA has not conducted quantitative risk assessments for any heat-formed carcinogens in coffee or it would have identified them in the Initial Statement of Reasons.

CERT is aware of only one quantitative risk assessment that OEHHA has undertaken for a listed carcinogen that is formed by roasting coffee beans - acrylamide. In 2005 OEHHA published a report titled “Characterization of Acrylamide Intake from Certain Foods” in which the Agency wrote:

In all cases the lower bound on acrylamide intake (population-based intake) exceeded 1.0 µg/day.... Based on the lower end of the range of consumption . . . , average consumption of coffee with 4.1 ppb or more acrylamide concentration would exceed the NSRL. Since actual consumption by coffee drinkers is greater, a lower concentration would also exceed the ... NSRL. The lower bound on what this would be is 1.9 ppb. Of the individual brewed coffee samples tested by FDA, 19 of 20 had levels higher than 4.1 ppb. All were above 1.9 ppb. Thus, OEHHA is fairly confident that the NSRL is exceeded for coffee drinkers.

Thus, the proposed regulation that declares no significant risk for any listed carcinogen in coffee is contrary to OEHHA’s own determination that the NSRL for acrylamide is exceeded in coffee drinkers.

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**V. FOURTH POINT - THE REGULATION CREATES A CATEGORICAL EXEMPTION FOR HEAT-FORMED CARCINOGENS IN COFFEE IN THE ABSENCE OF A QUANTITATIVE RISK ASSESSMENTS ESTABLISHING NO SIGNIFICANT RISK**

The proposed regulation states: “Exposures to listed chemicals in coffee created by and inherent in the process of roasting coffee beans or brewing coffee do not pose a significant risk of cancer.” Thus, the proposed regulation creates a categorical exemption from the cancer hazard warning requirement of Proposition 65 for heat-formed carcinogens in coffee. In this regard, the proposed regulation is similar to former 22 C.C.R. § 12713 which created a categorical exemption from the cancer hazard warning requirement of Proposition 65 for foods complying with other laws. As will be explained, that regulation was held to be inconsistent with and to conflict with Proposition 65, because it deemed exposure to carcinogens in food to pose no significant risk of cancer in the absence of quantitative risk assessments establishing no significant risks of cancer for exposure to carcinogens in food. Just as former 22 C.C.R. § 12713 was held to be unlawful because it deemed exposure to carcinogens in food to present no significant risk of cancer in the absence of quantitative risk assessments establishing such, the proposed regulation is likewise unlawful, because it too deems exposure to carcinogens in a food (coffee) to present no significant risk of cancer in the absence of any quantitative risk assessments establishing no significant risk for any heat-formed carcinogens in coffee.

Because the adoption, invalidation, and repeal of former 22 C.C.R. § 12713 may not be within OEHHA’s current institutional memory, a detailed recitation of the facts regarding adoption of the regulation, the lawsuit challenging its validity, its invalidation by the Sacramento Superior Court, and the Agency’s repeal of the regulation will therefore be provided.

On April 30, 1987, the Grocery Manufacturers Association (GMA), along with 19 members of the food and agriculture industry, submitted a petition to the Agency requesting that a standard of no significant risk be established for foods. Under that standard, any food that complies with state and federal food safety laws would be deemed not to pose a significant risk of cancer to the public.

On February 27, 1988, the Agency issued an emergency regulation concerning no significant risk levels for foods. “The emergency regulation . . . largely reflected the substance of the standard requested by GMA in the rulemaking proceedings. In particular, section 12713 generally provided that

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foods and substances used in foods that are lawful under state and federal food safety laws pose no significant risk of cancer within the meaning of the Act.

On May 31, 1988, a verified Complaint for Declaratory and Injunctive Relief was filed by the American Federation of Labor and Congress of Industrial Organizations (AFL-CIO), Environmental Resources Defense Council, Environmental Defense Fund, Sierra Club, Public Citizen, Inc., Campaign California, Citizens for a Better Environment, Silicon Valley Toxics Coalition, and Bernardo Huerta, against Defendants, George Deukmejian, Governor of the State of California; Clifford Allenby, Secretary of the Health and Welfare Agency; and Thomas E. Warriner, Deputy Secretary of the Health and Welfare Agency.

Paragraph 2 of the Complaint alleged that “defendants have thwarted the purposes of Proposition 65 by unlawfully exempting food, drugs, cosmetics and medical devices from the Act’s purview.” Paragraph 3 of the Complaint alleged that “The Act provides an exception to the warning requirement for carcinogens where ‘the person responsible can show that the exposure poses no significant risk [of cancer] assuming lifetime exposure at the level in question.’ § 25249.10(c). The Act places the burden of proof of demonstrating the absence of such significant risk on the person responsible for exposure to a carcinogen. *Id.*” Paragraph 4 of the Complaint alleged: “On February 27, 1988, the day the Act’s warning requirements became effective, defendants promulgated a set of ‘emergency regulations’ providing categorical exemptions from the ‘no significant risk’ provision for carcinogens found in food, drugs, cosmetics, or medical devices so long as they were being used in compliance with various preexisting state and federal laws. These exemptions were granted for all such products, across the board, even where no regulatory levels or controls have been set pursuant to such laws, and despite the fact that Proposition 65 was enacted because the People of California believed existing laws regulating carcinogens failed to adequately protect the public health.” The “emergency regulations” were identified in Paragraph 25 of the Complaint as being “contained in 22 CCR § 12713.”

Paragraph 5 of the Complaint alleged: “The regulations violate the Act by adopting in toto federal and state ‘standards’ without any factual or scientific basis for concluding that such standards meet the ‘no significant risk’ requirement of Proposition 65 and without regard to the adequacy or

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1 effectiveness of such standards to insure that carcinogens found in food, drugs, cosmetics or medical  
2 devices do not exceed the level representing ‘no significant risk’ within the meaning of the Act. Many  
3 of these standards have an insufficient scientific basis; others are for substances for which no cancer  
4 risk assessment has been performed; and many others are for substances for which regulatory levels  
5 have never even been established. Defendants’ regulations have therefore resulted, and will continue  
6 to result, in a serious obstacle to implementation of the Act in a timely and effective fashion.”

7 In the first paragraph of their prayer for relief, the plaintiffs prayed “That the court issue a  
8 declaratory judgment declaring that 22 CCR §1273 or any similar regulation that interprets Proposition  
9 65 as providing an automatic exemption from the ‘no significant risk’ requirement based upon  
10 conformity with other federal or state laws is unlawful.”

11 In the second paragraph of their prayer for relief, the plaintiffs prayed “The Court issue a  
12 preliminary and permanent injunction restraining defendant[s] . . . from enforcing Title 22 CCR  
13 §12713 and from promulgating any similar regulation that interprets Proposition 65 as providing an  
14 automatic exemption from the ‘no significant risk’ requirement based upon conformity with other  
15 federal or state laws.”

16 On June 2, 1988, the GMA filed a Motion for Leave to Intervene in the case. In its  
17 memorandum in support of its motion to intervene “on the side of defendants,” the GMA wrote: “GMA  
18 is an 80-year-old national trade association comprised of over 130 companies that manufacture food  
19 and other products sold in retail grocery stores throughout California and the United States. The  
20 member companies of GMA employ over 2.5 million people nationwide and have annual sales in  
21 excess of \$250 billion nationwide.”

22 The GMA wrote: “The provisions of the emergency regulation addressing foods were issued  
23 in response to a rulemaking petition submitted by GMA and other members of the food industry on  
24 April 30, 1987. The petition requested that a standard of no significant risk be established for foods  
25 that comply with California and federal food safety laws.” The GMA also acknowledged: “The  
26 challenged emergency regulation largely reflects the substance of the standard requested by GMA in  
27 the rulemaking proceedings.” GMA further alleged: “In the absence of section 12713’s authoritative  
28 determination, . . . GMA’s members would face great uncertainty and economic harm as a result of the

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multiplicity of enforcement actions permitted under the Act and the placement of the burden of proof on defendants in enforcement actions. . . . In addition, GMA’s members can have no assurance that they will be able to carry the difficult burden of proving a negative (an absence of significant risk) in each enforcement action that may be brought.” The GMA further alleged: “Petitioners seek invalidation of an emergency regulation that affects the entire food industry. If petitioners prevail, the regulation will be invalidated as to all persons subject to the regulation. Thus, as a practical matter, the decision in this action will have a direct effect on GMA and its members.”

On June 30, 1988 the defendants (the Governor and the Secretary and Undersecretary of the Health and Welfare Agency), filed their Answer to Complaint, denying that 22 CCR § 12713 was unlawful, and asserting as affirmative defenses that 22 CCR § 12713 does not contain any categorical exemptions from the warning requirement of Proposition 65 [Second Affirmative Defense], that the regulation “is a reasonable exercise of the Health and Welfare Agency’s authority to implement the provisions of the Act [Fourth Affirmative Defense], and “that the “Agency’s determination that the regulation . . . is reasonably necessary to effectuate the purposes of the statute is supported by substantial evidence.” [Fifth Affirmative Defense].

On August 11, 1988 the GMA’s motion for leave to intervene was granted and the GMA’s proposed complaint in intervention was filed.

On July 31, 1989, Plaintiffs filed their summary judgment motion; on September 5, 1989, the State Defendants and Intervenors filed their opposition papers; and on October 6, 1989 Plaintiffs filed their reply papers.

On November 7, 1989 the Honorable Ronald B. Robie (now appellate Justice Robie) issued a tentative ruling, which stated:

“The exemptions under §25249.10(c) (all references are to the Health and Safety Code) only apply to chemicals listed pursuant to § 25249.8 and further do not take effect until 12 months subsequent to the listing under §25249.8 . This means that when a chemical is listed, the person responsible for discharging or releasing the chemical has a one year grace period to show that the chemical meets the statutory requirement for an exemption from the warning requirement as authorized under § 25249.10.

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“The purpose of the statute, inter alia, is to protect the public and to ‘secure strict enforcement of the laws controlling hazardous chemicals.’ (§1(c) of the Initiative). The warning requirement is to aid in protecting the public by providing notice and to enforce the people’s right ‘[t]o be informed about exposures that cause cancer, birth defects and other reproductive harm.’ (§1(b) of the Initiative). In keeping with this policy, an exemption from the notice requirement must be strictly construed.

“By adopting § 12713 of the regulations and failing to provide a definition based upon a specific exposure to a particular listed chemical, the state has created a categorical exemption from the warning law for selected industries without specific regard to the chemicals involved.

“By defining ‘no significant risk’ solely in terms of approval by other governmental agencies it has also shifted the burden of showing the applicability of the exemption for a chemical from the responsible person upon whom the warning requirement is imposed. § 25249.6 imposes a warning requirement on every person knowingly discharging a chemical listed pursuant to § 25249.8 except during the first 12 months after listing (§ 25249.10(b)) or if a permanent exemption is applicable under § 25249.10(a)(c). Also, since the last sentence of the first paragraph of the regulation (22 CCR § 12713) places no time limits on developing specific levels to replace the interim blanket exemption, this, in effect, extends the 12 month grace period indefinitely. This is not consistent with the policies of the initiative.

“Under the regulation the warning requirement does not go into effect automatically under §25249, but rather arises only in an action to enforce the warning requirement under this section since the basis of the exemption is not exposure to any specific level of any specific chemical but rather the compliance with other regulatory laws. This would burden the public and others authorized to enforce the statute to individually sue to obtain a warning as to each listed chemical. At that time the discharger would be shielded by the regulation from presenting any substantive evidence as to risk and could rely on the fact it complies with various other regulatory programs. Defendant’s interpretation that the initiative accepted business as usual in regulatory terms as to these important industries is not correct.

“Defendant’s and interveners’ argument that anything except a blanket exemption for these industries will result in over warning is not a sufficient legal basis for departing from the requirements of the law.

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“The current regulation (although intended to implement §2249.10), cannot be squared with and is not consistent with that section and § 25249.5. It, therefore, is invalid on its face. The defendants have the authority to define ‘no significant risk’ and have done so in a manner more consistent with the law in other sections of the same regulation.”

On March 1, 1990 Judge Robie granted the plaintiffs’ motion for summary judgment, writing as follows:

“The court entered a tentative ruling on November 7, 1989. After hearing oral argument, the court requested further briefing by the parties. After receiving briefs from the plaintiff, defendants and interveners, the matter was submitted on February 9, 1990.

“The court, having considered the matters presented to it, now rules as follows:

“The court may properly invalidate a regulation where, on its face, the regulation is clearly and directly inconsistent with the plain language of the statute. . . .

“The exemptions under §25249.10(c) (all references are to the Health and Safety Code) only apply to chemicals listed pursuant to § 25249.8 and further do not take effect until 12 months subsequent to the listing under §25249.8. This means that when a chemical is listed, the person responsible for discharging or releasing the chemical has a one year grace period to show that the chemical meets the statutory requirement for an exemption from the warning requirement as authorized under §25249.10.

“The purpose of the statute, *inter alia*, is to protect the public and to ‘secure strict enforcement of the laws controlling hazardous chemicals.’ (§1a, §1(c) of the Initiative). The warning requirement is to aid in protecting the public by providing notice and to enforce the people’s right ‘[t]o be informed about exposures that cause cancer, birth defects and other reproductive harm.’ (§1(b) of the Initiative). In keeping with this policy, an exemption from the notice requirement must be strictly construed.

“By adopting § 12713 of the regulations and failing to provide a definition based upon a specific exposure to a particular listed chemical, the state has created a categorical exemption from the warning law for selected industries without specific regard to the chemicals involved.

“By defining ‘no significant risk’ solely in terms of approval by other governmental agencies it has also shifted the burden of showing the applicability of the exemption for a chemical from the

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1 responsible person upon whom the warning requirement is imposed. § 25249.6 imposes a warning  
2 requirement on every person knowingly discharging a chemical listed pursuant to § 25249.8 except  
3 during the first 12 months after listing (§25249.10(b) or if a permanent exemption is applicable under  
4 § 25249.10(a)(c). Also, since the last sentence of the first paragraph of the regulation (22 CCR §  
5 12713) places no time limits on developing specific levels to replace the interim blanket exemption,  
6 this, in effect, extends the 12 month grace period indefinitely. This is not consistent with the policies  
7 of the initiative. The discharger would be shielded by the regulation from presenting any substantive  
8 evidence as to risk and could rely on the fact it complies with various other regulatory programs.  
9 Defendants' interpretation that the Initiative accepted business as usual in regulatory terms as to these  
10 important industries is not correct.

11 "The current regulation (although intended to implement § 25249.10), cannot be squared with  
12 and is not consistent with that section and § 25249.5. It, therefore, is invalid on its face. The  
13 defendants have the authority to define 'no significant risk' and have done so in a manner more  
14 consistent with the law in other sections of the same regulation."

15 On April 16, 1990, Judge Robie signed a Judgment, which stated:

16 "In accordance with the Court's Ruling of March 1, 1990 granting Plaintiffs' Motion for  
17 Summary Judgment and denying Intervenors' Motion for Summary Judgment as moot, IT IS HEREBY  
18 ORDERED, DECREED and ADJUDGED as follows:

19 "1. Judgement shall be entered in favor of Plaintiffs American Federation of Labor and  
20 Congress of Industrial Organizations; Natural Resources Defense Council; Environmental Defense  
21 Fund; Sierra Club; Public Citizen, Inc.; Campaign California; Citizens for a Better Environment;  
22 Silicon Valley Toxics Coalition; and Bernardo Huerta, and against Defendants George Deukmejian,  
23 Governor of the State of California; Clifford Allenby, Secretary, Health and Welfare Agency; and  
24 Thomas E. Warriner, Deputy Secretary, Health and Welfare Agency, (hereafter "Defendants"), and  
25 against Intervenors the Grocery Manufacturers of America; the Proprietary Association; the  
26 Pharmaceutical Manufacturers Association; the Pharmaceutical Manufacturers Association, the  
27 Nonprescription Drug Manufacturers Association; the Cosmetic, Toiletry and Fragrance Association;  
28 and the Health Industry Manufacturers Association (hereafter "Intervenors").

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2. Section 12713 of Volume 22 of the California Code of Regulations (hereafter “22 CCR §12713”) is facially inconsistent with The Safe Drinking Water and Toxic Enforcement Act of 1986, H & S Code § 25249.5 et seq., and on that basis is declared null and void. . . .”

Just as former 22 C.C.R. § 12713 was held to be unlawful because it deemed exposure to carcinogens in food to present no significant risk of cancer in the absence of quantitative risk assessments establishing such, the proposed regulation is likewise unlawful, because it too deems exposure to carcinogens in a food (coffee) to present no significant risk of cancer in the absence of any quantitative risk assessments establishing no significant risk for any heat-formed carcinogens in coffee.

Just as former 22 C.C.R. § 12713 was held to be unlawful because it eliminated the defendant’s burden of proving that exposure to carcinogens in foods posed no significant risk of cancer, the proposed regulation is unlawful because it eliminates the defendant’s burden of proving that exposure to carcinogens in foods (i.e., heat-formed carcinogens in coffee) pose no significant risk of cancer.

**VI. FIFTH POINT - THE PROPOSED REGULATION BREACHES THE AGENCY’S AGREEMENT THAT IT WOULD NOT ADOPT ANY REGULATION DEEMING ANY EXPOSURE TO A CARCINOGEN IN FOOD NOT TO PRESENT A SIGNIFICANT RISK OF CANCER UNLESS BASED UPON SPECIFIC NUMERIC STANDARDS**

After judgment was entered in *AFL-CIO v. Deukmejian.*, the Agency and Intervenors appealed, and the case settled pursuant to a settlement agreement signed by counsel for the Governor and the Agency on December 23, 1992. The Settlement Agreement, which is available on OEHHA’s website, stated, in relevant part: “Defendants agree to repeal the regulation, effective July 1, 1993” (§12) and “agree that any provision which is adopted after the date of this agreement to define the term “no significant risk” of the Act for any food, drug, cosmetic or medical device product, and which employs standards derived from existing state or federal law shall be based upon specific numeric standards for the chemical, as evidenced by the rulemaking file. Such levels shall be consistent with and conform to sections 12703 and 12721 of title 22 of the California Code of Regulations.” (§13)

The proposed regulation violates the agreement of the Agency and the Governor in settling the *AFL-CIO v. Deukmejian* case that the Agency would not adopt any regulations that establish no significant risk in the absence of “specific numeric standards,” i.e., quantitative risk assessment.

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**VII. CONCLUSION**

For all the foregoing reasons, the proposed regulation is unlawful and should be withdrawn.

DATED: August 27, 2018

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\_\_\_\_\_  
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