SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF ALAMEDA

ENVIRONMENTAL LAW FOUNDATION, Plaintiff, v. BEECH-NUT CORPORATION, et al. Defendants.	No. RG11 597384 TENTATIVE AND PROPOSED STATEMENT OF DECISION Trial Date: April 8, 2013 Time: 8:30 a.m. Dept.: 17

I. INTRODUCTION

This case presents the question of whether defendants Beech-Nut Corporation et al. ("Defendants") are required by Proposition 65 to place warnings on their fruit, vegetable and grape drink products that they contain lead, an element known to the State of California to cause cancer and reproductive harm. There is no dispute that Defendants' products contain small amounts of lead.

Defendants argue that no warnings are required for three separate reasons: (1) any such warnings are preempted by federal law; (2) because the lead in their products is naturally

occurring and not anthropogenic, it does not constitute an "exposure" within the provisions of Prop 65; and (3) even if Prop 65 is not preempted and Defendants have not established the naturally occurring defense, they have established that the exposures in question are below the regulatory "safe harbor" level of 0.5 micrograms per day.

These arguments require the Court to resolve several previously unanswered legal questions pertaining to the meaning and effect of Prop 65 and the regulations adopted to implement it. Having resolved these questions in the manner set forth below and having considered the parties' extensive scientific and other evidence, the Court concludes that Defendants have not shown by a preponderance of the evidence that Prop 65 is preempted or that the regulatory "naturally occurring" defense is applicable to their products. They have, however, shown that each of their products is below the regulatory "safe harbor" exposure level, and for that reason, no warnings are required. The Court's analysis follow.

II. PROCEDURAL HISTORY

The complaint in this action was filed by plaintiff Environmental Law Foundation ("ELF" or "Plaintiff") on September 28, 2011. It alleges that Defendants produce, distribute and/or sell various canned or packaged fruit products, or fruit drinks, or baby foods, which contain lead at levels that require a warning under Prop 65. No such warnings are currently provided.

Lead is an element (Pb on the periodic table) which has been identified as a known carcinogen and a known reproductive toxin pursuant "The Safe Drinking Water and Toxic Enforcement Act of 1986," codified at Health & Safety Code sections 25249.5 et seq. ("Prop 65" or "the Act)." Prop 65 was adopted by the people of the State of California as an initiative on November 4, 1986.

The complaint seeks injunctive relief and civil penalties against Defendants for their alleged knowing and intentional exposure of consumers of their products to lead without first giving clear and reasonable warnings, in violation of section 25249.6 of the Act.[1]

Defendants filed answers beginning in December 2011, denying liability and raising various affirmative defenses. On April 12, 2012, a complaint in intervention was filed by stipulation, adding four more suppliers of private label products who are aligned with Defendants. Their answer was filed on July 26, 2012.

Despite early settlement efforts, Plaintiff filed a motion on May 4, 2012, seeking a preliminary injunction. However, after further informal discussions, Plaintiff agreed to drop that motion and instead to proceed on an agreed-upon schedule including deadlines for completion of lay and expert discovery, hearings on potentially dispositive motions, a pretrial conference on March 15, 2013, and trial on April 8, 2013. (Stip. & Order filed 6/8/2012.)

This case has been noteworthy because despite the strongly-held divergent views between Plaintiff and Defendants concerning the merits, counsel have worked cooperatively to present their respective arguments and evidence efficiently and persuasively. Thus on July 27, 2012, Plaintiff and the 16 Manufacturer Defendants[2] stipulated for purposes of this case only that Plaintiff be deemed to have met its burden of proof at trial; that those Defendants would not proceed on their First (failure to state a cause of action), Fifth (Compliance with Applicable Laws) and Ninth (Inadequate Notice) affirmative defenses; and, with approval of the Court, that discovery and adjudication of issues related to remedies be stayed and deferred until after

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[1] All further references are to the Health & Safety Code unless otherwise noted or to the regulations adopted pursuant to section 25249.12 of the Act.

[2] The Manufacturer Defendants who are parties to the stipulation and who participated in the trial are: Beech-Nut Nutrition Corp., Clement Pappas & Co., Inc.; Cliffstar, LLC; Del Monte Foods; Dole Packaged Foods, LLC; Gerber Products Company; The Hain Celestial Group, Inc.; Independent Food Processors Corp.; Smucker Natural Foods, Inc.; Kedem Foods Products Int'l; Langer Juice Company, Inc.; Pacific Coast Producers, Inc.; Seneca Foods Corp.; Tree Top, Inc.; Truitt Bros., Inc. and Welch's Foods, Inc., A Cooperative.

adjudication of those Defendants' liability, if any. A further stipulation was filed on August 28, 2012 regarding the admissibility of all parties' lead-testing data.

Another stipulation was filed and approved by the Court on August 31, 2012, which stayed the action, including discovery, with respect to the Retailer and Distributor Defendants; bifurcated the trial so that only specified Manufacturer Defendants' affirmative defenses would be tried on April 8, 2013; agreed that the disposition of those defenses which were actually litigated and subject to a written order of the Court would be binding on Plaintiff and the Retailer and Distributor Defendants; and provided that if Plaintiff were to establish liability of the Manufacturer Defendants during the first phase of the trial, the stay would be lifted and a second phase of trial would be scheduled to encompass both any remaining liability issues specific to the Retailer Defendants and remedy issues. (Stip. & Order filed 8/31/2012.)

On October 12, 2012 the parties reached agreement on a protocol for all expert discovery, which was largely completed in accordance with the previously agreed-upon schedule by December 21, 2012. On February 11, 2013 the parties filed their joint case management statement announcing their agreement that all direct expert testimony would be submitted by declaration and raising various trial related issues for the Court's consideration. The Court issued its tentative CMO in response on February 14, 2013 and heard argument on the few remaining disputed procedural issues on February 19, 2013.

On March 15, 2013 the Court held a pretrial conference. Both sides filed and served 50-page trial briefs, together with appendices of the key evidence and authorities. Defendants also lodged their seven experts' direct testimony (in the form of sworn declarations accompanied by the evidence and literature relied upon by each expert). Defendants filed ten in limine motions and Plaintiff filed two in limine motions. Over the next two weeks, the Court received responses to and ruled on the in limine motions. In addition, Plaintiff filed objections to relatively small portions of Defendants' expert declarations and lodged five experts' direct testimony (later reduced to four). Defendants filed a motion to bifurcate trial to proceed in a first phase with their

preemption and safe harbor defenses, separately from the naturally occurring defense. The Court denied that motion but, because of scheduling complications, directed the parties to present all expert testimony on the first two defenses before hearing evidence pertaining principally to the naturally occurring defense.

Live testimony of the parties' expert witnesses (cross, redirect, etc.) and one percipient witness for Plaintiff began on April 8, 2013 and continued for about ten trial days, concluding on April 29, 2013. The parties filed their closing trial briefs and decision trees requested by the Court on May 9, 2013. The Court heard closing arguments on May 16, 2013 and took the matter under submission.

The record in this case consists of several hundred pages of direct testimony (admitted into evidence subject to the Court's rulings on specific evidentiary objections as Defendants' Exhibits 6680 – 6686, and Plaintiff's Exhibits 2503 – 2506; a Reporter's Transcript of trial proceedings of 1481 pages; excerpts from the deposition transcripts of 16 defense persons most qualified and two expert witnesses who had been designated to testify at trial but were not called (JX 7384-7396),[3] and hundreds of trial exhibits consisting of thousands of pages admitted either as Joint Exhibits ("JX") or as Plaintiff ("PX") or Defendants ("DX") Exhibits.

Having fully considered all of the oral and documentary evidence as well as the briefs and arguments of counsel, and the pertinent authorities, the Court issues this Tentative and Proposed Statement of Decision pursuant to CRC 3.1590(b) and (c)(1). It is subject to objections pursuant to CRC 3.1590(g).

[3] On June 13, 2013 Plaintiff lodged additional objections to certain PMQ depositions already admitted into evidence. Plaintiff neither sought nor obtained leave to file these objections after both sides had rested and closing arguments had been completed. The objections are OVERRULED as untimely.

III. DEFENDANTS HAVE NOT ESTABLISHED FEDERAL PREEMPTION

Defendants' preemption defense primarily involves issues of law. It relies upon claimed direct conflicts between Prop 65 and two overlapping sets of federal laws: The first is Congress's creation and extensive funding and support of U.S. Department of Agriculture programs intended to improve the nation's health by encouraging increased consumption of fruits and vegetables, including packaged and canned fruits and vegetables and juice products like those which are at issue in this case. The second is the regulatory scheme created by the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq. ("FDCA"), including the powers granted to the Federal Drug Administration ("FDA") with respect to foods pursuant to the Nutrition Labeling and Education Act, 21 U.S.C § 393(b) et seq. ("NLEA").

Defendants do not assert federal preemption based upon an express act of Congress, or that Congress has intended to occupy the fields of "health through nutrition" or food and beverage labeling and safety to the exclusion of any state regulation. Rather, they argue that requiring their labels to carry a warning to the effect that the products contain lead, a substance known to the State of California to cause cancer and reproductive harm, would be an obstacle to federal objectives and amount to misbranding under the FDCA. Thus, Defendants argue, there is an implied but direct conflict between Prop 65 and federal law.

The California Supreme Court, following federal precedents, has made clear that there is a "strong presumption against preemption" in cases like this one:

> [B]ecause the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state law causes of action. In all pre-emption cases, and particularly in those in which Congress has legislated ... in a field which the States have traditionally occupied, we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress. We apply this presumption to the existence as well as the scope of preemption.
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> There can be no doubt that the presumption applies with particular force here. As the Court of Appeal acknowledged here, consumer protection laws such as the UCL, false advertising law, and CLRA, are within the states' historic police

> powers and therefore are subject to the presumption against preemption. Laws regulating the proper marketing of food, including the prevention of deceptive sales practices, are likewise within states' historic police powers. Indeed, as early as the 1860's, California was enacting laws regulating food marketing.
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> It is with these principles in mind that we consider whether it was the clear and manifest purpose of Congress to preclude states from providing private remedies for the violations of the state statutes at issue here.

(*Farm Raised Salmon Cases* (2009) 42 Cal.4th 1077, 1087-88, internal citations and quotations omitted. *See also, Physicians Committee For Responsible Medicine v. McDonald's Corp.* (2010) 187 Cal.App.4th 554, 564-65.) It is correct that *Farm Raised Salmon,* unlike *McDonald's*, was not a Prop 65 case, but the preemption principles it followed are applicable here.

With respect to the federal government's promotion and support of increased consumption of fruits and vegetables, Defendants do not rely upon the language of any federal law or regulation. Rather, they cite numerous federal publications which clearly evince such a policy.[4] One of Defendants' nutrition experts confirms the purpose and importance of federal programs promoting fruit and vegetable consumption. (See DX 6684, Keen Trial Decl., ¶¶ 17-26.) However, the only evidence in the record suggesting that a Prop 65 warning on Defendants' products would conflict with federal policy is the testimony of Dr. Carl Keen. (*Id*., ¶¶ 32-33.)[5] Dr. Keen is very knowledgeable, but he is not a psychologist or expert in how consumers react to warnings. Nor did he address, and Defendants did not provide, any other evidence which would support a finding that Prop 65 warnings on *their* products would cause California consumers not

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[4] The same policy motivated creation of the naturally occurring defense discussed in the next section. (See pp. 11-20, *infra*.)

[5] Defendants had designated Dr. Christine M. Bruhn as their consumer behavior expert, but she was withdrawn. Both sides designated deposition excerpts from Dr. Gavin Huntley-Fenner, who was Plaintiff's designated person to evaluate Dr. Bruhn's opinions. Dr. Huntley-Fenner has no expert opinion on whether a Prop 65 warning on a can of peaches might dissuade a purchaser from buying that can. (JX 7396 at 68:11-69:3.) Further, "[t]here is an open question about whether a person will read a warning on a specific product and apply it to products where no such warning is visible. . ." (*Id.*, 47:20-24.) He opined that consumers will seek alternate sources [without a Prop 65 warning], rather than give up fruits and vegetables entirely. (*Id.*,139:2-6.)

to eat *other* packaged fruits and vegetables that do not contain such warnings, or fresh fruits and vegetables, generally.[6]

The principal case Defendants rely upon to establish their preemption defense is *Dowhal v. Smithkline Beecham Consumer Healthcare* (2004) 32 Cal.4th 910. In that case, the Supreme Court reinstated the grant of a summary judgment for defendant based upon federal preemption. The product at issue in *Dowhal* was a nicotine patch marketed to smokers in an effort to help them stop smoking. Nicotine is a listed Prop 65 substance based upon reproductive toxicity.

However, nicotine is a drug, not a food product, and therein lies a critical difference between the analysis in *Dowhal* and the preemption argument in this case. Unlike food products, drugs like nicotine are required to have labels which must be approved in advance by the FDA. Defendants have pointed to no regulation of the FDA which requires prior federal approval of food labels for the packaged fruits and vegetables and grape juice involved in this case and the Court is not aware of any.

The issue before the Court in *Dowhal* was whether a conflict between Prop 65 and the FDCA existed which supported the trial court's grant of defendant's motion for summary judgment. The Food and Drug Administration Modernization Act of 1997, 21 U.S.C. § 379r(a) expressly preempts state laws with respect to labels for drugs which were not identical to federal laws or regulations. However, that express preemption provision contains an exception for state

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[6] The Court notes that the Lead Agency charged with enforcement of Prop 65 adopted the naturally occurring defense because of a concerns that warnings on foods like these could "unnecessarily reduce the availability of certain foods or could lead to unnecessary warnings, which could distract the public from other important warnings on consumer products." (See DX 5400/PX2301, Final Statement, quoted at pp. 16 - 18, *infra*.) Defendants provided expert testimony to the effect that lead is present in soils throughout the world, from which an inference can be drawn that all fruits and vegetables contain some lead. However, they did not provide evidence from which the Court could find that all other fruits and vegetables sold commercially in California would contain as much lead as their products, or that competitors' products would, subject to the naturally occurring and safe harbor defenses addressed later in this order, require warnings.

law initiative measures enacted before September 1, 1997, of which Prop 65 is the only one. (21 U.S.C. § 379r(d)(2).) The Court held that the exception did not preclude the possibility of preemption based upon a direct conflict between state and federal law. (*Dowhal,* 32 Cal.4th at 926.) Applying the direct conflict test to the undisputed facts in the record, the Court assumed that a "safe harbor" type of warning as provided for in section 12601(b)(4)(B) of the regulations (Cal. Code Regs., tit. 22 § 12601(b)(4)(B)) would be required by Prop 65, to the effect that: "WARNING: This product contains nicotine, a chemical known to the State of California to cause birth defects or other reproductive harm" was at issue in the case. (*Id.* at 927.)

However, in response to requests from the litigants before the Court and a citizen petition, the FDA had clearly stated that (1) it would not approve such a Prop 65 warning for nicotine patches and (2) it would, from August 17, 2001 forward, require those who had previously obtained FDA approval for over-the-counter nicotine patch labels to apply for permission to use a new label with the following uniform language:

> If you are pregnant or breast feeding, only use this medicine on the advice of your health care provider. Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known.

(32 Cal.4th at 943.) Thus, there were no triable issues as to whether a conflict existed between federal and state law.

Here, Defendants have not identified any federal policy or regulation with which a Prop 65 warning would be in direct conflict. As noted above, there is no evidence that a safe harbor type warning would result in California consumers eating fewer fruits and vegetables, and thus interfere with the strong federal policy of promoting increased consumption of fruits and vegetables.

Further, although it is clearly aware of this litigation, and has responded to it, the FDA has not taken the position that a safe harbor warning would conflict with its responsibilities to

assure the safety of America's food supply or would amount to misbranding in violation of section 343-1 of the FDCA.

Defendants rely principally on an FDA report, including a series of questions and answers, which the FDA posted on its website in 2010 and revised slightly in 2011. That report makes available to the public in easily understood language an overview of the results of the FDA's then-most recent (July 2010) evaluation of amounts of lead in some specific brands of commercial juice and food products that contain fruit. (DX 5772) The FDA tested 13 samples of apple juice, grape juice, peach slices, pears, mixed fruit and fruit cocktail, including some products intended for babies. Although the FDA regularly monitors the safety of food and juice products, it tested those products at that time because "they were among those cited in a recent action by the Environmental Law Foundation . . ." in this case. (*Id.*)

The FDA found, consistent with the undisputed evidence in this case, that "almost all of the products . . . contained a small amount of lead but in each case the level found was below FDA's current tolerable intake levels for lead." (*Id.*) The report also responded to its own question "What is FDA doing about lead in food products?" by saying:

> FDA has monitored the levels of lead in food products for decades. The agency has taken action whenever necessary to remove from the marketplace products that contain too much lead, and has worked with the food industry over the years to reduce the amount of lead in food products. Despite the decades-long reduction of lead intake from food in the United States, FDA is continuing to work to reduce the amount of lead in food products as much as possible, especially in foods frequently consumed by children. In 2006 for example, FDA lowered its recommended maximum level of lead in candy likely to be consumed by small children to .1 ppm [100 ppb]. FDA is in the process of reviewing the available data as it considers lowering its guidance level for lead in juice.[7]

[7] Defendants also rely on a letter from Michael M. Landa, Director of the FDA's Center for Food Safety and Applied Nutrition dated February 1, 2013. That letter responds to questions from the Director of the State of Washington, Department of Agriculture, about the Q and A discussed above. In that letter Mr. Landa makes clear that a language change regarding "below the tolerable intake level" was not a change in substance. (DX 5640.) Further, the Landa letter

(*Id*.)

Plaintiff argues that the FDA's Q and A does not have the requisite formality to constitute a federal policy that creates a direct conflict for federal preemption purposes. While the facts and pertinent provisions of federal law before the Supreme Court in *Dowhal* were certainly different from the FDA actions upon which Defendants rely in this case, the Court cannot conclude that communication with the public using a question and answer format on the FDA's website would never be a basis for federal preemption.

What is important here, however, is that Defendants have not shown by a preponderance of the evidence either that the FDA believes that Prop 65 warnings on their products would interfere with federal policy or that such warnings would in fact do so. Nor have they shown that Prop 65 warnings would interfere directly with the FDA's reasoned decision in 2010 not to publish an advisory or take any action beyond internet publication of its Q and A report while continuing to work with industry to lower lead levels in packaged fruits and vegetables and fruit drinks.

Finally, Defendants have not shown that any product warning potentially required by Prop 65 would be limited to the safe harbor warning provided for in section 12601(b)(4)(B), or would otherwise constitute misbranding under federal law. In summary, Defendants' evidence and argument do not overcome the presumption against preemption. Hence, the Court finds no direct conflict and rejects Defendants' federal preemption defense.

IV. DEFENDANTS HAVE NOT ESTABLISHED THE NATURALLY OCCURRING DEFENSE

Defendants argue that their evidence has shown that 90% or more of the lead in their products is naturally occurring. "Naturally occurring" in this sense means lead that has no anthropogenic source, that is, lead introduced into the fruits and vegetables by any known human

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implicitly verifies that as recently as January 2013 the Q and A represents the FDA's position on potential health problems caused by lead in products like those at issue here.

activity, including the actions of Defendants or those who supply them.[8] Defendants argue that because the lead in their products is naturally occurring, their products do not "expose" consumers to lead for purposes of section 25249.6 of the Act, and therefore no warnings are required.

Plaintiff responds that it is not enough that the lead in their products be entirely naturally occurring (and that it is not), and that Defendants have failed to meet the other requirements of section 25501. We begin by setting out the law and then address Defendants' evidence.

Unlike the exemption created by section 25249.10(c), the Act does not contain a naturally occurring defense. Nor does it define "expose" as that term is used in section 25249.6 of the Act.

In response to a petition submitted to the Health and Welfare Agency, the original "Lead Agency" designated by the Governor pursuant to section 25249.12 of the Act, the Agency initiated a formal rule making procedure which resulted in the adoption of section 2550l of the regulations (27 C.C.R. § 22501).[9] That section creates the "naturally occurring defense" and provides, in relevant part:

> (a) Human consumption of a food shall not constitute an "exposure" for purposes of Section 25249.6 of the Act to a listed chemical in the food to the extent that the person responsible for the exposure can show that the chemical is naturally occurring in the food.
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> (1) For the purposes of this section, a chemical is "naturally occurring" if it is a natural constituent of a food, or if it is present in a food solely as a result of absorption or accumulation of the chemical which is naturally present in the environment in which the food is raised, or grown, or obtained; for example, minerals present in the soil solely as a result of natural geologic processes, or toxins produced by the natural growth of fungi.

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[8] Subsection (a)(3) has a limited exception to this definition. See text, at p. 13.

[9] The petition, filed on April 29, 1987 by 20 different groups, including the Grocery Manufacturers of America, Inc., sought an exemption from the warning requirement of section 25249.6 for all food products which comply with certain federal safety regulations. (See *Nicolle-Wagner v. Deukmejian* (1991) 230 Cal.App.3d 652, 655.)

> (2) The "naturally occurring" level of a chemical in a food may be established by determining the natural background level of the chemical in the area in which the food is raised, or grown, or obtained, based on reliable local or regional data.
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> (3) A chemical is naturally occurring only to the extent that the chemical did not result from any known human activity. Where a food contains a chemical, in part naturally occurring and in part added as a result of known human activity, "exposure" can only occur as to that portion of the chemical which resulted from such human activity. For purposes of this section, "human activity" does not include sowing, planting, irrigation, or plowing or other mechanical preparation of soil for agricultural purposes; but does include the addition of chemicals to irrigation water applied to soil or crops.
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> (4) Where a chemical contaminant can occur naturally in a food, the chemical is naturally occurring only to the extent that it was not avoidable by good agricultural or good manufacturing practices. The producer, manufacturer, distributor, or holder of the food shall at all times utilize quality control measures that reduce natural chemical contaminants to the "lowest level currently feasible," as this term is used in Title 21, Code of Federal Regulations, Section 110.110, subdivision (c) (2001).

When Defendants' evidence is measured against the requirements of subsections (a)(1) through (a)(4) it does not satisfy section 25501.

A. Defendants Have Not Shown That The Lead In Their Products Is Solely Geogenic And Not Anthropogenic

The parties do not dispute that lead is "naturally present in the environment" within the meaning of subsection (a)(1), but Defendants have offered no evidence that the small amounts of lead in their products are present "*solely* as a result of absorption or accumulation of the chemical which is naturally present in the environment" (emphasis supplied). Defendants presented two experts, Dr. Samuel Bowring and Dr. J. Scott Angle, who are experienced, well-qualified and credible experts in their respective fields of geology and soil sciences, including plant uptake of heavy metals. They testified in effect that because of the limited ways that lead can get into fruits and vegetables (principally through their roots) and because almost no anthropogenic lead exists in the soil below depths of 30 centimeters, where most of the roots for most of the plants at issue are located, the vast majority of the small amount of lead taken up by

the plants and transmitted to the fruit from which the products are made is naturally occurring.[10] But however great the proportion of naturally occurring lead may be, "the lead in the products at issue is a mixture derived from multiple sources." (DX 6686, Bowring Trial Decl., ¶ 59.) Hence, unless the Court were to treat the word "solely" as used in subsection (a)(1) as meaning "predominantly," Defendants have not satisfied this element of section 25501.

Further, Plaintiff contends that the testimony of Dr. Bowring about the nature of background levels of lead throughout the world is insufficient because he did not rely upon "reliable local or regional data, as is permitted by subsection 25501(a)(2). Although that section does not require the use of reliable local or regional data to demonstrate that the lead is solely geogenic, if Defendants wish to establish that the lead in their products is naturally occurring under subsection (a)(1) and (a)(2) through the use of background levels, they must produce such evidence. In this case Defendants did not do that, and thus did not satisfy subsection 25501(a)(1).

B. Defendants Have Not Shown What Portion Of The Lead In Their Products Was Naturally Occurring.

When subsections (a)(1) and (a)(3) are read together, it appears that an alternative to satisfying subsection (a)(1) is to demonstrate the portion of the products at issue that are geogenic, and thus do not count toward an exposure for purposes of section 25249.6 of the Act,

[10] Plaintiff's expert, Dr. Russell Flegal, Jr., disputes many of the opinions expressed by Dr. Angle and Dr. Bowring, and contends that most of the lead in the products at issue is the result of aerial deposition of lead through industrial sources and leaded gasoline. The Court finds that Dr. Angle's testimony regarding the manner in which lead gets into the fruit of the plants at issue and Dr. Bowring's testimony regarding the properties and location of anthropogenic lead in soil are more persuasive than that of Dr. Flegal. Interestingly, Dr. Flegal agrees that there is no biological requirement for lead in plants and that even trace levels of lead are toxic to plants. (. PX 2506, Flegal Trial Decl., ¶53.) Hence, whether anthropogenic or naturally occurring, the amounts of lead in the fruits and vegetables at issue in this case, at least when they are harvested, are "trace levels." While the Court accepts Dr. Flegal's testimony that lead can possibly be introduced into the growing and processing of fruits and vegetables, there is little or no evidence that what *can* happen *did* happen here.

through some means other than evidence of background levels. Plaintiff's expert, Dr. Russell Flegal, Jr., testified that Defendants could have done isotopic analyses of their products to determine what portion is geogenic and what portion is anthropogenic. (PX 2506, Flegal Trial Decl., ¶¶ 178-181). Dr. Bowring convincingly testified as to why such testing is not realistic in the context of products like those at issue. (DX 6686, Bowring Trial Decl., ¶¶ 59-62.) However, what is important for purposes of this case is that Defendants did not provide either the appropriate natural background levels to satisfy subsection (a)(1) or any provide any other means of showing what portion of the lead in their products is geogenic and what portion is anthropogenic.

Defendants nonetheless argue that because of the importance of food products containing trace amounts of lead to healthy diets it should be easier to establish the naturally occurring defense than the safe harbor defense. Hence, they ask the Court to accept Dr. Angle and Dr. Bowring's testimony that virtually all of the lead in Defendants' products is geogenic based upon their opinions and the various materials they reviewed in forming those opinions. However, the Court has found little basis for Defendants' argument.

Apart from the language of section 25501 and the Final Statement of Reasons published in connection with its adoption there is little precedent to help determine whose interpretation of the naturally occurring defense is correct.[11] Section 25501 was challenged shortly after it was adopted in *Nicole-Wagner, supra*. Plaintiff in that case contended that the regulation was inconsistent with Prop 65, which makes no distinction between man-made and naturally occurring chemicals in food or otherwise and therefore the regulation was beyond the Agency's

[11] In *People v. Tri-Union Seafoods, LLC* (2009) 171 Cal.App.4th 1549, 1576 the Court of Appeal held that there was substantial evidence to support the trial court's determination that merthylmercury in tuna is naturally occurring. Perhaps because of its observation that "it is undisputed that the Tuna Companies do not add methylmercury to canned tuna products, and there is no process to remove the chemical from canned tuna" the Court did not interpret or apply subsections (a)(2), (3) or (4) of section 25501. *Id.*, at 1562.

authority to adopt. The trial court granted defendants' motion for summary judgment and the Court of Appeal affirmed, holding that the regulation was not in conflict with the Act and was appropriately adopted by the Agency to effect the purposes of Prop 65, as demonstrated by a review of ballot arguments and the Agency's Final Statement of Reasons issued with the final version of section 25501 as adopted.

Defendants point to the following portion of the opinion in *Nicole-Wagner* to support their view that the requirements of the section should be construed broadly to effectuate its purpose, that is, to provide an exemption for food products that is easier to establish than the statutory exemption of section 25249.10(c):

> We all presume, to some extent, that foods that have been eaten for thousands of years are healthful, despite the presence of small amounts of naturally occurring toxins. Were these substances not exempted from Health and Safety Code section 25249.6's warning requirements, the manufacturer or seller of such products would bear the burden of proving, under subdivision (c) of Health and Safety Code section 25249.10, that the exposure poses no "significant risk" to individuals. The administrative record in this matter indicates that such evidence largely does not exist. Thus, grocers and others would be required, in order to avoid liability under these statutes, to post a warning label on most, if not all, food products. The Agency's final statement of reasons for section 12501 includes the observation that the "[a]bsence of such an exemption could unnecessarily reduce the availability of certain foods or could lead to unnecessary warnings, which could distract the public from other important warnings on consumer products." Since one of the principal purposes of the statutes in question is to provide "clear and reasonable warning" of exposure to carcinogens and reproductive toxins, such warnings would be diluted to the point of meaninglessness if they were to be found on most or all food products.

(230 Cal.App.3d at 660-661, quoting from DX 5400/PX2301, the Agency's Final Statement of Reasons at p. 4].)[12] However, the portion of the *Nicole-Wagner* opinion Defendants rely upon is followed by this observation:

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[12] The Final Statement goes on to point out:

> Food is a basic daily necessity of life on a par with the water that we drink and the air that we breathe. For public health reasons, it is important to maintain an abundant supply of nutritious naturally occurring foods. Warnings for naturally occurring chemicals in food would not significantly enlighten the consumer about

> The regulation is also narrowly drawn. It is applicable only to naturally occurring chemicals in foodstuffs and not other products, such as pharmaceuticals and cosmetics. It takes pains to define "naturally occurring" in such a fashion so as to preclude chemicals which are in whole or in part the product of human activity. Thus, a chemical is "naturally occurring" only if it is a natural constituent of food or if it is present solely as a result of the absorption or accumulation of chemicals which are naturally present in the environment. Even if a chemical occurs naturally in a food, it is not deemed to be "naturally occurring," under the regulation, to the extent it is avoidable by good agricultural or manufacturing techniques. Natural chemical contaminants must be reduced to the "lowest level currently feasible.

(230 Cal.App.3d at 661.)

At the end of the day *Nicole-Wagner* did not decide and therefore is not authority on the question of how section 25501 of the regulations is to be interpreted. (Styne v. Stevens (2001) 26 Cal.4th 42, 57, citing authorities.) However, its citation to and reliance on the Final Statement prepared by the Agency helps direct the Court to that important source of "quasi-legislative" history and is helpful in addressing the parties' arguments here.

With respect to the general purpose of the defense, in addition to the materials quoted in *Nicole-Wagner*, the Agency made the following pertinent comments:

> The Act does not differentiate between exposures to naturally occurring chemicals and exposures to chemicals added by man. However, due to the abundance of foods which in their natural unprocessed state inherently contain low levels of carcinogens or reproductive toxicants, warnings could appear on a large number of food products, and consequently, diminish the overall significance of food warnings.
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> . . . . The rationale for this special treatment of food is the historical desire to preserve naturally occurring foods in the American food supply, despite the presence in those foods of small amounts of potentially deleterious substances, as well as a recognition of the general safety of unprocessed foods as a matter of consumer experience. . . . For these same reasons, it is reasonable and appropriate

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> his or her options and are more likely to cause confusion for the consumer who would be unable to differentiate between risks inherent in a food and those from added chemicals.

(*Id.* at p. 5.)

> to implement the Act so that warnings are not required for naturally occurring chemicals in food.
>
> . . . . Absence of such an exemption could unnecessarily reduce the availability of certain foods or could lead to unnecessary warnings, which could distract the public from other important warnings on consumer products.

(*Id.*, at pp. 3-4.)

While the Agency's reasons for excluding naturally occurring lead from determinations of food exposure for purposes of section 25249.6 are thus consistent with Defendants' arguments, the specific requirements of subsections 25501(a)(1), (2) and (3) cannot be read as broadly as Defendants argue. Defendants have not argued that these subsections are ambiguous. "Solely" means solely. "Reliable local or regional data" does not include broader studies which do not include data on each of the growing regions at issue here.[13] "That portion of the chemical which resulted from such human activity" may well permit a reasonable estimate of the percentage of lead in each product which is anthropogenic but Defendants' evidence of "predominance" and "majority" are not sufficient for the Court to assign a numerical value to the anthropogenic lead, which could then be measured against the 0.5 micrograms per day exemption under section 25249.10(c).

In short, viewed as a whole the Agency's language in sections 25501(a) (1), (2), and (3) and its Statement of Reasons for adopting that language required Defendants either to establish

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[13] Indeed, the Agency recognized "the difficulty of establishing the exact amount of 'naturally occurring' chemical [sic] in a particular food as the reason for permitting evidence of "the natural background level of chemical in the area in which the food was . . . grown . . . based on relevant and reliable local or regional data." *Id.*, at p. 7. The Agency also responded to comments suggesting adoption of the federal definition of "naturally occurring" by stating:

> Rather than using the federal definition in its entirety, the language of subdivision (a) was carefully selected and tailored to clearly describe the scope of the exemption so as to implement the Act in a reasonable manner.

Id., at p. 6.

that the lead in their products was solely geogenic or to establish the proportions that were geogenic. They did neither.

C. Defendants Have Also Failed To Demonstrate Efforts To Achieve The "Lowest Level Currently Feasible" as Required by Subsection (a)(4).

Finally, subsection (a)(4) makes clear that even though lead can be and is naturally occurring in foods, the defense provided by section 25501 is available only to the extent that the lead was not avoidable by good agricultural practices ("GAPs") and good manufacturing practices ("GMPs") and that the producers/suppliers of the foods have at all times used quality control measures ("QCMs") to reduce the lead to the "lowest level currently feasible." Plaintiff and Defendants presented extensive evidence with respect to each Manufacturing Defendant concerning its existing GAPs, GMPs, and QCMs. Dr. Leslie D. Bourquin examined thousands of pages of documents and, based on that review, opined that each Defendant follows GAPs, GMCs, and QCMs as those terms are generally understood in the food industry and by the FDA. However, he did not read the person most qualified depositions or visit Defendants' plants; Hence, his opinions on the ultimate facts necessary to establish compliance with subsection (a)(4) have limited value.

Plaintiff's expert, Dr. Allison Mitchell, found fault with all of the Defendants because, to a greater or lesser extent, they did not follow all of the guidelines of the Codex Alimentarius Commission's *Code of Practice for the Prevention and Reduction of Lead Contamination in Foods*. (JX7241.) The Court rejects Plaintiff's argument that such compliance is necessary to satisfy the requirements of subsection (a)(4). The Final Statement makes clear the Agency's intent:

> By encouraging food producers to use good agricultural and good manufacturing practices and to take all actions necessary to keep natural contaminant levels down to the lowest level feasible, this regulation accommodates the recommendation that the standard be achievable and realistic in light of currently available technology.
>
> * * * *

> This requirement ["lowest level currently feasible"] has been in existence for a substantial period of time, and should be quite familiar to the food industry.

(*Id.*, at p. 10.) Dr. Mitchell conceded that adoption of the Codex recommendations as the standard would be a new development – it has not been adopted by the FDA and she knows of no commercial food producer that follows all of its recommendations (Beechnut comes closest among Defendants). (11 RT 1194:19 - 1200:4.) Indeed, the Codex recommendations were not adopted until 2004, more than fifteen years after section 25501 was enacted. *Id.* The Agency thus could not have had them in mind when drafting section 25501(a)(4). Further, many of the recommendations in the Codex are not realistically achievable and would accomplish very little. For example, the recommendation to test each grower's soils for lead would require tremendous expenditures and would have little effect on the amount of lead in the products. Both Dr. Angle and Dr. Flegal agreed that the amount of lead in soil has little to do with the amount of lead in fruits and vegetables grown in the soil. (PX 2506, Flegal Trial Decl., ¶ 81); (DX 6682, Angle Trial Decl., ¶13.)

On the other hand, the Court rejects Dr. Bourquin's opinion that compliance with the FDA's 50 parts per billion (ppb) guideline for grape juice, ipso facto demonstrates that the level of lead in Defendants' products is at the lowest level currently feasible. Many of Defendants' products are substantially below that level already. (JX 7001 -- only a few products were in the range of 20-25 ppb; the rest were in the teens or lower). One defense witness has testified that levels of seven to fourteen ppbs are achievable for finished products. (JX 7392, Langer PMQ depo.at144:16-24.) Further, the FDA itself has made clear that it is reviewing its current lead content guidelines to determine whether they should be lower. (See DX 5772, quoted at p. 10, *supra*).[14]

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[14] Among the most cost-effective ways of further reducing lead content may be establishing specifications which suppliers agree to meet and periodic testing of raw fruits and vegetables and concentrates, which some Defendants already do, to assure that the specifications are being met.

Thus the Court only partially accepts Plaintiff's interpretation of the standards to be applied in determining whether the exemption under section 25501 has been established. The Court accepts Plaintiff's contentions that Defendants failed to adduce evidence showing the proportion of lead in their products which is naturally occurring, and that Defendants reasonably could have done more to reduce the lead in their products to the lowest level currently feasible. For these reasons Defendants have not established the naturally occurring defense.

V. DEFENDANTS HAVE ESTABLISHED THE SAFE HARBOR DEFENSE

Defendants' safe harbor defense is provided for in the Act itself and in the implementing regulations. Section 25249.10(c) provides that the warning requirements of section 25249.6 do not apply to an exposure to listed chemicals if:

> ...the person responsible can show that the exposure poses no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer, and that the exposure will have no observable effect assuming exposure at one thousand (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 pursuant to subdivision (a) of Section 2549.8. In any action brought to enforce Section 25249.6, the burden of showing that an exposure meets the criteria of this subdivision shall be on the defendant.

In construing and applying the exemption created by section 25249.10(c), the court in *DiPirro v. Bondo Corporation* (2007) 153 Cal.App.4th 150 made clear that the courts "are bound to broadly construe Proposition 65 to effectuate its remedial purpose" but also noted that:

> Proposition 65 was not intended to enact "an entirely one-sided public protection statute. The Act recognizes the interests of manufacturers and the users of needed chemicals," and seeks to balance the need for a warning of dangerous chemicals against the negative consequences that ensue from the decision to avoid use of a potentially beneficial product.

(153 Cal.App.4th at 190, n.29.)

In the this case Defendants presented substantial evidence that, under their view of what the statute and its implementing regulations require, each of the products tested meets the no observable effect test (the "NOEL") by showing that the average user who consumed their products was exposed to less than 0.5 micrograms per day of lead, averaged over a scientifically-appropriate period of fourteen days.

Plaintiff takes issue with Defendants' interpretation of the regulations and the application of the regulations to the agreed upon test results for the challenged products. (JX 7001.) In their view, it was inappropriate for Dr. Barbara Petersen, Defendants' primary nutrition expert, to average the lead test results for the products rather than evaluating each individual test score separately. It was also inappropriate for her to calculate averages using the geometric mean of the data presented for lead concentrations, as well as for the consumption data taken from the NHANES data base; and it was inappropriate for her to measure the frequency of eating occasions at all, much less by using the proprietary NET data base. Before commenting on the evidence at trial the Court must first address the legal questions determining whether the methodology applied by Dr. Petersen may be appropriate to establish the safe harbor defense under section 25249.10(c) given the evidence of low levels of toxicity in undisputed test results in this case.

Initially, it must be noted that because the safe harbor level for lead as a reproductive toxin (0.5 micrograms/day) is so much less than for lead as a carcinogen (15 micrograms/day), the focus of the evidence in this case was on reproductive toxicity. If Defendants have established the safe harbor defense for reproductive toxicity they have also established it for lead as a carcinogen.

With respect to reproductive toxins, section 25801 of the Regulations establishes two ways in which the level of exposure to a listed chemical "shall be deemed to have no observable effect (the "NOEL" level), assuming exposure at one thousand times that level." (27 CCR § 25801.) Under subsection (b)(1), the NOEL determination can be made by means of an

assessment that meets the standards described in section 25803 to arrive at the "maximum allowable dose level" ("MADL"). Under subsection (b)(2), the NOEL level of exposure can be determined by application of a specific regulatory level for the chemical in question as provided in section 25805. However, section 25801(a) also provides, in language applicable to both methods of proof under subsection (b), 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." (27 CCR § 25801(a).)

Consistent with section 25801(b)(2), section 25805(a) provides that "exposure to a chemical at a level which does not exceed the level set forth in subsection (b) for such chemical has no observable effect assuming exposure at one thousand (1,000) times that level." As noted above, the safe harbor level for lead is listed in subsection 25805(b) at 0.5 micrograms/day.

Regulation section 25821 provides further detail on ascertainment of "levels of exposure" for reproductive toxicity purposes. Subsection (a) provides: "For purposes of the Act, 'level in question' means the chemical concentration of a listed chemical for the exposure in question." Subsection (b) provides that the "level of exposure":

> shall be determined by multiplying the level in question (stated in terms of a concentration of a chemical in a given medium) times the reasonably anticipated rate of exposure for an individual to a given medium. The reasonably anticipated rate of exposure shall be based on the pattern and duration of exposure that is relevant to the reproductive effect which provided the basis for the determination that a chemical is known to the state to cause reproductive toxicity. (For example, an exposure of short duration is appropriate for a teratogenic chemical, whereas a chronic or protracted exposure is appropriate for one that retards fetal growth.)

(27 CCR § 25821(b).) Subsection 25821(c) then identifies assumptions to be used "to calculate the reasonably anticipated rate of exposure . . . unless more specific and scientifically appropriate data are available." Most important for present purposes, the second assumption directly relates to products like those at issue here:

> (2) For exposure to consumer products, the level of exposure shall be calculated using the reasonably anticipated rate of intake or exposure for average users of the consumer product. . . . The rate of intake or exposure shall be based on data for use of a general category or categories of consumer products, such as the United States Department of Agriculture Home Economic Research Report, Foods Commonly Eaten by Individuals: Amount Per Day and Per Eating Occasion, where such data are available.

(27 CCR § 25821(c).)

A. Was It Appropriate For Dr. Petersen To Average Lead Test Results To Determine Average Lead Content For Products?

Dr. Barbara Peterson testified in her trial declaration and at trial to the process by which she concluded that each of Defendants' challenged products satisfied the regulatory safe harbor level of 0.5 micrograms of lead from those products per day. In brief, she started with the test results for all tests of Defendants' products done by Plaintiff and Defendants. (JX 7001.) She averaged those test results. She then obtained consumption data about those products from the NHANES data base, the most authoritative source of such data for foods consumed in America. She averaged that survey data. She then determined the frequency with which average users consumed each of the products using a proprietary comprehensive data base known as the NET data base. For each product she then multiplied the average lead concentration times the amounts eaten per day times the frequency of consumption during fourteen day period covered by the NET survey data and compared the result with the 0.5 microgram/day standard. In each instance, using Dr. Peterson's methodology, the product met the exemption from notification standard set forth in section 25801(b)(2).

Plaintiff argues that Dr. Petersen's averaging of test results to determine the "level of exposure" or concentration of lead in the challenged products was inappropriate. If Plaintiff is correct, Defendants' safe harbor proof would be insufficient because there is no evidence that, without such averaging, each of the product tests showed a concentration which, when multiplied by the appropriate rate of exposure, results in exposures to average users of each of these products of less than 0.5 micrograms per day.

Plaintiff points to the following quotation from the Final Statement of Reasons which was published by the Agency:

> One commentator recommended that the regulation [now § 25821] 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. It does not distinguish between reproductive toxicants on the basis of their acute or chronic toxicity. It simply provides that the "level in question" must be one thousand times less than the level which would produce no observable effect. 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.

(PX2340/DX5233 at pp. 82-83.) The interpretation of the Act through the governing regulations adopted by the Agency is entitled to great weight. (*DiPirro, supra*, 153 Cal.App.4th at 192.) Although the Statement is not itself a regulation, and thus arguably is not dispositive of how the Act should be interpreted (see discussion at pp. 35-36, *infra*), it is consistent with Section 1(c) of the Act, as adopted at the election of November 4, 1986. That section identifies one purpose of the Act as "to secure strict enforcement of the laws controlling hazardous chemicals and deter actions that threaten public health and safety." (West's Annotated California Codes, Historical and Statutory Notes on Section 25249.5 at p. 322.) But before concluding as a matter of law that averaging lead content is not appropriate in this case it is important to review Dr. Peterson's reasons for averaging lead content in the tests of these products. Indeed, section 25801(a) permits, if not requires, that the Court do so.

Dr. Peterson testified during trial that averaging test results for lead content in food products is a necessary first step in performing an exposure assessment. Based upon her 30 years of experience performing about 1,000 such assessments, test results for food products will vary, not only from lot to lot, but from test to test within the same jar, bottle or package. She

attributed this variability principally to the nature of fruit and vegetable products and to the manner in which lead might or might not adhere to different components of such foods. (1 RT 35-44.)

Plaintiff's nutrition expert, Dr. Britt Burton-Freeman, was critical of Dr. Peterson's averaging of test data because of her concern that averaging would tend to mask individual relatively high results. However, she did not contradict Dr. Peterson's testimony concerning the variability of lead in individual containers of these products. As Dr. Peterson explained, the "food matrix" to which the lead may adhere is not homogeneous and the lead is in suspension, rather than in solution. These and other variability factors Dr. Peterson described render reliance on individual tests unhelpful. Dr. Burton-Freeman acknowledged that her position against averaging the test results was based on her own experience, not any regulatory requirement or scientific authority. (5 RT 547:15-19; 549:27-550:3; 550:27-551:3.)

To the extent that Dr. Burton-Freeman disagreed with Dr. Peterson concerning averaging the agreed upon test results, the Court finds Dr. Peterson's testimony to be far more persuasive. Although averaging will not disclose the results of the individual samples tested, those individual tests are not necessarily representative of the lead content of the container tested. It is only through conducting a sufficient number of individual tests and averaging the results that a reliable estimate of the lead concentration in the food products in this case to which consumers are exposed can be determined. Hence, on the record here, it was scientifically appropriate, indeed, it was scientifically necessary to average the lead concentration test results.

Returning to Plaintiff's reliance on the quotation from page 82 of the Final Statement, it is unclear that either the comment or the response was directed to the characteristics of food products. Certainly this portion of the Statement can be read to include all chemical concentrations, including those in foods. However, since the purpose of Prop 65 is to warn average users of products when they are being exposed to a concentration of lead that exceeds the maximum allowable level, it is essential that the best estimate of the amount of lead in the

products be the basis for a potential warning. Here the best estimate can only be determined by averaging the agreed upon test results on a product by product basis, as Dr. Peterson did. While her methodology did not comport with the comment on page 82 of the Statement, it is consistent with the direction in section 25801(a) of the regulations themselves that "nothing 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."[15]

B. Was It Appropriate For Dr. Petersen To Use The Geometric Mean In Averaging Test Results And Survey Data?

Dr. Peterson testified that she determined upon review of the test results that the data were "log normally distributed," that is, most of the data clustered around the same point with a few exceptions that would skew the results of an arithmetic mean. (DX 6680, Peterson Trial Decl., ¶¶ 18- 22.) For that reason, she analyzed the data in the manner she testified was statistically appropriate for such data using the geometric mean rather than the arithmetic mean.[16]

Dr. Burton-Freeman criticized this methodology as applied to the concentration test data and the consumption and frequency data discussed in the following sections. Plaintiff argues that use of the geometric mean was done in order to get lower results, but Dr. Peterson made clear that in each instance she examined the data to determine whether it was normally

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[15] Although addressing the question of "average user" rather than the question of whether averaging test results to determine levels of concentration of the listed substance, the following comment of the Court of Appeal in the *DiPirro* case is applicable here: "[W]e conclude that the statute envisions a case-by-case approach which takes into account the totality of the quantitative risk assessment evidence presented. . . ." (*DiPirro v. Bondo Corporation* (2007) 153 Cal.App.4th 150, 193, discussed more fully at pp.30-31, *infra*.)

[16] The parties agree that: "A geometric mean is a type of mean or average of a set of numbers which is derived by taking the n^{th} 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." (See Jointly Submitted Glossary of Technical Terms and Terms of Art, filed 4/2/2013.)

distributed or log normally distributed, and found that it was log normally distributed. Dr. Burton-Freeman did not contradict those characterizations of the data.

Dr. Peterson testified that her use of the geometric mean was dictated by the nature of the data, not because of any desire to obtain lower results. She has used the same methodology on about 1,000 other risk assessments, as well as in her work for the World Health Organization and the FDA. Indeed, Dr. Burton-Freeman has also analyzed log normally distributed data using geometric means in her published work, just not in her testimony in this case. The Court finds that Dr. Peterson's written and oral testimony in this case were far more persuasive than that of Dr. Burton-Freeman pertaining to using the geometric mean to average lead concentration test data, as well as the survey data discussed below, to arrive at her conclusions because of her uncontested determination that all of such data was log normally distributed.

C. Was It Appropriate For Dr. Petersen To Determine The Rate Of Exposure By Using Data From The NHANES "What We Eat In America" Data Base To Determine Amounts Eaten Per Eating Occasion And Number Of Eating Occasions Per Day, And To Determine Frequency Of Days On Which Foods Were Eaten Using A Proprietary Data Base?

The next step in Dr. Peterson's analysis was to examine data from the "What We Eat in America" data base maintained by the U.S. Center for Disease Control and Prevention National Center for Health Statistics ("NHANES"). There is no disagreement between the parties that the extensive NHANES national data used by Dr. Peterson is the best available data base to determine the amount of food consumed per eating occasion for the products in this case for California consumers. Indeed, its predecessor was specifically called out in section 25821(c) of the regulations as an example of the type of database which should be used for consumer products under Prop 65. Dr. Burton-Freeman also used this data for her analysis.

Dr. Peterson determined that the NHANES consumption data was log normally distributed and so calculated averages average consumption for each type of product using the geometric mean. She was criticized for doing so by Dr. Burton-Freeman. For the reasons

discussed above, the Court finds that it was appropriate to analyze data with a log-normal distribution using geometric means rather than arithmetic means to determine "average users of consumer products" within the meaning of section 25821(c).

1. Plaintiff's Reliance On Data From The 85th Percentile of the NHANES Data Base Is Misplaced.

Section 25821(c), quoted above at page 23, specifies the assumptions to "be used to calculate the reasonably anticipated rate of exposure to a chemical listed as causing reproductive toxicity, unless more specific and scientifically appropriate data are available. Dr. Burton-Freeman testified in her trial declaration that rather than averaging the consumption data reported in NHANES, as Dr. Peterson did, it was more appropriate to rely upon the 85th percentile of the NHANES data as representative of what the average consumer eats on one or more eating occasions on the same day. (See JX 7043 for the results of that analysis.)[17] In her trial declaration Dr. Burton-Freeman based this approach on her testimony that "consumption patterns tended to follow the serving size of products . . . . In other words, serving size is, by definition, based on what the typical or average consumer reports as being consumed...". (PX 2503, Burton-Freeman Trial Decl., ¶ 48.) In her opinion, "the 85th percentile of intake should be utilized [and not the geometric or arithmetic mean] because it represents intake patterns, it is consistent with RACC [reference amounts customarily consumed], and accordingly, already linked to product packaging sizes." (*Id.* at ¶ 49.)

On cross examination at trial, however, it turned out that Dr. Burton-Freeman looked at serving sizes on labels because Plaintiff's counsel asked her to do that, and to focus on the 85th percentile. (5 RT 562:15-24.) When confronted with her chart showing grams of food intake per day based upon the 85th percentile and the labels for various products, the 85th percentile number generally did not approximate the grams shown on the labels, but instead dramatically overstated

[17] Dr. Burton-Freeman also did an alternative calculation using the arithmetic mean of that data.

them. (5 RT 562-573.) By multiplying the agreed upon amounts of lead in each product by 85th percentile indications of grams eaten per day, Dr. Burton-Freeman presented lead intake per day in numbers which overstate average consumers' exposure to lead from Defendants' products.

Although Dr. Burton-Freeman did not know why counsel had suggested that she focus on the 85th percentile of the NHANES data for her analysis, Plaintiff's briefs and closing argument make clear that it is relying on the *DiPirro* case for the proposition that a standard based on the 75th or 85th percentile of users is representative of "average" users for purposes of section 25821(c). (Pl. Op. Trial Br., 11:22-2, n. 9; Pl. Post-Trial Br., 14:25-28 n.13.)

Plaintiff reads too much into *DiPirro*. In that case the product at issue was touch-up paint containing toluene, a listed Prop 65 substance. Plaintiff in *DiPirro* argued at trial and on appeal that defendant could not establish the exemption from reporting under section 25249.10(c) of the Act "if evidence shows 'any portion of the population' – that is, essentially any consumer – may be exposed to levels of toluene above the MADL with use of the product in a 'reasonably foreseeable manner' . . . . (153 Cal.App.4th at 190.) The Court of Appeal rejected plaintiff's proposed "any consumer" test for application of the exemption and found that there was substantial evidence to support the trial court's determination that defendant had satisfied its burden under section 25249.10(c). It was in that context that defendant argued it was sufficient to establish the exemption by showing that the levels of exposures to its toluene at the 75th or 85th percentile of its users was below the MADL for inhaled toluene, which defendant established pursuant to sections 25801(b)(1), 25803 and 25821. (*Id.*, at 194-196.)

DiPirro does not stand for the proposition that consumer data at the 85th percentile of consumption data which overstates the amounts of a listed chemical average users are exposed to is an appropriate substitute for actual consumption data to determine intake or exposure for average users. Rather, it stands for the following:

> . . .we think the language of the regulation reasonably supports an interpretation that excludes at least some nonconforming or unusually high intake consumers of a product when assessing exposure to consumer goods. (OEHHA, Final Statement

> of Reasons: Article 8 (June 1989) p. 84; see Cal.Code Regs., tit. 22, § 12821.) Subdivision (c) of section 12821 takes into account the factor that "[d]ifferent individuals take in different amounts" of a given medium of exposure, and by limiting the exposure assessment to "reasonably anticipated" use by "average consumers" seeks to deal with the "variability and fluctuation of the 'rate of exposure' " to resolve and avoid the concern with unreasonably requiring a "warning to all users of a product on the basis of occasional high consumption." (OEHHA, Final Statement of Reasons: Article 8 (June 1989) pp. 84–85; see Cal.Code Regs., tit. 22, § 12821.)
>
> The flexibility necessary to arrive at an appropriate exposure assessment is not provided by adhering to a standard that invariably requires the defendant to prove a level of exposure caused by its product that is 1,000 times below the NOEL for every user. Instead, we conclude that the statute envisions a case-by-case approach which takes into account the totality of the quantitative risk assessment evidence presented. . . .

(153 Cal.App.4th at 192-193.)[18] Hence, what happened in *DiPirro* is that defendant elected to counter plaintiff's "any consumer" argument by showing that even using data going to the 75th or 85th percentile of use, users were not exposed to the MADL level. In accepting defendant's argument, the *DiPirro* court was not endorsing use of the 75th or 85th percentile as a proxy for "average users." It simply held that the law did not require a warning when only users beyond the 85th percentile would be exposed to toluene above the MADL level. Based upon this reading of *DiPirro*, the Court rejects Plaintiff's proposal to accept the 85th percentile of the NHANES data base as a proxy for amounts consumed by average users and instead accepts Dr. Peterson's average consumption per day calculations based upon the geometric mean of the pertinent NHANES data.

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[18] Although toluene is listed under section 25805 of the regulations, setting a NOEL at 1,000 times 7000 micrograms per day of ingested toluene MADL level, defendant in *DiPirro* elected to defend under section 25801(b)(1) rather than (b)(2) by establishing a MADL of 13,000 micrograms per day. The exposure from touch up paint was through inhalation, rather than ingestion, and the rate of absorption for inhaled chemicals was 50 per cent. (*Id.*, at 166.)

2. The Regulations And The Evidence Support Determining "Rate of Exposure" Taking Into Account Frequency of Consumption.

The penultimate step in Dr. Peterson's safe harbor analysis (before comparing the numbers she derived to the 0.5 micrograms per day standard), was to determine the frequency with which the products are consumed by average users. Plaintiff contends that because lead is a teratogen, the NHANES data showing amounts consumed per eating occasion and per day should not be averaged, but should be presumed to be consumed daily.[19] Defendants contend that because of the low concentrations of lead in each of their products and because the products are typically not consumed on a daily basis, it is appropriate to consider frequency.

The parties do not dispute that the challenged products are not typically eaten on a daily basis, but are eaten intermittently. (DX 6680, Peterson Trial Decl., ¶ 30 [these are foods not consumed on an uninterrupted daily basis]; Burton-Freeman Trial Testimony 6 RT 671:8 - 672:14 [foods consumed about four times per month].) Dr. Peterson testified that, given the fact that they are not consumed every day, it would vastly overstate average consumers' exposure to assume that they would be consumed on a daily basis. Yet Plaintiff argues that is the appropriate methodology to be followed here, and point out that Dr. Peterson is a nutritionist, not an expert on the reproductive toxicity of lead.

Plaintiff's legal argument is that "if exposure to lead can cause reproductive harm based on a single day of exposure at any level, then a single day is the relevant pattern and duration of exposure." (Pl. Post-Trial Br. 13:6-9.) In other words, under Plaintiff's view of the law, if the level of lead concentration in *any* product could cause a reproductive harm from exposure on a

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[19] According to the parties' jointly filed glossary of technical terms, a "teratogen" is:

> A substance such as a chemical capable of interfering with the development of an embryo or fetus that may lead to birth defects or developmental malformations. A "frank teratogen" is a chemical that causes physical birth defects. A "behavioral teratogen" is a chemical that causes adverse behavioral effects.

(See Note 8, *supra.*)

single day, then a single day is the appropriate measure of exposure for *all* products, even those with dramatically lower lead contents.

(a) Does the Law Prohibit Taking Frequency of Lead Exposure from Food Products into Account?

Section 25249.10(c) is silent on this question but the regulations do address it. Section 25281(b) of the regulations, quoted above at page 23, makes clear that "level of exposure" is derived by multiplying the concentration in a given medium "times the reasonably anticipated rate of exposure for an individual to a given medium." That section goes on to specify that:

> The reasonably anticipated rate of exposure shall be based on the pattern and duration of exposure that is relevant to the reproductive effect which provided the basis for the determination that a chemical is known to the state to cause reproductive toxicity. (For example, an exposure of short duration is appropriate for a teratogenic chemical, whereas a chronic or protracted exposure is appropriate for one that retards fetal growth.)

In order to answer the historical question of what reproductive effect is pertinent to the lead exposures for reproductive toxicity under Prop 65, we look again to the Final Statement of Reasons. (DX 5233/PX2340.) The Statement's discussion of lead and ethylene oxide as the initial two reproductive toxicants listed under section 25805 begins with the observation that:

> Both are identified by the federal Occupational Safety and Health Administration (OSHA) as known human reproductive toxicants based upon evidence of their effects on humans, and this resulted in their inclusion on the Governor's initial list pursuant to section 25249.8(a) of the Act.

(*Id.* at p. 77.) The Statement goes on to acknowledge the difficulty in identifying a NOEL for reproductive toxicants "when the effects of concern are based upon human experience . . ." but cites to experience in the occupational setting "which suggests that exposure to certain regulated levels does not produce the reproductive effect of concern." (*Id.*, p. 78.) The Statement specifically addresses lead:

> The OSHA-permissible exposure limit for lead is 50 micrograms per cubic meter of air. One can calculate a daily exposure, as described above, of 500 micrograms per day. Dividing by 1,000 in this case yields an allocable level of 0.5 microgram of lead per day.

(*Id.*)

In discussing comments on what is now section 25821, the Statement provides the following language which Plaintiff relies upon as requiring that exposures to lead be evaluated as if they occurred every day:

> Since some reproductive effects, such as teratogenic responses or birth defects, may reflect an acute response during a brief period of intrauterine exposure, exposure to chemicals producing such effects should be assessed on the basis of short term exposure.
>
> Therefore, when one evaluates such a reproductive toxin, one needs to view the exposure as the one that may cause the acute 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.

(*Id.*, p. 85.) Plaintiff's argument that the Statement supports a "no averaging" position would be stronger if the Statement stopped there. However in the very next sentence the Statement makes clear that: "If it is scientifically more appropriate to evaluate a reproductive toxicant for chronic toxicity, this section does permit it." (*Id.*)

Defendants rely on that important qualifier and argue that, based on the agreed upon test results and the acknowledged infrequency of consumption, it is scientifically more appropriate to evaluate the exposures in this case using the two-week survey data Dr. Peterson obtained from the NET data base, rather than treat exposures to their products on the days they are eaten as if they were eaten daily. We turn to the science Defendants rely upon in the next section, but first must determine whether that evidence is legally relevant.

Plaintiff also relies on the testimony of Dr. James Donald to support its "per se no consideration of frequency under the 0.5 microgram per day" legal standard for lead. Dr. Donald testified on April 17, 2013 as a percipient witness subpoenaed by Plaintiff. It was established, preliminarily, that he was authorized to testify on behalf of OEHHA by his counsel, Supervising Deputy Attorney General Susan Fiering. (6 RT 691:24-692:8.) Dr. Donald testified to a policy

of OEHHA which permits taking frequency of exposure into account for lead when a defendant seeks to establish a defense under section 25801(b)(1) of the regulations, but not when, as here, the defense is based upon section 25801(b)(2). (6 RT 693:13-695:13.)

Plaintiff argues that this "policy" is entitled to significant deference because it is the interpretation of the agency charged with enforcement of the Act and its own regulations, citing *Yamaha Corporation of America v. State Board of Equalization* (1998) 19 Cal.4th 1, 12-13. The Court agrees that *Yamaha* establishes the standards to be applied in determining what weight to give Dr. Donald's testimony. However, under those standards, after giving due consideration to Dr. Donald's long tenure at OEHHA and knowledge of its workings, the Court must conclude that his policy testimony is entitled to little weight in interpreting the regulations.

Yamaha was a tax refund suit in which plaintiff had paid a use tax under protest and sought a refund. The issue was whether the use tax applied to promotional gifts Yamaha made to out of state recipients. The "deference" question was raised by a legal opinion by an attorney employed by the State Board of Equalization published in "the Business Taxes Law Guide" as an annotation pursuant to the Board's forty year practice of making such opinions publicly available. The Court of Appeal held that a published annotation which went against the taxpayer's position was dispositive and reversed the trial court's judgment for the taxpayer. The Supreme Court held that the Court of Appeal had applied the wrong standard in determining the annotation to be dispositive and reversed. The Supreme Court's holding may be excerpted as follows:

> An agency interpretation of the meaning and legal effect of a statute is entitled to consideration and respect by the courts; however, unlike quasi-legislative regulations adopted by an agency to which the Legislature has confided the power to "make law," and which, if authorized by the enabling legislation, bind this and other courts as firmly as statutes themselves, the binding power of an agency's interpretation of a statute or regulation is contextual: Its power to persuade is both circumstantial and dependent on the presence or absence of factors that support the merit of the interpretation. . . .
>
> Courts must, in short, independently judge the text of the statute, taking into account and respecting the agency's interpretation of its meaning, of course,

> whether embodied in a formal rule or less formal representation. Where the meaning and legal effect of a statute is the issue, an agency's interpretation is one among several tools available to the court. Depending on the context, it may be helpful, enlightening, even convincing. It may sometimes be of little worth.

(19 Cal.4th at 7.)

Applying the standards articulated in *Yamaha* to Dr. Donald's testimony that frequency of consumption is not taken into account under section 25801(b)(2), the Court finds it to be unconvincing for several reasons. Initially, Dr. Donald's testimony is not, of course, a formal regulation of OEHHA and, so far as the record shows, was not adopted by OEHHA in any formal way. Nor was his view expressed in the lengthy Final Statement of Reasons or in any other OEHHA publication.

The only written expression of this policy that Dr. Donald testified to was his declaration in an enforcement action brought by the Attorney General in 1991.[20] Unlike the published annotation in *Yamaha*, the declaration was not made generally available to the public by OEHHA. Indeed, although OEHHA maintains a website with extensive materials on how Prop 65 works, including the Act, the regulations under it, the Final Statements explaining the regulations, policies and procedures, and interpretative guidance, there is no mention of his declaration on the website, or any other written expression of the policy to which he testified. 6 RT 701:20 – 708:6. Further, although Dr. Donald testified that the policy he described was of

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[20] Although neither side asked many questions of Dr. Donald about his 1991 declaration, the record in this case establishes that the declaration (which was not admitted into evidence here, but was the subject of considerable testimony by other witnesses):

> was developed in the course of litigation regarding a product that is inapposite to the products at issue here – leaded crystal decanters ranged from 24% to 32% lead. Beverages stored in these decanters have been reported to have lead levels more than 1,000 times higher than the products at issue in this case, potentially at levels leading to acute effects.

(DX 6683, Murray Trial Decl. at ¶ 39.)

longstanding, he first discussed it with Dr. George Alexeeff, the Director of OEHHA, who apparently had no prior knowledge of it, only a week before he testified. (6 RT 709:9-14.)

On redirect examination Dr. Donald testified that he had communicated the policy he described "on some occasions" to members of the public. (6 RT 712:4-16.) There was no elaboration as to whether such communications were in private conversations or public seminars. The record is silent on that point.

Defendants do not contend that they were unaware of Dr. Donald's views as expressed in the 1991 declaration. The existence of the declaration became known to them, at the latest, when they reviewed the materials produced by Plaintiff in connection with the expert deposition of Dr. Howard Hu. There is no evidence as to whether Defendants were aware of Dr. Donald's views prior to the filing of this litigation. Be that as it may, on the present record, the Court cannot find that what was said in Dr. Donald's 1991 declaration constituted a policy of OEHHA, or that the policy he testified to at trial is one which was well known and of longstanding. As the Final Statement recognized:

> [P]ersons in the course of doing business, in order to avoid violation of the Act, will need to determine the applicability of the exemption prior to exposure, discharge or release. Therefore, they will need to know in advance what will be the assumed or expected "level in question" for purposes of the exemption.

(DX 5233/PX 2340, Final Statement at p. 82.) There is no evidence that Dr. Donald's declaration performed the function of advising those responsible for compliance with Prop 65 of any policy of OEHHA regarding averaging or frequency of exposure.

Further, Dr. Donald's expression of policy is unclear. Toward the end of his cross examination, the following exchange occurred:

> Q. Okay. The policy that you've described, if that policy were in fact in effect, it would apply to a whole range of foods, not just the foods in this case; isn't that right?
>
> THE WITNESS: It would depend on specific circumstances but it would certainly potentially pertain to other foods.

(6 RT 709:26-701:5.) Neither side sought an elaboration of what the "specific circumstances" would be as to the application of the policy to foods including those challenged in this case. Dr. Donald did not provide an opinion on behalf of himself or OEHHA that the circumstances in this case would preclude taking frequency of consumption into account. Hence, it is difficult to give his interpretation weight without understanding whether it would apply to this case and if so, why.

Further, Dr. Donald did not explain how his distinction between the manner of determining NOEL levels between section 25801(b)(1) and 25801(b)(2) can be reconciled with the language of section 25801(a):

> Nothing 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.

If the Agency had intended that regulatory principle to apply only to NOEL determinations made under section 25801(b)(1), presumably the quoted sentence would have appeared in that subsection instead of in subsection 25801(a). By its placement in subsection (a) it would appear to apply equally to those substances for which there is a specific regulatory level pursuant to subsection (b)(2) and section 25805. Indeed, subsection 25821 does not differentiate its provision between those applicable to section 25801(b)(1) and 25801(b)(2). As written, it appears to apply equally to both manners of establishing the pertinent NOEL.

Nor does Dr. Donald's interpretation account for the Final Statement's explanation of section 25821 that: "If it is scientifically more appropriate to evaluate a reproductive toxicant for chronic toxicity, this section does permit it." That expression also appears to apply equally to determinations made under both subsections (b)(1) and (b)(2).

Finally, and perhaps most importantly, Dr. Donald's articulation of policy does not appear to further the goals of Prop 65 in providing warnings to the public of potentially dangerous exposures to known carcinogens and reproductive toxins, at least as applied to the facts of this

case. It is undisputed that daily exposure to a product which contains 0.5 micrograms of lead would not require a warning under section 22801(b)(2). Yet, a study performed by Dr. Barbara D. Beck, a highly credentialed toxicologist who has used modeling to study the health effects of lead for over twenty five years, compared blood lead levels (and bone lead levels) from daily assumed exposures of 0.5 micrograms each day with the exposures identified by Dr. Peterson's study. According to Dr. 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 Dr. Peterson's analysis. The same was true when Dr. Beck multiplied the modeled safe harbor exposures and the Peterson exposures by 1,000 times. (DX 6685, Beck Trial Decl., ¶¶14-33.) Hence, at least in this case, consideration of Defendants' frequency of consumption evidence would not appear to result in exposing average users of those products to any risk of reproductive harm greater than the NOEL level established by the 0.5 micrograms per day standard. Since 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.

Taking all of these considerations into account, the Court declines to accept Plaintiff's "per se" no consideration of frequency, and turns instead to a consideration of whether the scientific evidence supports Defendants' methodology in this case.

(b) Does The Evidence Support Defendants' Reliance On Dr. Peterson's Fourteen Day Average Frequency Calculation To Show Exposures Of Less Than 0.5 Micrograms Per Day?

(1) Dr. Peterson

A further difference of opinion between Dr. Peterson and Dr. Burton-Freeman was the way in which Dr. Peterson determined frequency. In accordance with her testimony, she found the NHANES data base did not provide reliable evidence of frequency of eating occasions because its methodology called for surveying respondents for only two days of consumption.

(DX 6680, Peterson Trial Decl., ¶¶ 31-32.) She considered using a component of NHANES that measures frequency, but found that it wasn't appropriate for the products in this case because its categories were too broad to be meaningful. (*Id.,* ¶ 33.) Instead, she identified the NET data base, which, for more than thirty years has obtained dietary information from respondents covering a fourteen-day period, as an appropriate alternative. (*Id.* ¶ 34.)

Dr. Burton-Freeman had several criticisms of Dr. Peterson's use of the NET data base, with which she was only generally familiar. The Court has carefully considered each of those criticisms and Dr. Peterson's responses to them at trial, as well as the two experts' respective experience and training, and concludes that Dr. Peterson's presentation was persuasive and worthy of belief. However, Dr. Peterson's use of the NET fourteen-day survey data base can only be justified if it is appropriate from a toxicological point of view to average exposures over that length of time or longer in determining reproductive toxicity. Defendants presented two more witnesses to address this question.

(2) Dr. F. Jay Murray

Defendants called Dr. F. Jay Murray, Ph.D., a well-credentialed, board certified toxicologist with over thirty five years experience. (DX 6683, Murray Tr. Decl., ¶2.) Among Dr. Murray's credentials are his service on the Governor's initial Proposition 65 Scientific Advisory Panel from February 1987 – until late 1989, and as Chairperson of its Reproductive Toxicity Subcommittee. (*Id.,* at ¶3; 2 RT 181:28-182:16.) The role of the Panel at that time was to evaluate whether particular substances should be identified as carcinogens and/or reproductive toxins for inclusion on the Governor's list, and to review risk assessments and safe harbor levels that were established by the State during that time period. (*Id*., at 182:21-183:5.) Over the years in his profession as a consulting toxicologist, primarily for industrial clients, he has performed hundreds of risk assessments concerning the applicability of Prop 65.

Dr. Murray confirmed that lead is listed on the OEHHA website as a reproductive toxicant with respect to developmental toxicity, male reproductive toxicity, and female

reproductive toxicity. (*Id.* at 189:10-14.) In order to determine the pattern of exposure with respect to those potential harmful effects, for each potential harm he looks at the window of susceptibility for those effects and pharmacokinetic factors, including the half-life of the substance in question. "Window of susceptibility" concerns the period of time, whether measured in days, weeks or months, during which exposure to a particular toxin can cause the effects of concern. He based his testimony on his lengthy experience and his review of many published studies, including a lengthy monograph entitled "Health Effects of Low-Level Lead" published in June 2012 by the National Toxicology Program of the Office of Health Assessment and Translation of the U. S. Department of Health and Human Services. The monograph was admitted into evidence without objection. (DX 6577.)

Dr. Murray testified that the:

> reproductive effects of lead are dependent on the blood lead level. It all boils down to what is the blood lead level . . . you can't have reproductive toxicity from lead without an elevated blood lead level.

(2 RT 210:5-9.) Because lead has a half life in blood of about 30 days, the blood lead level measured on any given day reflects exposures not just from the day of measurement, but from the previous 29 days. Further, with respect to the most sensitive developmental reproductive effects, Dr. Murray testified that the window of susceptibility in the published literature for all of them is no shorter than one trimester of pregnancy. Although there has been some disagreement in the literature as to which trimester may be most important, and some evidence that the window is the entire nine month period, the shortest accepted window of susceptibility is a trimester, or three months. (*Id.*, at 190:24-191:10.)

Consequently, taking into account the pharmacokinetics of lead, including its half life in blood of 30 days or more and the window of susceptibility of at least one trimester for the most sensitive reproductive effects of concern in listing lead as a reproductive toxicant, Dr. Murray declared that use of survey data showing food consumption data over a period of fourteen days

constitutes a fully justified and indeed conservative way to determine the "rate of intake or exposure" pursuant to section 25821(c)(2) and (3). Dr. Murray opined that neither the long half life of lead in blood nor published literature concerning windows of susceptibility for the reproductive effects of concern would support treating exposures to low levels of lead like those in this case as if they occurred on a daily basis when in fact they did not. (DX 6683, Murray Trial Decl. ¶¶ 19 -23.)

(3) Dr. Carl L. Keen

Dr. Carl Keen is a Professor of Nutrition and Internal Medicine at U.C. Davis. His primary academic focus has been on developmental nutrition, including extensive research on the teratogenic effects (that is, effects on the fetus during pregnancy) of various trace elements and substances. (DX 6684, Keen Trial Decl., ¶¶ 4-6.) In addition to his academic work, from 1993 through 2012, Dr. Keen advised the State of California on Prop 65 related matters as a member of the OEHHA Developmental and Reproductive Toxin ("DART") Committee. His research has not specifically focused on lead and he has not performed risk assessments under Prop 65, but as a specialist in the teratogenic effects of substances, including lead, he is quite familiar with the published literature concerning lead.

Dr. Keen confirmed the testimony of Dr. Murray in several respects. His opinions regarding the pharmacokinetic properties of lead and windows of susceptibility for reproductive toxicity are essentially the same – lead has a half life in blood of about 30 days and the shortest window of susceptibility for injury to the central nervous system of the fetus, the most sensitive "end point," is at least one trimester during pregnancy. (*Id.* at ¶¶ 9-13.) In order for there to be an impact on the central nervous system of a fetus during pregnancy there must be an increase in the lead level of the mother's blood. (*Id.* at ¶ 15.) Based upon his experience and review of the academic literature, he too finds no support for the proposition that exposure to low levels of

lead through consumption of food on a single day could cause such an increase in blood lead levels. (*Id.* at ¶ 16; 3 RT 368:9-369:3; 372:25-373:3.)

In addition, he expanded on why it is absolutely essential to consider the dose of a potential teratogen, like lead, when evaluating the duration of exposure that is relevant to developmental harm. (3 RT 389:12-391:11.) He is aware of no studies showing that ingestion of lead can exert teratogenic effects at doses similar to those found in the products in this case or at 1,000 times those levels from a single exposure. (*Id.*)

(4) Dr. Howard Hu

Plaintiff sought to rebut and undermine the testimony of doctors Murray and Keen through the testimony of Dr. Howard Hu. Dr. Hu is an extensively published researcher who has specialized over many years on the potential teratogenic effects of lead. His credentials are impressive and his criticisms of some of Dr. Murray's opinions (in his trial declaration at ¶¶ 30, 39-41, 81, 82, 87-89, 94, and 99 – 101 and Dr. Keen's opinions at ¶¶ 91-92) deserved and received careful attention from the Court.

Dr. Hu acknowledged that the published literature confirms that the shortest window of susceptibility for developmental reproductive toxicity is one trimester except for one paper which looked at eight week intervals. (4 RT 444:25-445:5; 449:6-11.) Although the half life of lead in bones is many years, its half life in blood is, as Dr. Keen testified, about 30 days. In order for lead in bones to have a potential reproductive effect it must return to the mother's blood during pregnancy.

When Dr. Murray and Dr. Keen addressed Dr. Hu's criticisms of their opinions during redirect examination at trial, they did so convincingly. (See 2 RT 215:27-236:12 [Murray]; 3 RT 400:2-402:3 [Keen].) In the process, they confirmed that Dr. Hu's criticism of their testimony

was unfounded and, at the same time, pointed out significant errors and overstatements in Dr. Hu's testimony.[21]

Dr. Hu's lifelong research on and concern with the potential impacts of lead on pregnant women and children (PX 2504, Hu Trial Decl., ¶7) are impressive. But his unequivocal belief "that the level of lead that is currently in the defendants' products is not safe for consumers and should be reduced" (*Id.* at ¶¶ 2, 120) undermines the credibility of his advocacy for Plaintiff's "no averaging of exposure" testimony. As the redirect trial testimony of Dr. Murray and Dr. Keen and the cross examination of Dr. Hu made clear, there is little if any scientific evidence, as opposed to Dr. Hu's opinion, that exposures to Defendants' products on a single day would increase the blood lead level of pregnant women sufficiently, if at all, to cause a central nervous system deficit in the fetus. Since that is the most sensitive potential reproductive effect of any of those identified as the reasons lead was listed as a reproductive toxin under Prop 65, there is no scientific justification for treating exposures on actual days of consumption as if they occurred every day instead of taking actual frequency into account.

Hence, after weighing the conflicting scientific testimony the Court finds that it was scientifically appropriate not to treat exposure to Defendants' products as if exposure occurred every day, but instead to determine the average user's frequency of exposure using data from the fourteen day NET survey data base. When the results of that survey are combined with the lead concentration and amount consumed data discussed above, Dr. Peterson's analysis shows that Defendants' products satisfy the exemption under regulation sections 25801(b)(2) and 25821(c),

[21] For example, Dr. Hu relied upon studies involving single doses of lead given to laboratory animals as part of the basis for his opinion. (PX 2504, Hu Trial Decl., ¶ 93.) However, those single-dose studies were based upon injections, not ingestion, which meant that the test animals' blood received 100% of the injected lead. (Keen testimony, 3RT 373:10-20; 389:21-390:1; 391:22-393:3.) No one disputes that whatever the amount of lead that is consumed in food, because of the pharmacokinetic attributes of lead, only a small percentage of it gets into people's blood.

and therefore are exempt from the warning requirements pursuant to section 25249.10(c) of the Act.

VI. CONCLUSION

For the foregoing reasons, the Court rejects Defendants' federal preemption and naturally occurring defenses, but finds that they have satisfied their burden of proof under the safe harbor defense of regulation section 25801(b)(2) Consequently, Defendants need not provide Prop 65 warnings on their products, pursuant to section 25249.10(c) of the Act.

Pursuant to CRC 3.1590(g), the parties shall have 15 days within which to file and serve any objections to this tentative and proposed statement of decision. Upon review of any such objections the Court will determine whether to order a hearing (CRC 3.1590(k).) Defendants are directed to prepare a proposed form of judgment for consideration with any objections to this tentative and proposed statement of decision.

Dated: July 15, 2013

/s/
Steven A. Brick
Judge of the Superior Court