SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF LOS ANGELES

COUNCIL FOR EDUCATION AND RESEARCH ON TOXICS, a California corporation, acting as a private attorney general in the public interest;

Plaintiff,

vs.

STARBUCKS CORPORATION, a Washington corporation; et al.,

Defendants.

COUNCIL FOR EDUCATION AND RESEARCH ON TOXICS, a California corporation, acting as a private attorney general in the public interest,

Plaintiff,

vs.

BRAD BARRY COMPANY, LTD., a California corporation, et al.,

Defendants.

CASE NO. BC435759

PROPOSED STATEMENT OF DECISION AFTER TRIAL (PHASE II)

(Defendants' Alternative Significant Risk Level Affirmative Defense)

Trial on Phase II of this case concerning Defendants' affirmative defense of "Alternative Significant Risk Level," proceeded on September 5, 2017. Testimony was presented, documentary evidence introduced, and argument by counsel heard on

September 5, 6, 7, 8, 11, 12, 18, 19, 20, 25, 26; October 2, 3; and November 21, 2017. The parties thereafter submitted post trial briefings on December 22, 2017 and January 19, 2018.

Having considered all the testimonial and documentary evidence, as well as the written briefs and argument of counsel, and being fully advised in the premises, the Court now renders its Statement of Decision (Phase II).

I. PROCEDURAL BACKGROUND

1. On April 13, 2010, Plaintiff Council for Education and Research on Toxics (referred to herein as "Plaintiff" or "CERT"), a California corporation, acting as a private attorney general in the public interest, instituted Los Angeles Superior Court Case No. BC435759 against nineteen (19) defendants allegedly selling ready-to-drink coffee to millions of customers throughout the State of California.

2. On April 22, 2010, Plaintiff filed its First Amended Complaint alleging causes of action for (1) violations of Proposition 65 (Health & Safety Code, section 25249.6)[1] and (2) declaratory relief.

3. On May 9, 2011, Plaintiff filed Los Angeles Superior Court Case No. BC461182 against forty-six (46) additional defendants, alleging causes of action for violation of Proposition 65 and declaratory relief.

4. With the addition of more defendants, a total of ninety-one (91) defendants appeared in both actions.

[1] Unless otherwise indicated, all code sections refer to the Health & Safety Code.

5. In essence, Plaintiff claimed that Defendants, sellers of ready-to-drink coffee, failed to provide warnings to consumers that the coffee sold contained high levels of acrylamide, a toxic and carcinogenic chemical, in violation of Proposition 65 (the "Safe Drinking Water and Toxic Enforcement Act of 1986").

6. Defendants filed answers to the complaints, denying the material allegations thereof and asserting various affirmative defenses, including: a) the statutory defenses of "no significant risk level" and "alternative risk level"; b) violation of the First Amendment to the United States Constitution (right of free speech); and c) federal preemption (Supremacy Clause).

7. On May 1, 2013, the Court ordered that Cases Nos. BC 435759 and BC 461182 be consolidated for all purposes, and ordered that:

a) trial in the matter be bifurcated;
b) Phase I of the trial cover Defendants' affirmative defenses of (1) "no significant risk level"; (2) First Amendment; and (3) federal preemption;
c) Phase II address the issue of Defendants' affirmative defense of "alternative significant risk level."

8. Pursuant to stipulation, the parties agreed that Phase I of trial be litigated by Defendants Green Mountain Coffee Roasters, Inc., the J.M. Smucker Company, Kraft Foods Global, and Starbucks Corporation; and all other Defendants be bound by the Court's final rulings regarding the issues decided in Phase I of the trial.

II. STATUTORY AND REGULATORY FRAMEWORK

9. Proposition 65 was enacted by a citizen initiative in 1986.

10. In *People ex rel. Lungren v. Superior Court* (1996) 14 Cal.4th 294, the California Supreme Court described the purposes of Proposition 65 at 306:

> "The purposes of Proposition 65 are stated in the preamble to the statute, section 1, which declares in pertinent part: 'The people of California find that hazardous chemicals pose a serious potential threat to their health and well-being, that state government agencies have failed to provide them with adequate protection, and that these failures have been serious enough to lead to investigations by federal agencies of the administration of California's toxic protection programs. The people therefore declare their rights: (a) to protect themselves and the water they drink against chemicals that cause cancer, birth defects, or other reproductive harm.' [Citation.]"

11. By approving Proposition 65, the People of California also declared their rights "[t]o be informed about exposures to chemicals that cause cancer, birth defects, or other reproductive harm. . . ." and "[t]o secure strict enforcement of the laws controlling hazardous chemicals and deter actions that threaten public health and safety. . . ." (Historical and Statutory Notes, West's Annotated California Codes, § 25249.5.)

12. Proposition 65 (section 25249.6) provides:

> *"Required warning before exposure to chemicals known to cause cancer or reproductive toxicity.*
>
> 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."

13. Section 25249.8(a) states:

"*List of chemicals known to cause cancer or reproductive toxicity.* On or before March 1, 1987, the Governor shall cause to be published a list of those chemicals *known to the state to cause cancer* or reproductive toxicity within the meaning of this chapter, and he [sic] shall cause such list to be revised and republished in light of additional knowledge at least once per year thereafter." (Emphasis added.)

14. Subsection (b) of section 25249.8 states:

"*A chemical is known to the state to cause cancer* . . . if in the opinion of the state's qualified experts it has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer . . . or if a body considered to be authoritative by such experts has formally identified it as causing cancer. . . or if an agency of the state or federal government has formally required it to be labeled or identified as causing cancer. . . ." (Emphasis added.)

15. Title 27 California Code of Regulations ("CCR"),[2] section 25102, provides the following definitions:

"The 'Act' means the Safe Drinking Water and Toxic Enforcement Act of 1986 (Health and Safety Code Sections 25249.5 et seq.) which was originally adopted by California voters as Proposition 65 on November 4. 1986.

"Committee' means the carcinogen Identification Committee and the

[2] All references to CCR are references to Title 27 of the California Code of Regulations.

Developmental and Reproductive Toxicant (DART) Identification Committee of the Office of Environmental Health Hazard Assessment Science Advisory Board.

"Lead agency' means the Office of Environmental Health Hazard Assessment . . . .

"Listed chemical' means a chemical listed pursuant to Section 25249.8(a) of the Act."

16. CCR section 25305 provides for the powers and duties of the Carcinogen Identification Committee as follows:

"(a) As an advisory body to the Governor and the lead agency, the Carcinogen Identification Committee may undertake the following activities:

(1) Render an opinion . . . as to whether specific chemicals have been clearly shown, through scientifically valid testing according to generally accepted principles, to cause cancer.

(2) Identify bodies which are considered to be authoritative and which have formally identified chemicals as causing cancer.

(3) Identify specific chemicals that are required by state or federal law to have been tested for potential to cause cancer but which have not been adequately tested.

(4) Review or propose standards and procedures for determining carcinogenicity of chemicals.

(5) Review or propose standards, procedures and definitions related to the implementation, administration or interpretation of the Act . . . .

(6) Review the scientific basis for proposed *No Significant Risk Levels (NSRLs)* and other regulations proposed for Sections 25701 through 25721 (No Significant Risk Levels)." (Emphasis added.)

17. CCR section 25306 provides:

"Chemicals Formally Identified by Authoritative Bodies

(a) Pursuant to Section 25249.8(b) of the Act, a chemical is known to the state to cause cancer or reproductive toxicity if the lead agency determines that an authoritative body has formally identified the chemical as causing cancer or reproductive toxicity, as specified in this section."

18. Section 25249.10 provides:

"*Exemption from warning requirement*

Section 25249.6 shall not apply to any of the following:

(a) An exposure for which federal law governs warning in a manner that preempts state authority.

***

(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, . . . *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.*" (Emphasis added.)

19. As to the "*no significant risk level*" exemption, CCR section 25701 provides:

"(a) The determination of whether a level of exposure to a chemical known to the state to cause cancer poses *no significant risk for purposes of Section 25249.10(c) of the Act shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of the chemical as known to the state to cause cancer*. Nothing in this article shall preclude a person from using evidence, standards, risk assessment methodologies, principles, assumptions or levels not described in this article to establish that a level of exposure to a listed chemical poses no significant risk." (Emphasis added.)

20. For a determination of the level exposure to a listed chemical, CCR section 25703 states with regard to *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 . . .* (Emphasis added.)

***

"(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 . . . .*" (Emphasis added.)

21. As to "*lifetime exposure*" CCR section 25721(b) provides:

"For purposes of the Act, '*lifetime exposure*' means the reasonably anticipated rate of exposure for an individual to a given medium of exposure measured over a lifetime of seventy years." (Emphasis added.)

22. In reference to the *level of exposure to chemicals causing cancer*, CCR section 25721(a) provides:

"For the purposes of the Act, '*level in question*' means the chemical concentration of a listed chemical for the exposure in question. The exposure in question includes the exposure for which the person in the course of doing business is responsible and does not include exposure to a listed chemical from any other source or product." (Emphasis added.)

23. The methodology for determining *level of exposure* is set forth in CCR section 25721(c):

"For purposes of Section 25249.10(c) of the Act, the *level of exposure* to a chemical listed as causing cancer, assuming *lifetime exposure* at the *level in question*, shall be determined by multiplying the *level in question* (stated in terms of a concentration of a chemical in a given medium) times the reasonably anticipated rate of exposure for an individual to the given medium of exposure measured over a lifetime of seventy years." (Emphasis added.)

24. With respect to exposures to consumer products, such as coffee, CCR section 25721(d)(4) states:

"For exposures to consumer products, lifetime exposure shall be calculated

using the average rate of intake or exposure for average users of the consumer product, and not on a per capita basis for the general population."

25. Proposition 65 is a remedial statute intended to protect the public and, therefore, is to be construed broadly to accomplish its protective purposes. (*Lungren, supra,* 14 Cal.4th at p. 314.)

26. "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; accord *Hoitt v. Department of Rehabilitation* (2012) 207 Cal.App.4th 513, 523; *Price v. Starbucks Corporation* (2011) 192 Cal.App.4th 1136, 1145.)

27. 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 *Lungren, supra*, 14 Cal.4th at p. 324 [as a "remedial statute," Proposition 65 must be "construed broadly to accomplish [its] protective purpose"].)

28. In *Exxon Mobile Corp. v. Office of Environmental Health Hazard Assessment* (2009) 169 Cal.App.4th 1264, a case in which plaintiff challenged the listing under Proposition 65 of a chemical known to cause reproductive toxicity, the Court of Appeal discussed the deference that courts should give to an agency's interpretation of their regulations at 1280:

"As a starting point, the interpretation of an administrative regulation is subject to the same principles as the interpretation of a statute . . . .

[W]here the language of the regulation is ambiguous, it is appropriate to consider the agency's interpretation. [Citation.] Indeed, we defer to an agency's interpretation of a regulation involving its area of expertise, unless the interpretation flies in the face of the clear language and purpose of the interpretive provision." (Citations and quotation marks omitted.)

III. ACRYLAMIDE

29. Acrylamide has been listed under Proposition 65 as a chemical known to the State of California to cause cancer since 1990.

30. Acrylamide was listed based on its formal identification as a carcinogen by the International Agency for Research on Cancer and the U.S. Environmental Protection Agency.

31. The parties do not dispute that acrylamide is listed by the State of California as a chemical causing cancer.

IV. ACRYLAMIDE IN COFFEE

32. When coffee beans are roasted, a chemical reaction occurs (the Maillard reaction) causing the asparagine and sugars in green coffee beans to produce the chemical acrylamide. As coffee is brewed, the acrylamide in the ground roasted coffee beans dissolves in water, resulting in acrylamide being present in brewed coffee.

33. The parties do not dispute that roasting coffee causes the release of the chemical acrylamide, and that brewed coffee contains acrylamide.

34. Defendants do not dispute that they failed to provide warnings to consumers that the ready to drink coffee they sold contained high levels of acrylamide.

V. CONCLUSIONS FROM PHASE I OF THE TRIAL

35. In Phase I of the trial in this case, the Court concluded that Defendants failed to meet their burden of proof by preponderance of evidence on their affirmative defenses of "no significant risk level," First Amendment, and federal preemption to avoid the requirement of cancer hazard warning labels as to the existence of acrylamide in brewed coffee.

VI. PROCEEDINGS ON PHASE II OF TRIAL

36. On February 26, 2016, Plaintiff and most of the Defendants stipulated that defenses other than the "alternative significant risk level" defense would be dismissed as to liability issues, but would be preserved for remedy issues only.

37. Thereafter, most of the Defendants agreed to Stipulations of Fact that served as the basis for Plaintiff's motion for summary adjudication of its prima facie case.

38. On June 1, 2016, the Court issued its Order Granting Motion for Summary Adjudication of Plaintiff's Prima Facie Case Against Stipulating Roaster Defendants; and on April 20, 2016 the Court issued its Order Granting Motion for Summary Adjudication of Plaintiff's Prima Face Case Against Stipulating Retailer Defendants.

39. On September 5, 2017 trial commenced on Defendants' Alternative Significant Risk Level (ASRL) defense.

VII. THE ALTERNATIVE SIGNIFICANT RISK LEVEL (ASRL) DEFENSE

40. The ASRL affirmative defense is grounded on an exemption to the cancer hazard warning requirement of Health and Safety Code section 25249.6 provided in Section 25249.10(c), which states that section 25249.6 shall not apply to "[a]n exposure for which the person responsible can show that the exposure poses on significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer . . . ."

41. Pursuant to CCR, section 25701, subdivisions (a) and (b), "[t]he determination of whether a level of exposure to a chemical known to the state to cause cancer poses no significant risk for purposes of section 25249.10(c) . . . shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of the chemical as known to the state to cause cancer[,]" and "[a] level of exposure to a listed chemical, assuming daily exposure at that level, shall be deemed to pose no significant risk provided that the level is determined . . . [b]y means of a quantitative risk assessment that meets the standards described in CCR section 25703."

42. Defendants' "Alternative Significant Risk Level" (ASRL) defense is based upon their interpretation of CCR section 25703, subdivision (b)(1) "Quantitative Risk Assessment," a part of Proposition 65's implementing regulations.

43. CCR section 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 . . .

* * *

(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; . . ." (Emphasis added.)

44. "[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* (1998) 65 Cal.App.4th 1525, 1530.)

45. In determining the intent of CCR section 25703, the Court may consider that this section is headed "Quantitative Risk Assessment," and the Court may accord "considerable weight" to this heading.

46. Subsection (a) of CCR section 25703 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. . . ." (Emphasis added.)

47. Subsection (b) of CCR section 25703 does not state that a quantitative risk assessment is not required for carcinogens in cooked foods. Thus, subsection (b) cannot be construed as an exception to the quantitative risk assessment requirement.

48. Subsection (b) indicates that chemicals are to be "assessed in accordance with this *section*" (i.e., the entirety of the *section*, including the provisions of subsection (a) which specify how quantitative risk assessments must be done) and that "for chemicals assessed in accordance with this section, the risk level which represents *no significant risk*" can be "*an alternative level*" "where chemicals in food are produced by cooking necessary to render the food palatable or to avoid microbiological contamination," and where "sound considerations of public health *support* such an alternative level."

49. The Court concludes that to prove their ASRL defense, Defendants must proffer a quantitative risk assessment that satisfies the requirements of CCR section 25703 – the "Quantitative Risk Assessment" regulation.

50. Section 25703 allows a defendant to establish an exemption to liability by proving that exposure to the carcinogen in its product does not exceed an "alternative risk level" derived by a "quantitative risk assessment" where "sound considerations of public health support an alternative level."

51. In order to prevail on their alternative risk level defense in this case Defendants would have to: a) establish that acrylamide is created by cooking or processing necessary to render the coffee safe or palatable; b) demonstrate that "sound considerations of public health" justify applying an alternative (less strict) risk level; and c) present persuasive evidence of what would be an appropriate alternative risk level, taking into account the identified public health considerations. If any of these three factors are absent, the alternative risk level defense would not apply.

52. Thus, in order for Defendants to succeed on their ASRL defense under CCR section 25703, Defendants must prove that (1) "sound considerations of public health support an alternative level" for exposure to acrylamide in their coffee products, (2) such

"alternative level" is derived from a "quantitative risk assessment," and (3) that "assuming lifetime exposure" to the products, the exposure to acrylamide from Defendants' coffee products is below such "alternative level."

53. 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.

54. The fact that Defendants do not intentionally add acrylamide to their products is not a defense to liability under Proposition 65.

55. 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.

56. To quantify the risk of cancer from exposure to acrylamide in drinking coffee it is necessary to conduct a quantitative assessment of the risk of developing cancer from exposure to acrylamide in coffee.

57. The Health and Welfare Agency (the "Agency"), charged with implementing the Act at the time, in its Final Statement of Reasons, 22 California Code of Regulations, Division 2, for CCR section 12703, stated that its ". . . intention is that, whatever method of cocking is chosen, the amount of cooking which is necessary to avoid bacterial contamination or to render the food palatable should provide a basis for the application of a risk level other than a risk of 1×10^{-5}. [1 in 100,000]" (Final Statement of Reasons, CCR § 12703, at p. 7.)

58. The Final Statement of Reasons also provided the following:

"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, CCR § 12703, at p. 5.)

59. The Agency's Report continued:

a) "Several commenters to section 12501 of the regulations recommended that chemicals formed by cooking be considered as 'naturally occurring' chemicals which do not cause an exposure under the Act. [Citation.] This recommendation was also not adopted, since the definition of 'naturally occurring,' which was derived from federal regulation [ ], requires an absence of human activity, and cooking is a human activity." (Final Statement of Reasons, CCR § 12703, at p. 5.)

b) "This approach (assessment of the cancer risk and the health benefit to be obtained from the food) has the advantage of flexibility. It does not establish a rigid line with which businesses must comply or face liability. Necessary cooking may result in varying amounts of chemical by-products. To the extent that the cooking is necessary to avoid contamination or to render the food palatable, the level which is considered to pose no significant risk

should vary with the level of chemical by-product, and the public health benefit to be obtained." (Final Statement of Reasons, CCR § 12703, at p. 6.)

c) "The Agency's intention is that, whatever method of cooking is chosen, the amount of cooking which is necessary to avoid bacterial contamination or to render the food palatable should provide a basis for the application of a risk level other than a risk of 1×10^{-5}." (Final Statement of Reasons, CCR § 12703, at p. 7.)

VIII. DEFENDANTS' EVIDENCE AT TRIAL

60. Defendants' risk assessment expert, Lorenz Rhomberg, Ph.D, did not calculate an ASRL for acrylamide in coffee by means of any quantitative cancer risk assessment.

61. Dr. Rhomberg's risk assessment was not based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for listing acrylamide pursuant to section 25249.8.

62. Although Dr. Rhomberg performed a quantitative risk assessment of acrylamide, he did not undertake a quantitative risk assessment for acrylamide in coffee. Hence, he did not perform a risk assessment for a carcinogen (acrylamide) in a mixture (coffee). Dr. Rhomberg failed to undertake the type of quantitative risk assessment that is necessary to quantify the risk of cancer from exposure to acrylamide in coffee.

63. Dr. Rhomberg did not calculate an ASRL based on sound considerations of public health for exposure to acrylamide from consumption of coffee, as is required by CCR section 25703(b).

64. Rather than calculating an ASRL based on sound considerations of public health, Dr. Rhomberg simply did a quantitative risk assessment for acrylamide and applied it to calculate the 10^{-4} (1 in 10,000) risk level for humans.

65. Dr. Rhomberg's analysis is thus not "based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for listing." (Section 25249.10(c).)

66. Defendants relied on the testimony of Dr. David Kessler to provide a rationale for an ASRL that is 10 times greater than the No Significant Risk Level (NSRL) for acrylamide. Dr. Kessler provided two rationales for an ASRL that is 10 times greater than the NSRL for acrylamide (i.e., an ASRL based on a cancer risk of 10^{-4} rather than 10^{-5}): (1) that the FDA had regulated carcinogens in two foods (PCBs in fish and arsenic in rice) at the 10^{-4} standard rather than FDA's usual 10^{-6} standard; and (2) that the Office of Environmental Health Hazard Assessment (OEHHA) had once proposed (but ultimately rejected) regulating acrylamide in bread and cereal at a 10^{-4} level. These rationales lack scientific support, are not based on sound considerations of public health, and provide inadequate grounds for an alternative risk level.

67. Defendants did not present quantitative risk assessments for Defendants' individual products.

68. Defendants presented evidence of data generated by Covance Laboratories of the acrylamide concentrations in Defendants' brewed coffee products. This evidence was scientifically unreliable and inadmissible because the analytical chemistry method that Covance used to test Defendants' products was a novel and untested scientific technique that has not been generally accepted in the scientific community. (*People v. Kelly* (1976) 17 Cal.3d 24, 30-31; see *Sargon Enterprises, Inc., v. University of South Cal.* (2012) 55

Cal.4th 747, 769; *People v. Leahy* (1994) 8 Cal.4th 587, 604-13.)

69. Covance's analytical method was not executed using proper scientific procedures, and generated inaccurate results in its analyses. As a consequence, Covance's analytic data of the acrylamide levels of Defendants' brewed coffee products is also unreliable and inadmissible.

70. Defendants' witness who testified about the Covance data, Darryl Sullivan, is not academically qualified to explain the science underlying the method used by Covance or to testify whether the method is generally accepted in the scientific community. Thus, a proper foundation was not laid for the admissibility of the Covance data.

71. The testimony of Defendants' expert witness, Dr. Carolyn Scrafford, with respect to exposure assessment for each of Defendants' products, was based upon the scientifically unreliable and inadmissible Covance data of the acrylamide concentrations of Defendants' products.

72. Because the testimony of Defendants' expert, Dr. Scrafford, regarding exposure assessment, was based on unreliable data generated by Covance Laboratories of acrylamide levels in Defendants' brewed coffee products, her testimony is also without proper foundation and inadmissible.

IX. DEFENDANTS' BURDEN OF PROVING THEIR ALTERNATIVE RISK LEVEL DEFENSE

73. "[T]he burden of showing that an exposure meets *the criteria*" of the Alternative Significant Risk Level exemption "shall be on the defendant." (Section 25249.10, emphasis added.)

74. Defendants did not offer substantial evidence to quantify any minimum amount of acrylamide in coffee that might be necessary to reduce microbiological contamination or render coffee palatable. Rather, Defendants argued that acrylamide levels in coffee cannot be reduced at all without negatively affecting safety and palatability.

75. While Plaintiff offered evidence that consumption of coffee increases the risk of harm to the fetus, to infants, to children and to adults, Defendants' medical and epidemiology experts testified that they had no opinion on causation.

76. Although evidence showed that roasting coffee beans is necessary to make coffee palatable and roasting coffee beans reduces microbiological contamination in coffee, Defendants' proffered evidence that coffee itself confers some benefit to human health was not persuasive and was refuted by Plaintiffs' evidence.

77. Defendants failed to satisfy their burden of proving by a preponderance of evidence that consumption of coffee confers a benefit to human health.

78. Since Defendants failed to prove that coffee confers any human health benefits, Defendants have failed to satisfy their burden of proving that sound considerations of public health support an alternate risk level for acrylamide in coffee.

79. To establish their ASRL defense, Defendants must prove an alternative risk level for acrylamide in coffee by means of a scientifically valid quantitative risk assessment.

80. Defendants did not conduct a quantitative assessment of the risk of cancer from exposure to acrylamide in coffee.

81. Defendants did not present a quantitative risk assessment that quantitatively

compared any alleged health benefits with any adverse effects of coffee consumption.

82. Assuming *arguendo* that the testimony of Darryl Sullivan and Dr. Scrafford, and the data of Covance Laboratories was admissible in evidence and considered by the Court, Defendants nevertheless failed to meet their burden on the ASRL affirmative defense based on the credibility of witnesses and the weight of evidence being against Defendants.

83. Accordingly, the Court rules against Defendants and in favor of Plaintiff on Defendants' Alternative Significant Risk Level affirmative defense.

X. CONCLUSIONS

84. Defendants have the burden of proof to establish their Alternative Significant Risk Level affirmative defense by a preponderance of the evidence.

85. Defendants have failed to meet their burden of proof on their Alternative Significant Risk Level affirmative defense.

DATED: March 28, 2018

HONORABLE ELIHU M. BERLE
Superior Court of California
Los Angeles County