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IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

FIRST APPELLATE DISTRICT

DIVISION ONE

ENVIRONMENTAL LAW FOUNDATION, Plaintiff and Appellant, v. BEECH-NUT NUTRITION CORP. et al., Defendants and Appellants.	A139821 (Alameda County Super. Ct. No. RG11597384)

INTRODUCTION

Plaintiff, the Environmental Law Foundation (ELF), filed a complaint against Beech-Nut Nutrition Corporation and various other food manufacturers, distributors, and retailers, seeking enforcement of the provisions of the Safe Drinking Water and Toxic Enforcement Act of 1986, commonly referred to as Proposition 65 (Health & Saf. Code, § 25249.5 et seq.).[1] ELF alleged certain of defendants' products contain toxic amounts of lead sufficient to trigger the duty to provide warnings to consumers. After a bench trial, the trial court entered judgment in favor of defendants, concluding they had no duty to warn because they satisfactorily demonstrated that the average consumer's reasonably anticipated rate of exposure to lead from their products falls below relevant regulatory thresholds. ELF has appealed from the judgment. We affirm.

[1] Unless otherwise noted, all statutory references are to the Health and Safety Code.

FACTUAL AND PROCEDURAL BACKGROUND

I. Proposition 65 Warning Requirements and Lead

"Proposition 65, added by voter initiative in 1986, is a 'right to know' statute requiring companies that expose consumers to carcinogens or reproductive toxins to provide a warning, subject to specified defenses. Section 25249.6 states that '[n]o 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.' " (*People ex rel. Brown v. Tri-Union Seafoods, LLC* (2009) 171 Cal.App.4th 1549, 1555 (*Tri-Union*).)

Lead is a toxic metal that, even at low levels, may cause a range of health effects, including behavioral problems and learning disabilities. Young children are most at risk because their brains are developing. According to the United States Food and Drug Administration (FDA), lead is present in small amounts throughout the environment due to its natural occurrence and its release into the environment by human activities. Lead in soil can be deposited on or absorbed by plants, including plants grown for food. Lead that gets in or on the plant cannot always be completely removed by washing or other steps in the processing of the food.

Lead has been identified as a known carcinogen and reproductive toxin under Proposition 65. "The Act is enforced in accordance with regulations promulgated by the Office of Environmental Health Hazard Assessment [OEHHA], the primary agency that implements the Act. [Citations.]" (*Consumer Cause, Inc. v. Smilecare* (2001) 91 Cal.App.4th 454, 463-464.) Under California Code of Regulations, title 27 (Regulations), section 25821, subdivision (a),[2] "[t]he procedures for calculating the

[2] Subsequent references to Regulations are to the Proposition 65 regulations of title 27 of the California Code of Regulations.

exposure to a chemical in food start with the quantification of the 'chemical concentration of a listed chemical for the exposure in question.' [Citation.] This concentration is called the ' "level in question." ' [Citation.] The level in question is then multiplied by 'the reasonably anticipated rate of exposure for an individual' to the food. [Citation.] This rate of exposure must be 'based on the pattern and duration of exposure that is relevant to the reproductive effect' which formed the basis for listing the chemical as causing reproductive toxicity. [Citation.] Thus, an 'exposure of short duration' is the appropriate frame of reference for a teratogenic chemical. [Citation.] A teratogen is a chemical that can cause birth defects." (*Tri-Union, supra,* 171 Cal.App.4th at p. 1556.)

Section 25249.10, subdivision (c), provides that the warning requirements of section 25249.6 do not apply to an exposure to a listed chemical if "the person responsible can show . . . that the exposure will have *no observable effect* assuming exposure at one thousand (1,000) times the level in question for substances known to the state to cause reproductive toxicity, based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of such chemical . . . ." (Italics added.) This exemption is sometimes referred to as the "safe harbor" defense. (*DiPirro v. Bondo Corp.* (2007) 153 Cal.App.4th 150, 191 (*DiPirro*).)

"The 'no observable effect level,' or NOEL, is a scientific term denoting the maximum dose level at which a chemical is found to have no observable reproductive effect. [Citation.] The NOEL is determined through scientific inquiry and assessment as detailed in the framework set forth in the regulations. [Citations.] In turn, the NOEL is divided by 1,000 to arrive at the maximum allowable dose level (MADL), which is the threshold warning level for a listed chemical. [Citations.]" (*Tri-Union, supra,* 171 Cal.App.4th at p. 1555.) Thus, the MADL is set as one one-thousandth of the NOEL. "At trial, a defendant can secure the protection of the exposure exemption by

establishing (1) the NOEL; (2) the level of exposure in question, and ultimately that the level of exposure was 1,000 times below the NOEL. [Citations.]" (*Id.* at p. 1556.)

The OEHHA has already determined the MADL for lead. The regulations set the "safe harbor" warning threshold for carcinogenicity as to lead at 15 micrograms per day. (Regulations, § 25705.) The regulatory safe harbor level for reproductive toxicity for lead is 0.5 micrograms per day. (*Id.*, § 25805, subd. (b).) The OEHHA relied on the United States Occupational Safety and Health Administration's (OSHA) Permissible Exposure Limit (PEL) to establish the reproductive safe harbor level. OEHHA multiplied the OSHA PEL of 50 micrograms per cubic meter by 10 cubic meters (the amount OEHHA determined workers breathed over an eight-hour period) to yield a value of 500 micrograms, which it then divided by 1,000 to arrive at the 0.5 microgram-per-day standard.

II. Procedural History

On September 28, 2011, ELF filed suit against defendants seeking injunctive relief and civil penalties arising from defendants' alleged knowing and intentional exposure of consumers to lead-containing products without providing clear and reasonable warnings, in violation of Proposition 65. The products in question include foods intended predominantly or exclusively for babies and toddlers, such as baby foods, fruit juice, and packaged peaches, pears, and fruit cups.

Prior to trial, the parties stipulated that ELF would be deemed to have met its burden of proof with respect to its affirmative case. The parties did not dispute that defendants' products contain small amounts of lead, an element known to the State of California to cause cancer and reproductive harm. They also agreed to exchange test data concerning the concentration of lead measured in each of the products.

In March 2013, the parties submitted trial briefs and their expert witnesses' direct testimony. This testimony was presented in the form of sworn declarations accompanied by the evidence and literature on which the experts relied. In their brief, defendants

raised three arguments as to why no warnings were required for their products: (1) any such warnings are preempted by federal law, (2) the lead in their products is "naturally occurring" and therefore does not constitute an "exposure" under Proposition 65, and (3) the exposures in question fall below the regulatory "safe harbor" level for lead of 0.5 micrograms per day. Live testimony consisting of cross- and redirect examination of the parties' expert witnesses (and testimony from one percipient witness) began on April 8, 2013, and concluded after 11 trial days.

III. Testimony And Evidence

A. Defendants' Case

1. Dr. Barbara Petersen

Dr. Barbara Petersen is a nutritional biochemist. She has conducted food-related exposure analyses for more than 30 years and has done over 1,000 such studies, including work for the United Nations' Food and Agriculture Organization and the World Health Organization. For this case, she prepared an analysis to determine the average consumer's exposure to lead from each of the products at issue. She was provided with data from over 2,000 individual lead samples. She also obtained data concerning the amounts of the products eaten by average consumers, and the associated frequency with which the products are typically consumed over a two-week period.

Petersen used three types, or "buckets," of data to arrive at the average consumer's lead intake per day for each of the food products at issue: (1) the average lead levels in the food products, (2) the average amounts of the food products consumed per eating occasion, and (3) the average number of eating occasions on which the products are consumed. She then multiplied the three figures together to determine the average consumer's level of exposure to lead. Her results showed the exposure levels consistently fell below the safe harbor level of 0.5 micrograms per day. The average user's daily intake of lead from the consumption of each of the products was shown to

range from 0.001 micrograms to 0.42 micrograms, depending on the company and product type in question.

The underlying data used to calculate the average lead levels was derived from the data exchanged between the parties, including data from ELF. Petersen stated that she averaged the data samples taken from each product to provide a reliable estimate of that product's lead content. Single samples are less accurate because lead adheres differently to the different nutritional components of food. Additionally, lead is not homogenous within a product because it is held in suspension, not in solution. Because of these variables it is necessary to average data points in order to obtain a reasonable and reliable estimate of the actual lead levels in each product.

Petersen also relied on the U.S. Centers for Disease Control and Prevention National Center for Health Statistics' National Health and Nutrition Examination Survey (NHANES) database. The common name for this survey is "What We Eat in America." What We Eat in America is prepared by workers who interview household members and collect their food consumption data over a two-day period. ELF's expert Dr. Britt Burton-Freeman used this same data in preparing her analysis. Petersen testified that food consumption data is not plotted in a bell-shaped curve. Instead, it has peaks due to the presence of some high consumers. These peaks will distort the overall estimate if they are not properly accounted for. She elected to average the food consumption data because she was trying to estimate the lead exposure for the typical consumer. She stated the serving sizes found on product labels are not a reliable source of information for this purpose.

Petersen used the National Eating Trends (NET) survey to determine the frequency of consumption of the products. The survey method for the NET asks respondents to keep a food diary that covers a 14-day period. Petersen combined the NET and What We Eat In America because they both are conducted nationwide and collect information for thousands of foods. They also both contain estimates for children

under two years of age. The FDA has contracted with Petersen's firm to prepare software so that it can use the NET in tandem with What We Eat In America. The tools her firm has designed to capture information from both surveys have been tested and validated.

In her analysis for this case, Petersen computed averages using the geometric mean, not the arithmetic mean.[3] When she first analyzed the data, she observed there were some high numbers that skewed the data such that they were "log normally distributed." Her decision to use the geometric mean was based on her conclusion that the data were not "normally distributed," that is, they did not follow the standard bell-shaped curve but were instead "log normally distributed." It is possible to verify this type of distribution by comparing the geometric and arithmetic means. If the geometric mean is lower than the arithmetic mean, this indicates that the data were logged normal. If the two measurements are the same, then the data were normally distributed. She explained that the geometric mean is widely used in scientific analyses of log normal distributions, including studies relating to Proposition 65, to ensure that exposure estimates reliably reflect an accurate average.

2. Dr. F. Jay Murray

Dr. F. Jay Murray is a consulting toxicologist for business and government agencies. He served for three years on the Proposition 65 Scientific Advisory Panel.

Murray testified that blood lead levels are the primary biomarker for lead exposure. Because of the long half-life of lead and the stability of blood lead levels, low-level exposures to lead must be analyzed over an extended period of time. Measurement of the pattern and duration of exposure to lead should be analyzed over at least a 30-day period. Petersen's exposure analysis was limited to a two-week period, which is even

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[3] The parties agreed that: "A geometric mean is a type of mean or average of a set of numbers which is derived by taking the nth root the product being the result of multiplying together all numbers in a dataset." An "arithmetic mean" is "the sum of values of a set of data points divided by the number of data points in the set."

more conservative. Murray opined that lead does have a clearly identified safe threshold level; however, the thresholds for some health effects of lead have not been reliably established to date. He admitted there is some evidence that prenatal exposure to lead causes measurable neurologic effects in children, and that a single exposure to lead can impact blood lead levels if there is a high enough dose. He also acknowledged that lead stored in our bones can be released into the blood and impact blood lead levels. About 73 percent of the lead in children's bodies is stored in their bones.

In conducting his own risk assessments, Murray relies on the safe harbor level established by the state and the NOEL that is used to establish the MADL. The reproductive safe harbor level presumes that one can be exposed to a thousand times the safe harbor level without suffering any adverse reproductive effects. The OEHHA has not taken a position as to whether averaging exposures to lead is appropriate when performing evaluations under Proposition 65. Murray opined that there is no reasonable scientific theory to support a claim that the exposure to lead from the consumption of defendants' products on a single day could cause adverse reproductive or developmental impacts.

3. Barbara D. Beck

Barbara D. Beck is a board-certified toxicologist. In her work, she has analyzed scientific literature to calculate the dose of chemicals the body receives under different exposure scenarios, and to predict likelihood of health effects attributable to such exposures. In the present case, she was asked to assess the quantitative impacts on blood lead and bone lead of consumption of defendants' products as compared to the safe harbor level of lead, using modeling to quantify the impacts and conduct this comparison. Specifically, she was asked to test ELF's expert's assertion that exposure to a single dose of lead from defendants' products will result in a higher blood lead level than if that same dose is spread over time.

The models Beck used in her analysis are known as the O'Flaherty model and the Leggett model, which also known as the ICRP model. Both models can analyze the impact of intermittent exposures on blood lead or bone lead. She had to use both models because the O'Flaherty model cannot be used for intermittent exposures over the period of gestation.

Modeling was performed for products containing the highest average value of lead in each of three food categories (packaged fruit, juice, and baby food). The models were based on Petersen's food intake data for the average consumer over a 14-day period. In each case, the impact on blood lead and bone lead from actual consumption for the products produced results that were the same, or slightly lower than, the impact from daily consumption of a food containing lead at the MADL level. Modeling was performed on two female age groups (average 21-year-olds and average 28-year-olds) and four-month-old children under several exposure scenarios.

Blood lead modeling is used because lead exposure is best understood based on how much a particular dose affects blood lead level. The dose in food is not a direct indication of blood lead level. A model is needed to predict that level. Health effects of lead are also evaluated based on blood lead levels. The Proposition 65 MADL value is based on the OSHA permissible exposure level, which is ultimately based on blood lead levels. Here, the models showed the exposures, even the peaks arising from a single exposure, do not exceed the blood level amounts associated with the safe harbor. Even when Beck modeled using Burton-Freeman's analysis, the levels did not exceed the safe harbor blood lead levels.

4. Dr. Carl Keen

Dr. Carl Keen is developmental nutritionist and professor of nutrition and internal medicine in the Department of Nutrition at University of California at Davis. He has done significant research on the impact that maternal nutrition has on embryonic and fetal development. He also served for 19 years as a member of the Developmental and

Reproductive Toxin Committee for the OEHHA. The committee provides OEHHA with scientific expertise on issues related to the putative reproductive toxicities of select metals and compounds that have been identified by the state as being of potential concern with respect to reproductive risk.

Keen testified that the developmental harm caused by lead has never been isolated to a specific day or period during pregnancy. Scientific literature does not suggest that short, one-day exposures at levels such as those at issue here cause an increase in maternal blood lead levels. It is a scientifically sound and well-accepted practice to evaluate the effects of exposure to lead at the levels seen in food products based on the frequency with which they are consumed over an extended period of time.

B. ELF's Case

1. Dr. Howard Hu

Dr. Howard Hu holds an M.D. from the Albert Einstein College of Medicine and a Sc.D. in Epidemiology from the Harvard School of Public Health. He has devoted much of his professional career to studying the adverse health effects that can result from exposure to lead. Hu opined that when performing an exposure assessment under Proposition 65, one should not average a consumer's lead exposure across several days or weeks. He also opined that the level of lead in defendants' products is not safe for consumers and should be reduced. This case is the first in which he was asked to provide testimony as an expert relating to Proposition 65. On cross-examination, he stated that low-level lead exposure associated with blood levels less than 10 micrograms per deciliter is not a "frank teratogen"—that is, it does not cause birth defects. He admitted Regulations, section 25821 does not state that exposure must be assessed based on a single day.[4]

[4] Murray disagreed with Hu's assertion that the OEHHA had "formally adopted the position" that only one-day exposures should be considered for purposes of compliance with Proposition 65. Hu's statement concerned leaded crystal decanters, a product that is

For purposes of this litigation, the parties have agreed that the "window of susceptibility for exposure to lead" shall mean the period of time during which exposure may cause a reproductive, including developmental, effect. Hu admitted he had not seen epidemiological literature that identified a window of susceptibility as an interval shorter than either eight weeks or a single trimester. He also admitted that in animal studies that administered lead during pregnancy, only one of the studies demonstrated the reproductive toxicity of a single exposure to lead.

Keen had criticized Hu's opinion that even a single exposure to lead can cause reproductive toxicity because the studies Hu relied on involve animals who were given lead by intravenous injection. When asked about his opinion that "there is now a consensus among the scientific community that lead does not have a safe threshold," Hu admitted that in several cases the authorities that he relied on actually stated that no clearly established threshold level for lead-induced toxicity had been established. As to his opinion that the level of lead in defendants' products is unsafe, he disagreed with the FDA's previous conclusion that the level of lead found in defendants' products does not pose an unacceptable risk to health. Although Hu has published an article relating to the OSHA PEL in which he urged OSHA to lower that level, the agency has not acted to do so. He also disagrees with the OEHHA standard for the NOEL that governs lead exposure in California.

2. Dr. Britt Burton-Freeman

Dr. Britt Burton-Freeman is the Director of the Center for Nutrition Research for the Institute for Food Safety and Health. The present case is the first time she has been designated as an expert witness. She testified on cross-examination that this was the first exposure analysis she had done for lead. She has never personally assessed the level of lead in a food product.

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inapposite to the products at issue here. His position has never been adopted by OEHHA in any formal or informal agency communication.

Burton-Freeman testified that in contrast to Petersen, she would analyze individual lead dose levels because averaging obscures the presence of higher levels of lead in some products. In her view, it is important to show the high levels so that one can decide whether these levels indicate a possible unintended introduction of lead through manufacturing or other processes. In opining that lead levels should not be averaged, she did not rely on any scientific observation about how fruit and lead interact with each other. She did not deny that it is very common for researchers to average the lead concentrations in food products.

Burton-Freeman used two different kinds of methodologies to assess the level of exposure of lead in defendants' products. One method was to define average consumers as those who consume foods at the 85th percentile. The other method calculated an eating occasion number and then calculated a frequency number. As to the 85th percentile, she stated her belief that this method is an appropriate way to measure the intake of the average consumer because the 85th percentile approximates the serving size of the products as shown on the FDA's serving size labels. Although she started from the same stipulated test data as Petersen, she calculated exposures in a range as high as 0.05 to 29.38 micrograms per day.

Unlike Petersen, Burton-Freeman used the NHANES What We Eat In America survey only. She did not use the NET. She had never worked with the NET database and believed that it does not reflect the United States' population and therefore does not reflect the average consumer. Even assuming the FDA has determined it is appropriate to use consumption data from the NHANES and frequency data from the NET in preparing an exposure analysis, she would still disagree with Petersen's approach.

Also in contrast to Petersen, Burton-Freeman used the arithmetic mean and not the geometric mean. In her opinion, the geometric mean is not necessary or appropriate because it artificially lowers the results. Because she wanted to demonstrate all the underlying data, she believed no form of normalization should be used, even if the data

were logged normal. She also used descriptive statistics and not comparative statistics because she wanted to describe the sets of data, not compare the sets of data to any other sets of data.

Burton-Freeman agreed the NHANES study is a two-day tool. On the first day, it identifies a population of everyone who has consumed the product on a particular day. Nonconsumers are removed from the survey. The second day looks at the number of people who are repeat consumers of the product. With respect to the food products at issue in this case, the actual rate of second-day intake is between 10 and 30 percent, depending on the product. She did not agree that her analysis overestimates consumption even though the first day in the NHANES study has a total population of 100 percent. She acknowledged that short-term food studies like the NHANES have been criticized because they overestimate consumption. She also admitted that her method, which involved extrapolating principles from the National Cancer Institute's model and applying those principles to the NHANES data, has not been validated in any reported study.

In her testimony, Petersen criticized Burton-Freeman's use of the 85th percentile. In her view, it is error to use the 85th percentile analysis because it does not reflect an average. Petersen had never seen anyone use that measurement as an indication of average exposures. The 85th percentile is the high end of the distribution.[5] Petersen also

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[5] In its brief on appeal, ELF indicates that the use of the 85th percentile was based on our approval in *DiPirro, supra,* 153 Cal.App.4th 150, of a consumption pattern based on using the 85th percentile to reflect the "average consumer," rendering Burton-Freeman's approach "entirely reasonable and 'properly protective' of the consumer under Proposition 65." In *DiPirro*, the trial court accepted a model that included 75 to 85 percent of the users of automobile touch-up paint in determining the exposure of an average consumer. (*Id.* at p. 175.) We affirmed the lower court's finding but did not suggest that this percentage was relevant in all cases. In fact, we specifically observed that other standards, including a 95 percent standard, could be appropriate in some cases. (*Id.* at p. 194, fn. 30.)

criticized Burton-Freeman's work because she relied on the NHANES survey for both eating occasion and frequency. That survey only covers a two-day period, resulting in Burton-Freeman assuming that every product was consumed at least once over that time span. This methodology is flawed because the NET data shows these foods are not eaten that often. The methodology used by Burton-Freeman would work better for things that tend to be consumed every day, like coffee or bread.

3. James Donald

James Donald was called by plaintiffs as a percipient witness. He is a senior toxicologist with the OEHHA and chief of the reproductive toxicology and epidemiology section.

Donald testified that the safe harbor number is the number OEHHA believes meets the statutory requirements for exposures that are exempt from the warning requirement. The OEHHA does not have a policy that differs from the information that is contained in its publicly available documentation regarding the MADL. The appropriate time frame of exposure is calculated on a microgram-per-day basis. In Donald's view, the OEHHA believes its regulations permit combining days of exposure with days of nonexposure in determining whether the MADL has been exceeded. However, this approach is *not* permitted for purposes analyzing the regulatory safe harbor defense.

On cross-examination, Donald admitted he had not discussed his view on this point with everyone in the relevant group in OEHHA. In order to find this interpretation of the regulations, a member of the public would have to call his office and pose the question to someone there. This policy is not available on the policy page of the agency's website. Donald admitted there is no written guideline expressing the policy he articulated.

IV. Ruling And Statement Of Decision

After closing briefs were filed, the trial court heard closing arguments on May 16, 2013.

On July 31, 2013, the trial court filed its 45-page statement of decision. The court determined defendants had not established federal preemption or that the regulatory "naturally occurring" defense was applicable to their products. The court concluded, however, that warnings were not required as each of their products was at or below the regulatory safe harbor exposure level. The court found the expert testimony and analysis presented by defendants to be "far more persuasive" that ELF's analysis. For example, the court rejected Burton-Freeman's use of the 85th percentile of the NHANES database "as a proxy for amounts consumed by average users," instead accepting Petersen's average consumption per day calculations based on the geometric mean.

On August 7, 2013, the trial court filed its judgment in favor of defendants. This appeal followed.[6]

DISCUSSION

I. Standard of Review

It was defendants' burden to show, by a preponderance of the evidence, that the levels of lead in their products fall within the regulatory safe harbor. (Regulations, § 25805, subd. (b); Evid. Code, § 115.) "A party required to prove something by a preponderance of the evidence 'need prove only that it is more likely to be true than not true.' [Citation.] Preponderance of the evidence means ' "that the evidence on one side outweighs, preponderates over, is more than, the evidence on the other side, *not necessarily in number of witnesses or quantity*, but in its effect on those to whom it is addressed." (Italics added.)' [Citation.] In other words, the term refers to 'evidence that has more convincing force than that opposed to it.' [Citation.]" (*Tri-Union*, *supra*, 171 Cal.App.4th 1549 at p. 1567.)

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[6] Defendants have filed a protective cross-appeal, contesting the trial court's rulings in favor of ELF on the "naturally occurring" and preemption defenses. In light of our conclusion that the judgment based on the regulatory safe harbor defense should be affirmed, we need not address the issues raised in the cross-appeal.

"When findings of fact are challenged on appeal, we are bound by the familiar and highly deferential substantial evidence standard of review. This standard calls for review of the entire record to determine whether there is any substantial evidence, contradicted or not contradicted, to support the findings below. We view the evidence in the light most favorable to the prevailing party, drawing all reasonable inferences and resolving all conflicts in its favor. [Citations.]" (*Tri-Union, supra*, 171 Cal.App.4th 1549 at p. 1567.)

"The substantial evidence rule applies equally to expert and lay testimony. Thus, expert testimony does not constitute substantial evidence when based on conclusions or assumptions not supported by evidence in the record [citation], or upon matters not reasonably relied upon by other experts [citation]. Further, an expert's opinion testimony does not achieve the dignity of substantial evidence where the expert bases his or her conclusion on speculative, remote or conjectural factors. [Citation.] When the trial court accepts an expert's ultimate conclusion without critically considering his or her reasoning, and it appears the conclusion was based on improper or unwarranted matters, we must reverse the judgment for lack of substantial evidence. [Citation.] On the other hand, the trial court is free to reject testimony of a party's expert, so long as the trier does not do so arbitrarily. [Citation.]" (*Tri-Union, supra*, 171 Cal.App.4th 1549 at pp. 1567-1568.)

II. Use Of Averaging Test Results Over Multiple Lots

ELF claims the trial court erred in interpreting the relevant regulations so as to allow defendants to average lead test results over multiple lots, instead of evaluating each lot individually. ELF claims the need for a warning should be evaluated independently for each individual test result on a product including the single highest one, without regard to the other data in the record on the same product. In support of its contention ELF asserts that the OEHHA "has explicitly rejected Dr. Petersen's methodology of reducing multiple lots into a single average lead concentration instead of considering the lead concentration of individual lots."

As evidence of this rejection, ELF relies on a passage within the OEHHA's final statement of reasons (FSOR) for Article 8 of the Proposition 65 regulations: "One commentator recommended that the regulation provide guidance for determining the chemical concentration of a listed chemical, since the level of a listed chemical in a product may fluctuate from unit to unit of production, and specifically recommended that it refer to 'level in question' as the mean or average level of a listed chemical unless exposure to the listed chemical produced acute adverse reproductive effects as the result of a brief period of exposure. . . . The Act does not appear to provide a basis for such a distinction. . . . A consistent interpretation of the words 'level in question' appears to be much less confusing and more consistent with the Act. Accordingly, this recommendation was not adopted."

Contrary to ELF's interpretation, the gist of this passage is not that averaging contaminants over units of production is impermissible. Rather, the passage reflects the agency's view that lending different meanings to the term "level in question" with respect to chemicals that produce acute adverse reproductive effects, as contrasted with those that produce chronic effects, would be confusing and inconsistent with the Act. Thus, we do not read the passage as stating an agency policy that "oppose[s] the use of averages when determining compliance with food standards."

Additionally, we do not perceive the method of averaging across lots for a single product to be the same as " 'the deliberate mixing of adulterated food with good food,' " a strategy that ELF correctly notes has been rejected by the FDA. In the first place, the present case does not concern adulterated food. As Petersen indicated, and ELF fails to refute, samples from defendants' products show various levels of lead not just across units but *within each individual unit* depending on how the lead has bonded with the sample's constituents. Accordingly, we cannot concur with ELF's position that Petersen's methodology "would allow products with levels above the MADL to be sold

without a warning based on the fact that other samples of the same product bought by different consumers were below the MADL."

ELF next asserts that Regulations, section 25801, subdivision (a), cited by the trial court in its statement of decision, does not undermine the "prohibition against averaging across lots." The cited regulation, on its face, applies to establishing "that a level of exposure has no observable effect," not the MADL. The regulation includes the statement that "[n]othing in this article shall preclude a person from using evidence, standards, assessment methodologies, principles, assumptions or levels not described in this article to establish that a level of exposure has no observable effect at one thousand (1,000) times the level in question." (*Ibid*.) As we have indicated, we do not believe there is a prohibition against averaging across lots. Hence, even if the trial court's reliance on Regulations, section 25801, subdivision (a) was erroneous, the error is harmless.

III. Sufficiency of the Evidence to Support Averaging Across Lots

"Evidence Code section 801 provides: 'If a witness is testifying as an expert, his testimony in the form of an opinion is limited to such an opinion as is: [¶] (a) Related to a subject that is sufficiently beyond common experience that the opinion of an expert would assist the trier of fact; and [¶] (b) Based on matter . . . that is *of a type* that reasonably may be relied upon by an expert in forming an opinion upon the subject to which his testimony relates, unless an expert is precluded by law from using such matter as a basis for his opinion.' (Italics added.) Subdivision (b) clearly permits a court to determine whether the matter is of a *type* on which an expert may reasonably rely." (*Sargon Enterprises, Inc. v. University of Southern California* (2012) 55 Cal.4th 747, 769-770.) This statute has been construed to mean "that the matter relied on must provide a reasonable basis for the particular opinion offered, and that an expert opinion based on speculation or conjecture is inadmissible." (*Lockheed Litigation Cases* (2004) 115 Cal.App.4th 558, 564.)

ELF claims there was insufficient evidence to support the use of the methodology of averaging across lots. ELF contends defendants were required to demonstrate that the concentration data used to calculate exposure were "adequate in number or representative as to the numerous various lead contamination sources." Specifically, ELF states that a "fatal omission" in Petersen's opinion "is a lack of any showing that she calculated the average lead concentration based on data that are scientifically and statistically sound for this purpose." [7] It relies on *In re Marriage of Riddle* (2005) 125 Cal.App.4th 1075, 1082-1083 for the rather self-evident principle that "[a] sample must be representative of what is being sampled."

We first observe this argument was not timely raised in the trial court and may therefore be deemed forfeited on appeal. (See *Locke v. Warner Bros., Inc.* (1997) 57 Cal.App.4th 354, 368; see also *Johnson v. Greenelsh* (2009) 47 Cal.4th 598, 603 [issues not raised in the trial court cannot be raised for the first time on appeal]; *Dietz v. Meisenheimer & Herron* (2009) 177 Cal.App.4th 771, 799-800 [appellant asserting error must have raised the issue in the trial court and given the trial court an opportunity to correct the error].) While ELF asserts insufficiency of the evidence objections are not waived even if raised for the first time on appeal, its objection does not go to the sufficiency of the evidence but instead argues that Petersen used a statistically flawed

[7] Amicus Curiae Mateel Environmental Justice Foundation requests that we take judicial notice of the following mathematical principles: (1) Under the laws of statistical inference and probability an estimate of a population parameter from a randomly selected sample necessarily contains random error which can be estimated and expressed in a confidence interval; and (2) the geometric mean is always smaller than the arithmetic mean, except in the special case where all the data are exactly the same. We grant the request. (Evid. Code, § 452, subd. (h), 459, subd. (a); see *People v. Bradley* (1982) 132 Cal.App.3d 737, 743, fn. 6.)

methodology in conducting her analysis. This objection should have been made prior to the trial court's issuance of its proposed statement of decision.[8]

Even assuming the argument is not forfeited, Petersen testified that the data she used are not extraordinarily high or low, but are in line with the results from the FDA's own multi-decade testing program. She also testified that changing the number of samples did not affect the result of her calculations. ELF asserts Petersen lacked sufficient data for many of the products, even when using both ELF's and defendants' test results. It notes that of the 106 different products identified in Petersen's analysis, 57 had less than 10 individual lab test results, 30 had five or less results, and five products had only a single test result. Yet ELF offers no compelling argument as to why the number of samples is insufficiently representative of the products tested. Instead it relies on Petersen's own conclusion that a result exceeding the MADL was not a reliable estimate of average lead exposure because it was based on only five data points. We note the single product in question was a fruit juice blend that included some juices that were not within the scope of the current case. This anecdotal evidence is insufficient to demonstrate that Petersen's analysis was based on statistically unreliable data.

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[8] At oral argument appellant spent much of its time on the Petersen "methodology" at trial. As indicated below, we, like the trial court, find her approach legally appropriate. We note further that after full discovery, appellants submitted but two motions in limine and "objections to relatively small portions of defendants' expert declarations." Appellants' objection to the evidentiary basis for Petersen's expert testimony was addressed by the trial court's statement of decision: "[T]he testing data the parties agreed could be admitted *without objection* at trial [now] provided an inadequate evidentiary basis for Dr. Petersen's expert testimony on the lead concentrations in Defendants' products. Plaintiff did not make this argument in its opening trial brief, its posttrial brief, its decision tree identifying issues for the Court to decide[,] or at closing argument. Indeed, Plaintiff's expert, Dr. Burton-Freeman[,] used the same testing data to support her different conclusions . . . . It is far too late in this case for Plaintiff to introduce a new argument about the *claimed inadequacy of the testing data used by both sides* during trial." (Italics added).

Taking another tactic, ELF questions the data used in the Beech-Nut sweet potato product because the product includes raw sweet potatoes that are processed in different facilities by various suppliers. ELF points out that there is no analysis as to whether the six data points used to determine the lead levels in the Beech-Nut product constitute a sufficient number of individual tests such that a reliable estimate of the lead concentration in the product can be determined.

We note Burton-Freeman also relied on the exact same data as Petersen in determining that the products contain excessive levels of lead. Thus, the same argument that ELF seeks to use to invalidate defendants' expert's conclusions can be used to invalidate its own expert's opinion stating contrary conclusions. Further, in criticizing Petersen's methodology, Burton-Freeman faulted defendants for failing to individually assess each ingredient source and each of the various manufacturing processes and facilities. Her reason for advocating doing so was that an analysis of individual lead testing results "would clearly identify problematic samples," thereby allowing "track[ing] them to the source of the issue for remediation." However, this case does not involve food safety law enforcement or remediation. The purpose of the data used in this case was not to conduct a product recall, but simply to determine whether Proposition 65 consumer warnings are or are not appropriate, regardless of the source of the ingredients that are used in the manufacturing process.

We do not disagree with the proposition the reliability of sampling is increased when more data points are used. However, we are not persuaded that the methodology employed by Petersen invalidates her opinions. In sum, we are satisfied that the evidence relied on by both Petersen and Burton-Freeman is the type of evidence that expert witnesses may reasonably rely on in forming their opinions.

IV. Averaging Exposure Over Time

The trial court concluded there was no scientific support for ELF's assertion that "exposures to Defendants' products on a single day would increase the blood lead level

of pregnant women enough to cause a central nervous system deficit in the fetus." ELF claims the trial court erred in interpreting the regulations so as to allow defendants to average the level of exposure over multiple days instead of evaluating the exposure on the day the food is actually consumed. As they admit, all of defendants' toxicologist experts opined that the level of lead in the products at issue was insufficient to cause reproductive harm based on a single day of exposure. Thus, absent an underlying legal or scientific error, substantial evidence supports the conclusion that it was appropriate to evaluate the level of exposure over time.

Under the regulations, the "level of exposure" is determined by "multiplying the level in question . . . times the reasonably anticipated rate of exposure for an individual to a given medium." (Regulations, § 25821, subd. (b).) The level of exposure is based in part on the "pattern and duration of exposure that is relevant to the reproductive effect which provided the basis for the determination that [lead] is known to the state to cause reproductive toxicity." (*Ibid*.) The same regulation describes a number of default assumptions for use in calculating the reasonably anticipated rate of exposure. For example, "[w]here a maternal exposure to a chemical listed as causing reproductive toxicity has an effect on the [embryo or fetus], the level of exposure shall be based on the reasonably anticipated rate of exposure for the mother during the nine-month gestation period." (Regulations, § 25821, subd. (c)(3).)

The FSOR states that in evaluating a reproductive toxins, "one needs to view the exposure as the one that may cause the acute [reproductive] effect. For example, if a food is eaten once per week, and if that food contains a teratogen, a proper assessment would require the assumption that ingestion of that food will occur on any day and, hence, every day[,] of the pregnancy. In other words, averaging to a daily intake would be inappropriate, since the embryonic response ought to be assumed to occur on the day of the ingestion of that food." The statement also provides, however, that "[i]f it is

scientifically more appropriate to evaluate a reproductive toxicant for chronic toxicity, this section does permit it."

ELF first claims the trial court committed "legal error" because the determination of whether a reproductive toxin is capable of acute toxicity, as opposed to chronic toxicity, is not limited to a consideration of "exposures to Defendants' products." Instead, ELF asserts "the relevant 'pattern and duration of exposure' should be based on the effects that can result from levels of lead that are higher than the actual level in Defendants' products." ELF also contends defendants' failure to evaluate whether short-term exposure to higher levels of lead is capable of causing harm is fatal to their safe harbor defense. We disagree. As we stated in *DiPirro,* Proposition 65 "envisions a case-by-case approach which takes into account the totality of the quantitative risk assessment evidence presented." (*DiPirro, supra,* 153 Cal.App.4th 150, 193.)

As noted above, Petersen relied on the NET survey for average eating occasions over a 14-day period. Substantial evidence established that the products here are eaten no more frequently than four times per month. Experts on both sides agreed that there is at least an eight-week "window of susceptibility" to lead. In other words, eight weeks is the shortest period during which an exposure to lead at levels detected in the products would be expected to have an adverse reproductive effect. Even Hu conceded on cross-examination that the evidence supported the eight-week time frame. Further, it was undisputed that the challenged products are not typically eaten on a daily basis.

In an amicus brief, the Attorney General advances ELF's claim, contending Proposition 65's regulations prohibit the trial court from allowing defendants to average the single-day lead exposure from their products over a number of days between consumption before comparing the exposure to the 0.5 microgram per day regulatory MADL. She urges that a defendant that relies on a regulatory MADL must accept a

single-day exposure period.[9] According to her, defendants are prohibited from converting the single-day maximum exposure of 0.5 micrograms into an average exposure over 14 days (7 micrograms per 14 days) because they did not independently determine a MADL based on an average exposure over an extended and defined period of time. Thus, they are not allowed to calculate average exposure to a reproductive toxicant and then compare it to the regulatory MADL, which is set as maximum single-day exposure.[10] In support of this assertion, she relies on Donald's testimony and claims the trial court improperly declined to give deference to this testimony.

"[W]hile interpretation of a statute or regulation is ultimately a question of law, we must also defer to an administrative agency's interpretation of a statute or regulation involving its area of expertise, unless the interpretation flies in the face of the clear language and purpose of the interpreted provision." (*Communities for a Better Environment v. State Water Resources Control Bd.* (2003) 109 Cal.App.4th 1089, 1104.) Although administrative agencies' interpretation of their regulations and language is entitled to great weight, we will not defer when the construction is unauthorized, unreasonable, or clearly erroneous. (See *North Gualala Water Co. v. State Water Resources Control Bd.* (2006) 139 Cal.App.4th 1577, 1607.) As the trial court noted, the evidence supplied by Donald was insufficient to demonstrate that his views represent the authorized, formal policy of the OEHHA. We concur with that assessment.

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[9] A company can establish its own MADL if it wishes, for which OEHHA has also issued regulations. (Regulations, § 25803.) In this case, defendants elected to use the regulatory safe harbor level adopted by OEHHA.

[10] We note the MADL for carcinogenic exposure is also set at a per-day level. (See Regulations, § 25705.) We further note that the regulatory MADL for lead is based on workplace inhalation exposure, not exposure caused by consumption of food. These factors suggest there is room for alternative scientifically appropriate methods of determining levels of exposure from food products containing lead.

According to Beck's model, the effect on the blood lead levels of women of child-bearing age and four-month old children from exposures at the safe harbor level would be greater than or equal to the effect from exposures shown by Petersen's analysis. As the trial court observed, "[s]ince no warning would be required under the modeled regulatory NOEL standard it is difficult to see why frequency of use should not be considered in determining whether that standard has been met in this case." In sum, on the record here, we cannot conclude that the trial court erred in accepting defendants' experts' opinions that the products qualify for the exemption under the safe harbor defense of Regulation 25801, subdivision (b)(2).

DISPOSITION

The judgment is affirmed.

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Dondero, J.

We concur:

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Humes, P.J.

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Jenkins, J.*

* Associate Justice of the Court of Appeal, First Appellate District, Division Three, assigned by the Chief Justice pursuant to article VI, section 6 of the California Constitution.

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