

MAR 28 2018

Sherri R. Carter, Executive Officer/Clerk

By Kelly Jameson, Deputy

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.

CASE NO. BC435759

**PROPOSED STATEMENT OF
DECISION AFTER TRIAL (PHASE II)**

**(Defendants' Alternative Significant
Risk Level Affirmative Defense)**

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.

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

1 September 5, 6, 7, 8, 11, 12, 18, 19, 20, 25, 26; October 2, 3; and November 21, 2017.
2 The parties thereafter submitted post trial briefings on December 22, 2017 and January
3 19, 2018.
4

5 Having considered all the testimonial and documentary evidence, as well as the
6 written briefs and argument of counsel, and being fully advised in the premises, the Court
7 now renders its Statement of Decision (Phase II).
8

9 I. PROCEDURAL BACKGROUND
10

11 1. On April 13, 2010, Plaintiff Council for Education and Research on Toxics
12 (referred to herein as "Plaintiff" or "CERT"), a California corporation, acting as a private
13 attorney general in the public interest, instituted Los Angeles Superior Court Case No.
14 BC435759 against nineteen (19) defendants allegedly selling ready-to-drink coffee to
15 millions of customers throughout the State of California.
16

17 2. On April 22, 2010, Plaintiff filed its First Amended Complaint alleging causes of
18 action for (1) violations of Proposition 65 (Health & Safety Code, section 25249.6)¹ and
19 (2) declaratory relief.
20

21 3. On May 9, 2011, Plaintiff filed Los Angeles Superior Court Case No. BC461182
22 against forty-six (46) additional defendants, alleging causes of action for violation of
23 Proposition 65 and declaratory relief.
24

25 4. With the addition of more defendants, a total of ninety-one (91) defendants
26 appeared in both actions.
27

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

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

5
6 6. Defendants filed answers to the complaints, denying the material allegations
7 thereof and asserting various affirmative defenses, including: a) the statutory defenses of
8 “no significant risk level” and “alternative risk level”; b) violation of the First
9 Amendment to the United States Constitution (right of free speech); and c) federal
10 preemption (Supremacy Clause).

11
12 7. On May 1, 2013, the Court ordered that Cases Nos. BC 435759 and BC 461182 be
13 consolidated for all purposes, and ordered that:

- 14
15 a) trial in the matter be bifurcated;
16 b) Phase I of the trial cover Defendants’ affirmative defenses of (1) “no
17 significant risk level”; (2) First Amendment; and (3) federal preemption;
18 c) Phase II address the issue of Defendants’ affirmative defense of “alternative
19 significant risk level.”

20
21 8. Pursuant to stipulation, the parties agreed that Phase I of trial be litigated by
22 Defendants Green Mountain Coffee Roasters, Inc., the J.M. Smucker Company, Kraft
23 Foods Global, and Starbucks Corporation; and all other Defendants be bound by the
24 Court’s final rulings regarding the issues decided in Phase I of the trial.

25
26 II. STATUTORY AND REGULATORY FRAMEWORK

27
28 9. Proposition 65 was enacted by a citizen initiative in 1986.

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

4 “Lead agency” means the Office of Environmental Health Hazard
5 Assessment

6 “Listed chemical” means a chemical listed pursuant to Section 25249.8(a)
7 of the Act.”

8
9 16. CCR section 25305 provides for the powers and duties of the Carcinogen
10 Identification Committee as follows:

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

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

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

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

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

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

26 (6) Review the scientific basis for proposed *No Significant Risk*
27 *Levels (NSRLs)* and other regulations proposed for Sections 25701 through
28 25721 (No Significant Risk Levels).” (Emphasis added.)

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1 17. CCR section 25306 provides:

2 *“Chemicals Formally Identified by Authoritative Bodies*

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

7
8 18. Section 25249.10 provides:

9
10 *“Exemption from warning requirement*

11
12 Section 25249.6 shall not apply to any of the following:

13
14 (a) An exposure for which federal law governs warning in a manner that
15 preempts state authority.

16 ***

17 (c) An exposure for which the person responsible can show that the
18 exposure poses *no significant risk* assuming *lifetime exposure* at the *level in*
19 *question* for substances known to the state to cause cancer, . . . *based on*
20 *evidence* and *standards of comparable scientific validity to the evidence*
21 *and standards which form the scientific basis for the listing of such*
22 *chemical* pursuant to subdivision (a) of Section 25249.8. In any action
23 brought to enforce Section 25249.6, the *burden of showing that an*
24 *exposure meets the criteria of this subdivision shall be on the defendant.”*

25 (Emphasis added.)

26
27 19. As to the “*no significant risk level*” exemption, CCR section 25701 provides:
28

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1 “(a) The determination of whether a level of exposure to a chemical known
2 to the state to cause cancer poses *no significant risk for purposes of Section*
3 *25249.10(c) of the Act shall be based on evidence and standards of*
4 *comparable scientific validity to the evidence and standards which form the*
5 *scientific basis for the listing of the chemical as known to the state to cause*
6 *cancer. Nothing in this article shall preclude a person from using evidence,*
7 *standards, risk assessment methodologies, principles, assumptions or levels*
8 *not described in this article to establish that a level of exposure to a listed*
9 *chemical poses no significant risk.” (Emphasis added.)*

10
11 20. For a determination of the level exposure to a listed chemical, CCR section 25703
12 states with regard to *Quantitative Risk Assessment*:

13
14 “(a) A quantitative risk assessment which conforms to this section shall be
15 deemed to determine the *level of exposure* to a listed chemical which,
16 assuming daily exposure at that level, poses no significant risk. The
17 *assessment shall be based on evidence and standards of comparable*
18 *scientific validity to the evidence and standards which form the scientific*
19 *basis for listing the chemical as known to the state to cause cancer . . .*
20 (Emphasis added.)

21 ***

22 “(b) For chemicals assessed in accordance with this section, the risk level
23 which represents no significant risk shall be one which is calculated to
24 result in one excess case of cancer in an exposed population of 100,000,
25 assuming *lifetime exposure* at the *level in question*, except where sound
26 considerations of public health support an *alternative level*”
27 (Emphasis added.)

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1 21. As to “lifetime exposure” CCR section 25721(b) provides:

2 “For purposes of the Act, ‘lifetime exposure’ means the reasonably
3 anticipated rate of exposure for an individual to a given medium of
4 exposure measured over a lifetime of seventy years.” (Emphasis added.)
5

6 22. In reference to the *level of exposure to chemicals causing cancer*, CCR section
7 25721(a) provides:

8
9 “For the purposes of the Act, ‘level in question’ means the chemical
10 concentration of a listed chemical for the exposure in question. The
11 exposure in question includes the exposure for which the person in the
12 course of doing business is responsible and does not include exposure to a
13 listed chemical from any other source or product.” (Emphasis added.)
14

15 23. The methodology for determining *level of exposure* is set forth in CCR section
16 25721(c):

17
18 “For purposes of Section 25249.10(c) of the Act, the *level of exposure* to a
19 chemical listed as causing cancer, assuming *lifetime exposure* at the *level in*
20 *question*, shall be determined by multiplying the *level in question* (stated in terms
21 of a concentration of a chemical in a given medium) times the reasonably
22 anticipated rate of exposure for an individual to the given medium of exposure
23 measured over a lifetime of seventy years.” (Emphasis added.)
24

25 24. With respect to exposures to consumer products, such as coffee, CCR section
26 25721(d)(4) states:

27
28 “For exposures to consumer products, lifetime exposure shall be calculated

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1 [W]here the language of the regulation is ambiguous, it is appropriate to
2 consider the agency's interpretation. [Citation.] Indeed, we defer to an
3 agency's interpretation of a regulation involving its area of expertise, unless
4 the interpretation flies in the face of the clear language and purpose of the
5 interpretive provision." (Citations and quotation marks omitted.)
6

7 III. ACRYLAMIDE
8

9 29. Acrylamide has been listed under Proposition 65 as a chemical known to the State
10 of California to cause cancer since 1990.
11

12 30. Acrylamide was listed based on its formal identification as a carcinogen by the
13 International Agency for Research on Cancer and the U.S. Environmental Protection
14 Agency.
15

16 31. The parties do not dispute that acrylamide is listed by the State of California as a
17 chemical causing cancer.
18

19 IV. ACRYLAMIDE IN COFFEE
20

21 32. When coffee beans are roasted, a chemical reaction occurs (the Maillard reaction)
22 causing the asparagine and sugars in green coffee beans to produce the chemical
23 acrylamide. As coffee is brewed, the acrylamide in the ground roasted coffee beans
24 dissolves in water, resulting in acrylamide being present in brewed coffee.
25

26 33. The parties do not dispute that roasting coffee causes the release of the chemical
27 acrylamide, and that brewed coffee contains acrylamide.
28

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

3
4 V. CONCLUSIONS FROM PHASE I OF THE TRIAL
5

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

11
12 VI. PROCEEDINGS ON PHASE II OF TRIAL
13

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

17
18 37. Thereafter, most of the Defendants agreed to Stipulations of Fact that served as the
19 basis for Plaintiff’s motion for summary adjudication of its prima facie case.

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

25
26 39. On September 5, 2017 trial commenced on Defendants’ Alternative Significant
27 Risk Level (ASRL) defense.
28

1 VII. THE ALTERNATIVE SIGNIFICANT RISK LEVEL (ASRL) DEFENSE

2
3 40. The ASRL affirmative defense is grounded on an exemption to the cancer hazard
4 warning requirement of Health and Safety Code section 25249.6 provided in Section
5 25249.10(c), which states that section 25249.6 shall not apply to “[a]n exposure for
6 which the person responsible can show that the exposure poses on significant risk
7 assuming lifetime exposure at the level in question for substances known to the state to
8 cause cancer”

9
10 41. Pursuant to CCR, section 25701, subdivisions (a) and (b), “[t]he determination of
11 whether a level of exposure to a chemical known to the state to cause cancer poses no
12 significant risk for purposes of section 25249.10(c) . . . shall be based on evidence and
13 standards of comparable scientific validity to the evidence and standards which form the
14 scientific basis for the listing of the chemical as known to the state to cause cancer[,]”
15 and “[a] level of exposure to a listed chemical, assuming daily exposure at that level,
16 shall be deemed to pose no significant risk provided that the level is determined . . . [b]y
17 means of a quantitative risk assessment that meets the standards described in CCR
18 section 25703.”

19
20 42. Defendants’ “Alternative Significant Risk Level” (ASRL) defense is based upon
21 their interpretation of CCR section 25703, subdivision (b)(1) “Quantitative Risk
22 Assessment,” a part of Proposition 65’s implementing regulations.

23
24 43. CCR section 25703. Quantitative Risk Assessment.

25 (a) A quantitative risk assessment which conforms to this *section* shall
26 be deemed to determine the level of exposure to a listed chemical which,
27 assuming daily exposure at that level, poses no significant risk. The
28 assessment shall be based on evidence and standards of comparable scientific

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1 validity to the evidence and standards which form the scientific basis for
2 listing the chemical as known to the state to cause cancer . . .

3 * * *

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

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

11 (Emphasis added.)

12
13 44. “[I]t is well established that . . . section headings may properly be considered in
14 determining legislative intent, and are entitled to considerable weight.” (*People v. Hull*
15 (1991) 1 Cal.4th 266, 272; accord *In re Carr* (1998) 65 Cal.App.4th 1525, 1530.)

16
17 45. In determining the intent of CCR section 25703, the Court may consider that this
18 section is headed “Quantitative Risk Assessment,” and the Court may accord
19 “considerable weight” to this heading.

20
21 46. Subsection (a) of CCR section 25703 states: “A quantitative risk assessment which
22 conforms to *this section* shall be deemed to determine the level of exposure to a listed
23 chemical which, assuming daily exposure at that level, poses no significant risk. . . .”
24 (Emphasis added.)

25
26 47. Subsection (b) of CCR section 25703 does not state that a quantitative risk
27 assessment is not required for carcinogens in cooked foods. Thus, subsection (b) cannot
28 be construed as an exception to the quantitative risk assessment requirement.

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

8
9 49. The Court concludes that to prove their ASRL defense, Defendants must proffer a
10 quantitative risk assessment that satisfies the requirements of CCR section 25703 – the
11 “Quantitative Risk Assessment” regulation.

12
13 50. Section 25703 allows a defendant to establish an exemption to liability by proving
14 that exposure to the carcinogen in its product does not exceed an “alternative risk level”
15 derived by a “quantitative risk assessment” where “sound considerations of public health
16 support an alternative level.”

17
18 51. In order to prevail on their alternative risk level defense in this case Defendants
19 would have to: a) establish that acrylamide is created by cooking or processing necessary
20 to render the coffee safe or palatable; b) demonstrate that “sound considerations of public
21 health” justify applying an alternative (less strict) risk level; and c) present persuasive
22 evidence of what would be an appropriate alternative risk level, taking into account the
23 identified public health considerations. If any of these three factors are absent, the
24 alternative risk level defense would not apply.

25
26 52. Thus, in order for Defendants to succeed on their ASRL defense under CCR
27 section 25703, Defendants must prove that (1) “sound considerations of public health
28 support an alternative level” for exposure to acrylamide in their coffee products, (2) such

1 “alternative level” is derived from a “quantitative risk assessment,” and (3) that
2 “assuming lifetime exposure” to the products, the exposure to acrylamide from
3 Defendants’ coffee products is below such “alternative level.”
4

5 53. Proposition 65 provides an express exemption from liability for chemicals that
6 occur naturally in food. However, such exemption does not apply to carcinogens that are
7 formed during the cooking process of natural food.
8

9 54. The fact that Defendants do not intentionally add acrylamide to their products is
10 not a defense to liability under Proposition 65.
11

12 55. The Act does not allow any categorical exemption from liability for failure to
13 warn except based upon a specific numerical value (i.e., a level of a listed chemical) that
14 is calculated by means of a quantitative cancer risk assessment conducted in accordance
15 with the Act.
16

17 56. To quantify the risk of cancer from exposure to acrylamide in drinking coffee it is
18 necessary to conduct a quantitative assessment of the risk of developing cancer from
19 exposure to acrylamide in coffee.
20

21 57. The Health and Welfare Agency (the “Agency”), charged with implementing the
22 Act at the time, in its Final Statement of Reasons, 22 California Code of Regulations,
23 Division 2, for CCR section 12703, stated that its “. . . intention is that, whatever method
24 of cooking is chosen, the amount of cooking which is necessary to avoid bacterial
25 contamination or to render the food palatable should provide a basis for the application of
26 a risk level other than a risk of 1×10^{-5} . [1 in 100,000]” (Final Statement of Reasons,
27 CCR § 12703, at p. 7.)
28

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1 58. The Final Statement of Reasons also provided the following:
2

3 “Prior to this regulatory action, interested parties . . . requested that the
4 Agency prevent the potential of liability under the Act as a result of the
5 cooking of food. A petition from thirteen food, drug, cosmetic and medical
6 device organizations requested that the Agency provide that exposure to
7 chemicals which result from cooking pose no significant risk. [Citation.]
8 *This proposal was not adopted, however, because the Agency could not be*
9 *certain that all exposures which result from all manner of cooking in fact*
10 *pose no significant risk.” (Final Statement of Reasons, CCR § 12703, at p.*
11 *5.)*
12

13 59. The Agency’s Report continued:
14

15 a) “Several commenters to section 12501 of the regulations recommended
16 that chemicals formed by cooking be considered as ‘naturally occurring’
17 chemicals which do not cause an exposure under the Act. [Citation.] This
18 recommendation was also not adopted, since the definition of ‘naturally
19 occurring,’ which was derived from federal regulation [], requires an
20 absence of human activity, and cooking is a human activity.” (Final
21 Statement of Reasons, CCR § 12703, at p. 5.)
22

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

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

3
4 c) “The Agency’s intention is that, whatever method of cooking is chosen,
5 the amount of cooking which is necessary to avoid bacterial contamination or
6 to render the food palatable should provide a basis for the application of a
7 risk level other than a risk of 1×10^{-5} .” (Final Statement of Reasons, CCR §
8 12703, at p. 7.)

9
10 **VIII. DEFENDANTS’ EVIDENCE AT TRIAL**

11
12 60. Defendants’ risk assessment expert, Lorenz Rhomberg, Ph.D, did not calculate an
13 ASRL for acrylamide in coffee by means of any quantitative cancer risk assessment.

14
15 61. Dr. Rhomberg’s risk assessment was not based on evidence and standards of
16 comparable scientific validity to the evidence and standards which form the scientific
17 basis for listing acrylamide pursuant to section 25249.8.

18
19 62. Although Dr. Rhomberg performed a quantitative risk assessment of acrylamide,
20 he did not undertake a quantitative risk assessment for acrylamide in coffee. Hence, he
21 did not perform a risk assessment for a carcinogen (acrylamide) in a mixture (coffee).
22 Dr. Rhomberg failed to undertake the type of quantitative risk assessment that is
23 necessary to quantify the risk of cancer from exposure to acrylamide in coffee.

24
25 63. Dr. Rhomberg did not calculate an ASRL based on sound considerations of public
26 health for exposure to acrylamide from consumption of coffee, as is required by CCR
27 section 25703(b).

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

2
3 69. Covance's analytical method was not executed using proper scientific procedures,
4 and generated inaccurate results in its analyses. As a consequence, Covance's analytic
5 data of the acrylamide levels of Defendants' brewed coffee products is also unreliable
6 and inadmissible.

7
8 70. Defendants' witness who testified about the Covance data, Darryl Sullivan, is not
9 academically qualified to explain the science underlying the method used by Covance or
10 to testify whether the method is generally accepted in the scientific community. Thus, a
11 proper foundation was not laid for the admissibility of the Covance data.

12
13 71. The testimony of Defendants' expert witness, Dr. Carolyn Scrafford, with respect
14 to exposure assessment for each of Defendants' products, was based upon the
15 scientifically unreliable and inadmissible Covance data of the acrylamide concentrations
16 of Defendants' products.

17
18 72. Because the testimony of Defendants' expert, Dr. Scrafford, regarding exposure
19 assessment, was based on unreliable data generated by Covance Laboratories of
20 acrylamide levels in Defendants' brewed coffee products, her testimony is also without
21 proper foundation and inadmissible.

22
23 IX. DEFENDANTS' BURDEN OF PROVING THEIR ALTERNATIVE RISK
24 LEVEL DEFENSE

25
26 73. "[T]he burden of showing that an exposure meets *the criteria*" of the Alternative
27 Significant Risk Level exemption "shall be on the defendant." (Section 25249.10,
28 emphasis added.)

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1 74. Defendants did not offer substantial evidence to quantify any minimum amount of
2 acrylamide in coffee that might be necessary to reduce microbiological contamination or
3 render coffee palatable. Rather, Defendants argued that acrylamide levels in coffee
4 cannot be reduced at all without negatively affecting safety and palatability.
5

6 75. While Plaintiff offered evidence that consumption of coffee increases the risk of
7 harm to the fetus, to infants, to children and to adults, Defendants' medical and
8 epidemiology experts testified that they had no opinion on causation.
9

10 76. Although evidence showed that roasting coffee beans is necessary to make coffee
11 palatable and roasting coffee beans reduces microbiological contamination in coffee,
12 Defendants' proffered evidence that coffee itself confers some benefit to human health
13 was not persuasive and was refuted by Plaintiffs' evidence.
14

15 77. Defendants failed to satisfy their burden of proving by a preponderance of
16 evidence that consumption of coffee confers a benefit to human health.
17

18 78. Since Defendants failed to prove that coffee confers any human health benefits,
19 Defendants have failed to satisfy their burden of proving that sound considerations of
20 public health support an alternate risk level for acrylamide in coffee.
21

22 79. To establish their ASRL defense, Defendants must prove an alternative risk level
23 for acrylamide in coffee by means of a scientifically valid quantitative risk assessment.
24

25 80. Defendants did not conduct a quantitative assessment of the risk of cancer from
26 exposure to acrylamide in coffee.
27

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

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

2
3 82. Assuming *arguendo* that the testimony of Darryl Sullivan and Dr. Scrafford, and
4 the data of Covance Laboratories was admissible in evidence and considered by the
5 Court, Defendants nevertheless failed to meet their burden on the ASRL affirmative
6 defense based on the credibility of witnesses and the weight of evidence being against
7 Defendants.

8
9 83. Accordingly, the Court rules against Defendants and in favor of Plaintiff on
10 Defendants' Alternative Significant Risk Level affirmative defense.

11
12 X. CONCLUSIONS

13
14 84. Defendants have the burden of proof to establish their Alternative Significant Risk
15 Level affirmative defense by a preponderance of the evidence.

16
17 85. Defendants have failed to meet their burden of proof on their Alternative
18 Significant Risk Level affirmative defense.

19
20 DATED: March 28, 2018


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

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