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**FILED**  
Superior Court of California  
County of Los Angeles

**DEC 05 2023**

David W. Stayton, Executive Officer/Clerk of Court  
By: P. Herrera, Deputy

**SUPERIOR COURT OF THE STATE OF CALIFORNIA  
FOR THE COUNTY OF LOS ANGELES**

Coordination Proceeding  
Special Title (Rule 3.550)  
  
PROPOSITION 65 RICE PRODUCT  
CASES  
  
CONSUMER ADVOCACY GROUP, INC.,  
in the public interest,  
  
Plaintiff,  
  
v.  
  
GULF PACIFIC RICE CO. INC., a Texas  
Corporation; GULF PACIFIC INC., a Texas  
Corporation; and DOES 1-20,  
  
Defendants.

JCCP No. 4816  
  
Lead Case No. BC553427  
Coordinated Case(s): BC553427,  
BC549139, BC553852, BC554810,  
BC554594, 34-2014-00165277, CGC-13-  
536301 and BC571487

**PROPOSED STATEMENT OF  
DECISION**

Hon. Elihu M. Berle  
Department 6  
Spring Street Courthouse

The parties having stipulated to the issues of the Phase 1 trial in this matter (see page 5 *infra*), Phase 2 trial before the Court, sitting without a jury, proceeded on January 17, 2023. Reuben Yeroushalmi of Yeroushalmi & Yeroushalmi, Keith A. Robinson of Keith A. Robinson Law Group, and Kenneth W. Ralidis of Law Offices of Kenneth W.

1 Ralidis appeared for Plaintiff Consumer Advocacy Group, Inc.; and Carol Brophy, David  
2 Charles Bolstad, Jennifer Singh and Dennis E. Raglin of Steptoe & Johnson, LLP appeared  
3 for Defendant Gulf Pacific Rice Co., Inc.

4 Evidence was received and argument was heard on January 17, 18, 23, 24, 25, 26,  
5 27, 30, 31; February 1, 2, 6, 22, 23, 24, 27, 28; June 1, 8 and August 25, 2023.

6  
7 **I. STATUTORY BACKGROUND**

8 1. “Proposition 65, added by voter initiative in 1986, [known as the  
9 Safe Drinking Water and Toxic Enforcement Act of 1986, referred to as the  
10 “Act”] is a ‘right to know’ statute requiring companies that expose  
11 consumers to carcinogens or reproductive toxins to provide a warning,  
12 subject to specified defenses. Section 25249.6<sup>1</sup> states that ‘[n]o person in  
13 the course of doing business shall knowingly and intentionally expose any  
14 individual to a chemical known to the state to cause cancer or reproductive  
15 toxicity without first giving clear and reasonable warning to such  
16 individual, except as provided in Section 25249.10.’” *Environmental Law*  
17 *Foundation v. Beech Nut Nutrition Corp.* (2015) 235 Cal.App.4th 307.  
18 (“*Beech Nut*”)

19 2. “Lead is a toxic metal that, even at low levels, may cause a range of  
20 health effects, including behavioral problems and learning disabilities. . . .  
21 According to the United States Food and Drug Administration (FDA), lead  
22 is present in small amounts throughout the environment due to its natural  
23 occurrence and its release into the environment by human activities. Lead  
24 in soil can be deposited on or absorbed by plants, including plants grown  
25 for food. Lead that gets in or on the plant cannot always be completely  
26 removed by washing or other steps in the processing of the food.” (*Ibid.*)  
27

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<sup>1</sup>Unless otherwise noted, all statutory references are to the Health and Safety Code.

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1 3. “Lead has been identified as a known carcinogen and reproductive  
2 toxin under Proposition 65. 'The Act is enforced in accordance with  
3 regulations promulgated by the Office of Environmental Health Hazard  
4 Assessment, the primary agency that implements the Act.' . . . “[t]he  
5 procedures for calculating the exposure to a chemical in food start with the  
6 quantification of the ‘chemical concentration of a listed chemical for the  
7 exposure in question.’ . . . This concentration is called the “level in  
8 question.” . . . The level in question is then multiplied by the 'reasonably  
9 anticipated rate of exposure for an individual' to the food. . . . This rate of  
10 exposure must be 'based on the pattern and duration of exposure that is  
11 relevant to the reproductive effect' which formed the basis for listing the  
12 chemical as causing reproductive toxicity. . . . Thus, an ‘exposure of short  
13 duration’ is the appropriate frame of reference for a teratogenic chemical. . . .  
14 A teratogen is a chemical that can cause birth defects.” (*Ibid.*)

15 4. “Section 25249.10, subdivision (c), provides that the warning  
16 requirements of section 25249.6 do not apply to an exposure to a listed  
17 chemical if “the person responsible can show . . . that the exposure will  
18 have *no observable effect* assuming exposure at one thousand (1,000) times  
19 the level in question for substances known to the state to cause reproductive  
20 toxicity, based on evidence and standards of comparable scientific validity  
21 to the evidence and standards which form the scientific basis for the listing  
22 of such chemical . . . .” (*Italics in original.*) This exemption is sometimes  
23 referred to as the “safe harbor” defense.” (*Ibid.*)

24 5. “The ‘no observable effect level,’ or NOEL, is a scientific term  
25 denoting the maximum dose level at which a chemical is found to have no  
26 observable reproductive effect. . . . The NOEL is determined through  
27 scientific inquiry and assessment as detailed in the framework set forth in  
28 the regulations. . . . In turn, the NOEL is divided by 1,000 to arrive at the

1 maximum allowable dose level (MADL), which is the threshold warning  
2 level for a listed chemical.” . . . Thus, the MADL (maximum allowable  
3 dose level) is set as one one-thousandth of the NOEL. “At trial, a  
4 defendant can secure the protection of the exposure exemption by  
5 establishing (1) the NOEL; (2) the level of exposure in question, and  
6 ultimately that the level of exposure was 1,000 times below the NOEL.”

7 *(Ibid.)*

8 6. “The Office of Environmental Health Hazard Assessment (OEHHA)  
9 has already determined the MADL for lead. The regulations set the “safe  
10 harbor” warning threshold for carcinogenicity as to lead at 15 micrograms  
11 per day. The regulatory safe harbor level for reproductive toxicity for lead  
12 is 0.5 micrograms per day. (*id.* § 25805, subd. (b).) The OEHHA relied on  
13 the United States Occupational Safety and Health Administration's (OSHA)  
14 permissible exposure limit (PEL) to establish the reproductive safe harbor  
15 level. OSHA multiplied the OSHA PEL of 50 micrograms per cubic meter  
16 by 10 cubic meters (the amount OSHA determined workers breathed over  
17 an eight-hour period) to yield a value of 500 micrograms, which it then  
18 divided by 1,000 to arrive at the 0.5 microgram-per-day standard. (*Ibid.*)

19  
20 **II. PROCEDURAL HISTORY**

21 7. This action was commenced on August 1, 2014 by Plaintiff Consumer Advocacy  
22 Group, Inc. (“CAG”) filing a “Complaint for Penalty and Injunction,” seeking a permanent  
23 injunction mandating Proposition 65 compliant warnings and penalties under Health &  
24 Safety Code, section 252495 et seq.

25 8. In its Complaint, CAG alleges that Defendants Gulf Pacific Rice Co., Inc. and Gulf  
26 Pacific, Inc. (collectively “Gulf”) was a “manufacturer, distributor, promoter, or retailer of  
27 rice, which includes but is not limited to, Gulf Pacific ‘Heart Healthy’ ‘Low Fat’  
28 ‘Premium’ ‘Whole Grain’ ‘Brown Rice’ ‘Product of USA’ ‘Net Wt. 16 oz (1 LB) 454g’

1 Barcode: '7 20579 72801 2' ('rice')."

2 9. CAG alleges that Gulf knew or should have known that lead had been identified by  
3 the State of California as a chemical known to cause cancer and reproductivity toxicity,  
4 and therefore was subject to Proposition 65 warning requirements.

5 10. CAG alleges that Gulf exposed California consumers and users of rice to lead  
6 without first providing any type of clear and reasonable warning of such to the exposed  
7 persons before the time of exposure, in violation of Proposition 65.

8 11. CAG further alleges that Gulf is liable for civil penalties of up to \$2,500.00 per day  
9 per individual exposure to lead from rice, pursuant to Health & Safety Code, section  
10 25249.7(b).

11 12. On March 6, 2020 CAG and Gulf entered into a stipulation which provided, among  
12 other things, the following:

13  
14 "RECITALS"

15 1. CAG has alleged one case of action against Gulf Pacific  
16 relating to the following product: "Heart Healthy" "Low Fat" "Premium"  
17 "Whole Gran" "Brown Rice" "Product" of USA" "Net Wt. 16 oz (1 LB)  
18 454g" Barcode 720579 72801 2 ("RICE") ("the Product").

19 2. The cause of action alleges that the Product contains lead and  
20 causes consumer exposure to lead in violation of Proposition 65, without a  
21 proper warning.

22 3. The Court ordered the following issues within the scope of  
23 Phase 1: (a) whether Defendants are a "person in the course of doing  
24 business"; (b) whether Defendants "knowingly" exposed any individual to  
25 the listed chemical; (c) whether Defendants "intentionally" exposed any  
26 individual to the listed chemical; (d) whether there was an "exposure"; and  
27 (e) that no "clear and reasonable warning was provided. ("Phase 1")

28 IT IS STIPULATED AND AGREED:

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1 1. Gulf Pacific agrees to stipulate to Phase 1 of this case in its  
2 entirety in favor of CAG. Phase 1 issues include: (a) whether Defendants  
3 are a “person in the course of doing business”; (b) whether Defendants  
4 “knowingly” exposed any individual to the listed chemical; (c) whether  
5 Defendants “intentionally” exposed any individual to the listed chemical;  
6 (d) whether there was an “exposure”; and (e) that no “clear and reasonable”  
7 warning was provided. (“Phase 1”)

8 2. CAG and Gulf Pacific stipulate and agree that CAG has met  
9 its prima facie burden pursuant to California Health & Safety Code  
10 § 25249.6 against Gulf Pacific and in favor of CAG in the instant  
11 Complaint as to the first cause of action as to the Product.”  
12

13 13. The Court approved of the stipulation of the parties and entered its order on  
14 March 6, 2020.

15 14. During the trial, counsel for CAG stated:  
16 “... there's a stipulation to Phase 2, which defines what product is in this  
17 case, and it's defined by the UPC code. The three other doc – products that  
18 counsel is referring to is not the same UPC Code, and so, therefore, would  
19 not be an issue in this trial.” (Trial Transcript, 1/26/23 pp. 5:25 – 6:2)  
20

21 **III. UNDISPUTED MATTERS**

22 15. Proposition 65, officially known as the “Safe Drinking Water and Toxic  
23 Enforcement Act of 1986” was enacted by the voters of California in November 1986.

24 16. Proposition 65 requires businesses to provide warnings to Californians as to  
25 significant exposures to chemicals that cause cancer, birth defects, or other reproductive  
26 harm.

27 17. Proposition 65 requires California to publish a list of chemicals known to cause  
28 cancer, birth defects or other reproductive harm.

1 18. The Office of Environmental Health Hazard Assessment (“OEHHA”) administers  
2 the Proposition 65 program. OEHHA determines in many cases whether chemicals meet  
3 the scientific and legal requirements for placement on the Proposition 65 list and  
4 administers regulations that govern warnings and other aspects of Proposition 65.

5 19. Lead was placed on OEHHA's list of chemicals as a carcinogen known to cause  
6 cancer, birth defects or other reproductive harm in 1986. OEHHA has set the "safe  
7 harbor" level or MADL for lead of .5 micrograms per day.

8 20. Gulf is an importer, processor, and distributor of rice.

9 21. Gulf imports rice from outside of the United States.

10 22. Gulf sells rice to the California market.

11 23. Samples of Gulf's rice were purchased by CAG’s investigator from California  
12 retailers.

13 24. There were no warnings regarding lead included on the packaging of Gulf’s rice  
14 purchased by CAG.

15 25. Samples of the Gulf's rice were taken by CAG’s investigator and delivered to  
16 Positive Lab Service for testing.

17 26. A sample of Gulf Pacific ® ‘Heart Healthy’ ‘LOW FAT’ ‘PREMIUM’ ‘HOLE  
18 GRAIN’ ‘BROWN RICE’ ‘Product of USA’ ‘NET WT. 16 OZ (1LB) 454g’ Barcode: ‘7  
19 20579 72801 2’ was tested at Positive Labs.

20 27. The results from Positive Labs indicated that Gulf’s rice contained elevated levels  
21 of lead.

22 28. Based on its investigation and the results that CAG received from Positive Labs,  
23 CAG consulted with its attorneys and with experts regarding Gulf's rice.

24 29. CAG concluded that Gulf's rice violated Proposition 65 and issued 60-Day Notices  
25 of Violation of Proposition 65 to Gulf.

26 30. CAG filed an enforcement action complaint against Gulf on August 1, 2014.

27 31. CAG alleges that Gulf Pacific violated Proposition 65.

28 32. Gulf, in the course of doing business, sold and/or distributed the rice that is the

1 subject of CAG's complaint.

2 33. Gulf “knowingly” and “intentionally” exposed consumers of its rice to lead, a  
3 chemical, listed by OEHHA in accordance with the regulations for the administration of  
4 Proposition 65.

5 34. Lead is a toxic chemical, that even at low doses, is associated with a range of  
6 adverse health effects.

7 35. Gulf did not provide clear and reasonable warnings regarding lead on Gulf's  
8 packaging to consumers of its rice.

9  
10 **IV. GULF'S CONSTITUTIONAL DEFENSES**

11 **A. First Amendment to the Constitution of the United States**

12 36. Commercial speech receives less protection under the First Amendment than  
13 expressive or political speech.

14 37. There are two potential tests for commercial speech legislation under the First  
15 Amendment. The *Zauderer*<sup>2</sup> test applies when legislation compels a disclosure. The  
16 *Central Hudson*<sup>3</sup> test applies when legislation prohibits or restricts commercial speech,  
17 which is not applicable in this case.

18 38. A disclosure that passes the *Zauderer* test, even when the government requires  
19 health and safety warnings, is not constitutionally violative compelled speech.

20 39. The government may require warnings, or other disclosures, as long as the  
21 compelled disclosure is reasonably related to the government's interest.

22 40. The *Zauderer* test has three elements: whether the notice is (1) purely factual,  
23 (2) noncontroversial, and (3) not unjustified or unduly burdensome.

24 41. Proposition 65 warning requirements contain factual guidelines.

25 42. Lead is known to the State of California to cause cancer and birth defects or other  
26

27  
28 <sup>2</sup> *Zauderer v. Office of Disciplinary Counsel* (1985) 471 U.S. 626

<sup>3</sup> *Central Hudson v. Public Serv. Comm. of N.Y.* (1980) 447 U.S. 557



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1 reproductive harm.

2 43. Proposition 65’s warning requirement is purely factual and uncontroversial.

3 44. Mandatory disclosures necessarily involve some burden, but that burden is only  
4 undue when it “effectively rules out the speech it accompanies.”

5 45. Given the narrow requirements for a warning and specific exemptions under  
6 Proposition 65 where no warning is required at all, the required disclosure does not impose  
7 an undue burden.

8 46. Proposition 65 is reasonably related to the State of California’s substantial interest  
9 in protecting the health, safety, and welfare of its citizens.

10 47. Gulf has not met its defense burden as to the *Zauderer* test; Proposition 65 warning  
11 labels are constitutional under *Zauderer*.

12 48. Proposition 65 warnings are reasonably related to a substantial government interest  
13 in protecting the health, safety, and welfare of Californians from exposures to toxins.

14 49. Required warnings under Proposition 65 are not in violation of the First  
15 Amendment to the United States Constitution.

16 **B. Due Process Under the Constitution of the United States**

17 50. The constitutional right to due process requires that any statute must be sufficiently  
18 definite to provide adequate notice of the conduct proscribed, and provide sufficiently  
19 definite guidelines for the statute's enforcer, in order to prevent arbitrary and  
20 discriminatory enforcement.

21 51. Due process requires that statutes provide fair warning of any prohibited conduct,  
22 provide adequate standards for enforcement and adjudication of liability, and do not inhibit  
23 the exercise of First Amendment rights when a law touches on First Amendment freedoms.

24 52. OEHHA’s regulations state what information is required in a warning, and provide  
25 specific examples of a clear and reasonable warning which is deemed compliant when  
26 used.

27 53. The list of chemicals known to cause cancer and/or reproductive harm is revised  
28 and re-published each year on OEHHA’s website, which OEHHA is mandated to maintain.

1 54. A statute should be upheld if the language can be made reasonably certain by  
2 reference to other sources.

3 55. Proposition 65 is not in violation of due process under the Constitution of the  
4 United States.

5 **C. Commerce Clause of the United States Constitution**

6 56. Proposition 65 is a California state law that was passed in 1986 by California voters  
7 to protect the health and safety of Californians.

8 57. Proposition 65 regulates evenhandedly in the interest of public health.

9 58. Assessing whether state law violates the United States Constitution commerce  
10 clause requires the court assess (1) whether the state law discriminates against interstate  
11 commerce; and (2) whether the state law nevertheless incidentally burdens interstate  
12 commerce.

13 59. A state law that regulates evenhandedly, but nevertheless has incidental effects on  
14 interstate commerce, is valid as long as its burden on interstate commerce is not clearly  
15 excessive in relation to its putative local benefits. This is known as the *Pike*<sup>4</sup> balancing  
16 test.

17 60. Proposition 65 does not prohibit Gulf from selling rice at lower prices outside of  
18 California, or from shifting the costs of Proposition 65 compliance to Californians.

19 61. Under the applicable regulations, manufacturers and distributors of a product may  
20 enter into written agreements to allocate the responsibility of providing a warning in lieu of  
21 providing a warning themselves.

22 62. Gulf has not shown that any burden placed on interstate commerce by Proposition  
23 65 substantially outweighs its benefits.

24 63. Gulf's "extraterritorial effects" arguments are without merit.

25 64. The Court concludes that Proposition 65 does not violate the Commerce Clause of  
26 the United States Constitution. Additionally, Proposition 65 does not breach the principles  
27

28 \_\_\_\_\_  
<sup>4</sup>*Pike v. Bruce Church* (1970) 397 U.S. 137.

1 of government separation of powers, or violate article III, section 3 of California's  
2 Constitution.

3 **D. Federal Preemption**

4 65. State legislation may be expressly preempted, impliedly preempted, or preempted  
5 through the federal government's occupation of a particular field.

6 66. Whether federal law preempts state law is fundamentally a question of whether  
7 Congress has intended such preemption.

8 67. The federal government provides express preemption over state legislation with  
9 respect to over-the-counter drug labeling. (FDCA, 21 U.S.C. 379r(a).) Proposition 65 has  
10 an exception to warnings for over-the-counter drugs. (Section 25249.10; see *Center for*  
11 *Environmental Health v. Perrigo* (2023) 89 Cal.App.5th 1.)

12 68. The Federal Food, Drug, and Cosmetic Act (“FDCA”) was enacted pursuant to  
13 Congress's intent to protect Americans from adulterated food and deceptively packaged  
14 products.

15 69. There is no express preemption language in the Federal Food, Drug, and Cosmetic  
16 Act as to food products.

17 70. Proposition 65 is based on California's interest in protecting the health, safety, and  
18 welfare of its citizens from unwitting exposures to toxic chemicals.

19 71. The federal government has deliberately declined to enact legislation to preempt  
20 state warnings on food products.

21 72. State legislation may be preempted if it is impossible for a party to comply with  
22 both the state and federal legislation.

23 73. A state law may be preempted if it actually conflicts with federal law.

24 74. For a state law to be the object of preemption based on conflict with federal law,  
25 the conflict with federal law must be of substance and not trivial or insubstantial.

26 75. Proposition 65 warnings may be communicated via multiple methods.

27 76. Where the federal law preempts the use of certain methods of communication,  
28 leaving other methods available, it cannot be said that the federal law “governs warning,”

1 since "warning" includes all methods.

2 77. Proposition 65 warning labels can be communicated through a variety of methods,  
3 with great flexibility.

4 78. Proposition 65 warning requirements were designed to avoid prescribing any  
5 particular warning method specifically so as not be in conflict with federal regulations.

6 79. Proposition 65 provides exemptions to the warning requirement, for both Safe  
7 Harbor levels and for naturally occurring toxins.

8 80. The FDA does not preapprove food labels, nor does it necessarily pursue  
9 enforcement measures regarding all objectionable labels.

10 81. Regulation of food and beverages is an area in which Congress has long expressed  
11 its awareness of state legislation and has consistently tolerated the state's competing  
12 interests and regulatory control.

13 82. Rather than impede a federal objective, Proposition 65, as a whole, complements  
14 the federal government's objective and is not preempted.

15 83. The Court concludes Proposition 65 is not preempted by federal law.  
16

17 **V. Gulf's Safe Harbor Affirmative Defense - Exposure Below MADL**

18 84. "In 1989, after an extensive administrative process, the Agency [OEHHA]  
19 adopted regulations governing its implementation of Proposition 65,  
20 including article 8, 'No Observable Effect Levels.' (Cal. Code Regs., title  
21 27, §§ 25801-25821.) The Agency determined the MADL for lead, setting  
22 the regulatory safe harbor level for reproductive toxicity at 0.5 micrograms  
23 per day. (Cal. Code Regs., title 27, § 25805, subd. (b).) In its 'Final  
24 Statement of Reasons' (FSOR), the Agency explained the need for adoption  
25 of these regulations. 'The Act [Proposition 65] exempts discharges,  
26 releases and exposures which, making certain assumptions, pose no  
27 significant risk of cancer or would produce no observable reproductive  
28 effect. The Act specifies that any claim of exemption under Health and

1 Safety Code section 25249.10, subsection (c) must be based upon evidence  
2 and standards of comparable scientific validity to the evidence and  
3 standards which form the scientific basis for the listing of the substance as a  
4 chemical known to the state to cause cancer or reproductive toxicity.

5 However, ... the Act does not specify levels of exposure to reproductive  
6 toxins which have no observable effect, and provides no methods for  
7 determining those levels. ...' (*Mateel Environmental Justice Foundation v.*  
8 *Office of Environmental Health Hazard Assessment* (2018))

9 85. "The Agency recognized that '[t]here is no fixed way to perform the steps  
10 necessary to specifically determine ... no observable effect. The methods  
11 used may vary depending upon the data available, and the objectives of the  
12 risk assessor or risk manager. The purpose of these regulations is to  
13 provide some 'safe harbor' levels and methodologies, and criteria for  
14 exposure assessment, which will assist persons in making certain that their  
15 discharges, releases or exposures pose no significant risk or would have no  
16 observable effect within the meaning of the Act. ...' (*Ibid.*)

17 86. "The Agency also recognized that lead had been included on the Governor's  
18 initial listing of chemicals known to cause reproductive toxicity because it  
19 had been identified by OSHA as a known human reproductive toxicant  
20 based upon evidence of its effects on humans ... and the Agency relied on  
21 OSHA's PEL of 50 micrograms per cubic meter to establish the  
22 reproductive safe harbor level. 'OSHA multiplied the OSHA PEL of 50  
23 micrograms per cubic meter by 10 cubic meters (the amount OSHA  
24 determined workers breathed over an eight-hour period) to yield a value of  
25 500 micrograms, which [the Agency] then divided by 1,000 to arrive at the  
26 0.5 microgram-per-day standard.' (*Beech Nut, supra*, 235 Cal/App.4th at  
27 pp. 313-314.) 'The reproductive safe harbor level presumes that one can be  
28 exposed to 1,000 times the safe harbor level without suffering any adverse

1 reproductive effects. ... ' (*Ibid.*)

2 87. "In setting the MADL, the Agency acknowledged the difficulties in setting a  
3 NOEL for reproductive toxicants: 'The difficulty in identifying a NOEL for  
4 reproductive toxicants when the effects of concern are based upon human  
5 experience rather than animal bioassays is that there is often no precise data  
6 predicting what levels will produce no observable effect. However, there is  
7 experience derived from the occupational setting which suggests that  
8 exposure to certain regulated levels does not produce the reproductive  
9 effect of concern. Hence, the Agency has utilized certain limits for  
10 occupational exposures as surrogates for the NOEL in the workplace. The  
11 levels set forth in subsection (b) represent one one-thousandth of the  
12 occupational exposure limits. This approach is consistent with the purposes  
13 of the Act. ... ' (*Ibid.*)

14 88. In order to determine whether Gulf's rice contained lead below maximum allowable  
15 level (MADL), an analysis must be undertaken to:

- 16 a) identify the "reasonable anticipated rate of exposure" of the average  
17 consumer;  
18 c) calculate the level of exposure;  
19 d) compare the level of exposure to the MADL Safe Harbor level of .5 µg/day  
20 (.5 micrograms per day).

21 89. CAG tested a bag of Gulf's Whole Long Grain Brown Rice, the product in question,  
22 through Positive Lab Service.

23 90. Gulf tested 12 bags of Gulf's whole Long Grain Brown Rice through K-Prime  
24 Laboratory.

25 91. The rice tested by Gulf was ground rice flour, which according to Gulf's expert  
26 Dr. Barbara Petersen, is the same as whole rice for testing purposes.

27 92. Dr. Petersen evaluated each of the test results and averaged the test results.

28 93. Since lead in rice is not homogenous, but randomly distributed, averaging gives the

1 most reliable results for calculating lead in rice.

2 94. Use of the geometric mean, rather than arithmetic mean, is more appropriate in  
3 calculating average amounts of lead in rice because it reduces the effect of "outlier" test  
4 results.

5 95. Use of geometric mean is the generally accepted scientific method for the  
6 determination of the central tendency of a set of data.

7 96. Averaging across lots for food exposures and using the geometric mean to average  
8 the values was found appropriate and in accordance with Proposition 65 and its regulations  
9 in the case of *Environmental Law Foundation v. Beech-Nut Nutrition Corp.* (2015)  
10 235 Cal.App.4th 307. ("*Beech Nut*")

11 97. According to Gulf's expert witness Dr. Barbara Beck, the appropriate time period to  
12 calculate the average for consumption of rice is 30 days or longer. The 30-day averaging  
13 period is based on the toxicology of lead. In consideration of the reproductive effects that  
14 were the basis of listing of lead under Proposition 65, it is appropriate to average lead  
15 exposure over a 30-day (or longer) time period.

16 98. Dr. Petersen found that the lead level in the rice product in question averaged  
17 (geometric mean) 1.9 parts per billion for Gulf's sample and 2.6 parts per billion for the  
18 combined samples of Gulf and CAG.

19 99. Data from the U.S. Center for Disease Control and Prevention's National Center for  
20 Health Statistics' National Health and & Nutrition Examination Survey ("NHANES") is  
21 the most robust and reliable source of consumer use data for consumer use of rice.

22 100. NHANES data is designed to be representative of the entire population in the  
23 United States, and to capture how often foods are consumed, when they are consumed and  
24 how much is consumed, NHANES data is publicly available and is frequently used by  
25 state and federal regulators, including OEHHA for food consumption analysis.

26 101. Based on data from NHANES, Dr. Petersen calculated the average amount of rice  
27 consumed by the average consumer in grams per eating occasion (g/EO) and calculated the  
28 frequency of rice consumption.

1 102. Utilizing NHANES studies, Dr. Peterson determined that using Gulf's data, the  
2 average user consumed 126 grams per eating occasion (126 g/EO), calculated by the  
3 geometric mean.

4 103. Utilizing NHANES studies, Dr. Peterson determined that using Gulf data, the  
5 frequency of consumption of rice by the average consumer was .06 eating occasion per day  
6 (EO/day) over 30 day period (geometric mean). Using combined Gulf and CAG data, the  
7 frequency of consumption of rice by the average consumer was .06 EO/day (geometric  
8 mean).

9 104. Multiplying amount of rice per eating occasion (g/EO) by the frequency of  
10 consumption (EO/day) by the lead level of rice (parts per billion or micrograms per  
11 kilogram), Dr. Peterson arrived at the figures of .01  $\mu$ /day (microgram per day), using  
12 Gulf's data, and .01  $\mu$ /day, using combined Gulf and CAG data. All calculations were  
13 based on geometric mean rather than arithmetic mean.

14 105. Thus, according to Dr. Petersen, Gulf's rice test data shows that the daily intake of  
15 lead by the average user is 0.01  $\mu$ g/day (geometric mean). When using combined Gulf and  
16 CAG test data, average users daily intake of lead is 0.01  $\mu$ g/day (geometric mean).

17 106. These calculations indicate that the level of exposure to lead in rice is less than the  
18 MADL of 0.5  $\mu$ g/day.

19 107. Based on these calculations, concluding a MADL exposure to lead of less than .05  
20  $\mu$ /day, Gulf's Safe Harbor defense would be established and a Proposition 65 would not be  
21 required.

## 22 23 **VI. CONCLUSIONS**

24 108. CAG purchased the Gulf bag of brown rice at issue on July 18, 2013, and served a  
25 Proposition 65 Notice of Violation on Gulf or about May 8, 2014.

26 109. The Complaint in this case was filed on August 1, 2014, more than one year after  
27 the product was purchased.

28 110. For testing purposes, rice flour is the same as rice, just in ground up form. They are



1 not two separate products.

2 111. California Code of Regulations, CCR title 27, section 25821(c)(2) and section  
3 25721(d)(4) set forth the guidelines for calculating a listed chemical exposure in food.

4 112. For consumer products, the pattern and duration of exposure is to be determined by  
5 using the “reasonably anticipated rate of intake or exposure for average users of the  
6 consumer product, and not on a per capita basis for the general population.”

7 113. The reasonably anticipated rate of exposure is based on the pattern and duration of  
8 exposure that is relevant to the reproductive effect which provided the basis for the  
9 Proposition 65 listing.

10 114. A defense to a Proposition 65 claim exists when a defendant can establish that the  
11 level of exposure of the chemical in question to the average user is below the amount  
12 regulations establish as the “Safe Harbor” level.

13 115. To determine whether the level of exposure of the chemical in question to the  
14 average user is below the “Safe Harbor” level, the regulations require the following steps:  
15 (1) identification of the “level in question” – i.e., concentration of lead in the Product, (2)  
16 establishment of the “reasonably anticipated rate of exposure” of the “average user,” (3)  
17 identification of the “level of exposure,” and (4) comparison of the “level or exposure” to  
18 the Safe Harbor level.

19 116. California Code of Regulations, CCR title 27, § 25821(c)(2) and 25732(d)(4) set  
20 forth the guidelines for calculating exposure in this case.

21 117. The regulatory Safe Harbor level for lead is expressed in units of exposure per day  
22 (in micrograms rather than as a concentration such as parts per billion).

23 118. The “reasonably anticipated rate of exposure” is the average daily exposure to lead  
24 for the average consumer of each Product.

25 119. The frequency of consumption must be considered when determining the “level of  
26 exposure” to lead from the Product.

27 120. Proposition 65 requires using more than a single data point. It mandates that  
28 assessments be based on averaging, and the regulations consistently use terms “average

1 user,” “reasonably anticipated use,” and “rate of intake or exposure,” all of which require  
2 multiple data points to assess.

3 121. OEHHA listed lead as a reproductive toxicant and developed the MADL based on  
4 chronic exposure.

5 122. The U.S. Centers for Disease Control and Prevention's National Center for Health  
6 Statistics' National Health & Nutrition Examination Survey (“NHANES”) is appropriate to  
7 be used to determine consumer use data for consumption of the rice product at issue.

8 123. NHANES includes data concerning all consumers of rice, including Asians.  
9 NHANES measures consumption rates of the average consumer, which by its very  
10 definition includes all ages, genders, races, frequent eaters, and infrequent eaters.

11 124. A valid food exposure assessment pursuant to Proposition 65 regulations and the  
12 NHANES database requires consumption data from all ethnicities who consume the food,  
13 as well as data from men, women and children.

14 125. Pursuant to Proposition 65 regulations, using NHANES for calculating lead  
15 exposure in this case provides for the inclusion of all consumers of the food, and is not  
16 limited to any specific subpopulation, ethnicity, gender or other subcategory.

17 126. An assessment that uses data from just one ethnicity is not a valid, representative  
18 sample.

19 127. Using a thirty-day average period for the calculation of product consumption is  
20 appropriate for the determination of lead exposure of consumers.

21 128. Proposition 65 regulations require the averaging of consumption data to determine  
22 compliance with the MADL.

23 129. Both CAG and Gulf Pacific have tested the noticed product for lead content.

24 130. Gulf's expert Dr. Barbara Petersen utilized a two-step process to calculate the  
25 reasonably anticipated rate of exposure, determining: (1) the amount of product consumed;  
26 and (2) the frequency of consumption by the average consumer of the product.

27 131. Using Gulf data, Dr. Peterson calculated the lead level in the rice product in  
28 question to be 1.9 parts per billion (ppb). Using combined Gulf and CAG data, Dr.

1 Peterson calculated lead level in the rice to be 2.6 ppb (geometric mean used for  
2 calculations).

3 132. Dr. Peterson calculated amounts consumed per eating occasion to be 126 g/EO  
4 using Gulf data and using combined Gulf and CAG data (geometric mean).

5 133. Dr. Peterson calculated frequency of product consumption to be .06 EO/day using  
6 Gulf data and using combined Gulf and CAG data (geometric mean).

7 134. Gulf's data and exposure analysis shows that the average rice product daily intake  
8 of lead is 0.01  $\mu$ /day (geometric mean) determined by multiplying the "reasonably  
9 anticipated rate of exposure" of rice by the "level in question" of lead in the Product.

10 Using both Gulf and CAG data, the average rice product daily intake of lead would be  
11 .01 $\mu$ /day (geometric mean).

12 135. Dr. Petersen's exposure assessment shows the level of lead in the subject rice is  
13 below the MADL Safe Harbor level of 0.5  $\mu$ g/day.

14 136. The Court finds Dr. Petersen's testimony to be credible.

15 137. Based on the evidence and credibility of witnesses, the Court concludes that Gulf  
16 has met its burden of proof by preponderance of the evidence to establish that the level of  
17 exposure to lead from the subject product did not exceed the Safe Harbor level, i.e., the  
18 Maximum Allowable Dose Level ("MADL") provided in Proposition 65 regulations of .05  
19  $\mu$ g/day.

20 138. Based on the totality of evidence presented, the Court concludes that Gulf has met  
21 its burden of proof by preponderance of evidence to establish that it was in compliance  
22 with Proposition 65 at the time the rice product in question was purchased, and that the  
23 product did not require Proposition 65 warnings.

24  
25 DATED: December 5, 2023

  
HONORABLE ELIHU M. BERLE  
JUDGE OF THE SUPERIOR COURT