Litigating the Exposure Exemption Defense

Practical Tips and Experience from the Trenches

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The Panel

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Plaintiff's *Prima Facie* Burden

Plaintiff must show that California consumers come into contact with a listed chemical.

Food products are ingested so that is the main method of contact with any listed chemicals in food although there is also potentially some dermal exposure depending on the type of food.

For other durable consumer products (e.g. a backpack) contact is dermal and also potentially oral through hand to mouth contact.

OEEHA has guidance on hand to mouth transfer rates for lead.

Plaintiff likely has to show exceedance of the regulatory MADL for lead or cadmium exposures from foods since they are directly ingested

What is the Exposure Defense?

For listed reproductive toxins, Health & Safety Code Section 25249.10(c) provides that no warning is required if defendant can establish that the exposure in question does not exceed a level that is *1,000 times below* the no observable effect level (the "NOEL").

For listed carcinogens, Health & Safety Code Section 25249.10(c) provides that no warning is required if defendant can establish that the exposure in question does not increase a person's risk of cancer by more than 1 in 100,000 otherwise referred to as the No Significant Risk Level (the "NSRL").

Affirmative Defense: No Exposure Requiring a Warning

- If plaintiff meets its *prima facie* burden of demonstrating a product causing an exposure to a listed chemical without a warning, Defendants bear the burden of proof that the level of exposure does not exceed the applicable MADL or NSRL.
- The regulatory standard is whether the “average user” or consumer of the product in question is exposed to a level of the listed chemical in excess of the applicable MADL or NSRL.
- Establishing one of these defenses requires experts in both toxicology and average consumption/usage of the product at issue

Regulatory Guidance on Calculating and Exposure

- **27 California Code of Regulations Section 25721** provides guidance on calculating an exposure to a listed carcinogen
- **27 California Code of Regulations Section 25821** provides guidance on calculating an exposure to a listed reproductive toxin
- Reproductive exposures can be from listed teratogens, developmental toxins and can be specific to male or female reproductive harm
- Depending on the reproductive toxin and type of harm there can be disputes about whether single exposure in excess of the MADL requires a warning

27 CCR § 25821

Section 25249.10(c) is the defendant's statutory affirmative defense, which provides that no warning is required for carcinogens if: (1) the exposure poses no significant risk assuming lifetime exposure at the level in question; or for reproductive toxins, (2) the exposure will have no observable effect assuming exposure at 1000 times the level in question.

OEHHA has issued regulations that explain how the exposure assessment process occurs. (*See* 27 CCR § 25700, *et seq*. for cancer risk, and 27 CCR § 25800, *et seq*. for reproductive toxicity).

Section 25821

(c) The following assumptions shall 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:(1) The assumptions set forth in subsection (d) of Section 25721 shall 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.

(2) For exposures 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, and not on a per capita basis for the general population. 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.

(3) Where a maternal exposure to a chemical listed as causing reproductive toxicity has an effect on the conceptus (embryo or fetus), the level of exposure shall be based on the reasonably anticipated rate of exposure for the mother during the nine-month gestation period.

Exposure Defense for Other Consumer Products

- Calculating exposures to listed chemicals form listed chemicals in durable consumer products also begins with how often the average consumer handles or uses the product.
- From average use the amount of the chemical coming into contact with the person typically through dermal exposure must then be calculated.
- Depending on the listed chemical at issue and the type of harm at issue further calculation of hand to mouth exposures from handling the product may be necessary or appropriate.

Exposure Defense for Food Products

- Most food litigation involves alleged reproductive harm from heavy metals in food such as lead, cadmium, mercury or arsenic
- These elements can be partially or wholly naturally occurring
- Calculating exposures for food products typically starts with an analysis of the amount of the specific food at issue consumed by the average person on a given eating occasion based on the NHANEs survey of foods consumed by the average person
- For chemicals listed as reproductive toxin such as lead plaintiffs and defendants often dispute whether averaging exposures based on frequency of consumption is also appropriate

Averaging Disputes Related to the Exposure Defense

Is a single test result from plaintiff sufficient to establish the amount of a listed chemical in a food or other consumer product?

Is averaging multiple test results appropriate for establishing the amount of a listed chemical in food or other consumer products?

Does toxicology for the listed chemical in question support averaging exposure based on frequency of consumption or use of the food or consumer product in question.

Recent trial court decisions currently on appeal have addressed these issues.

Science Evolves

The PEOPLE ex rel. Edmund G. BROWN, Jr. v. Tri-Union Seafood, LLC, et al., (2009) 171 Cal.App.4th 1549

"[W]e must recognize that scientific research on issues such as the source of methylmercury in the ocean is ongoing, and a trial court determination on whether and/or to what extent methylmercury in tuna is naturally occurring is based on the state of the scientific inquiry at a given point in time. Therefore, unlike findings based on an historical occurrence such as facts giving rise to a tort or a crime, findings based on scientific inquiry and research can easily become dated and outmoded as science develops and new research explains the phenomena in question more thoroughly and completely. " 'Science is not an encyclopedic body of knowledge about the universe. Instead, it represents a process for proposing and refining theoretical explanations about the world that are subject to further testing and refinement.' " (Daubert v. Merrell Dow Pharmaceuticals, Inc. (1993) 509 U.S. 579, 590, 113 S.Ct. 2786, 125 L.Ed.2d 469, construing the term " 'scientific . knowledge' " as used in rule 702 of the Federal Rules of Evidence governing admissibility of expert testimony.) The high court captured succinctly the essential difference: "[T]here are important differences between the quest for truth in the courtroom and the quest for truth in the laboratory. Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly." (Daubert v. Merrell Dow Pharmaceuticals, Inc., supra, at pp. 596-597, 113 S.Ct. 2786.)"

Calculating Exposure in Food Compared to Non-Food Products

What is the “reasonably anticipated rate of intake or exposure”?

Who are the “average users of the consumer product”?

What is a “per capita basis” and why can’t you use that?

How does my lab test data factor into all this?

How do you figure out how much the average user eats of the food in question?

How does the chemical in question (i.e., lead) factor into how you calculate exposure?

Environmental Law Foundation v. Beech-Nut Nutrition Corp.

(2015) 235 Cal.App.4th 307

In *Beech-Nut*, the Court of Appeal upheld the lower court's ruling that demonstrated that the average consumer's reasonably anticipated rate of exposure to lead was below the Safe Harbor level. Court endorsed the following:

Lead is *not* a teratogen at the levels present in foods, and thus, it is scientifically appropriate in Prop 65 assessments to average lead exposures over at least eight weeks. (235 Cal.App.4th at 327-28).

The "**geometric mean" is appropriate** to calculate the average rate of intake of the food products. (*Id.* at 315-16, 330.) This mean is a statistical tool intended to correct heavily skewed data sets and regularly employed by scientist from the U.S. EPA, FDA, and the vast majority of academics.

Averaging lead test data for food products across different ingredient sources (and even manufacturing facilities) is representative because the trace levels of lead at issue reflected what consumers would be exposed to in the marketplace and are generally consistent with those observed over several decades by the U.S. FDA. (*Id.* at 323-24).

For food, the National Health and Nutrition Examination Survey **("NHANES"),** and NPD Group's National Eating Trends **("NET"),** are appropriate sources to determine the average user's frequency and serving size (*Id.* at 316).

Dietary Exposure Calculation

ollowing formula:

Average consumer's exposure (Micrograms chemical/day) = Average chemical level in product (ppm; micrograms per gram) x Average amount consumed per eating occasion (grams/EO) x Average number of eating occasions per day (EO/day)

The Gulf Pacific Rice Trial – *currently on appeal*

Case involved whole grain brown rice.

Defendant argued

Beech-Nut applied and that the appropriate method to calculate included using multiple test data points, averaging of the test result data, including across lots of the rice, and applying the geometric mean, were appropriate.

Relied on *Beech-Nut* to argue the best consumption data was from NHANES and the best frequency data from NPD.

Plaintiff argued

The geometric mean was not appropriate as it diluted the true level of lead

Testing any other rice than that from the exact same lot was not appropriate as it would allow the defendant to "wash out" problematic test results.

The "average user" should be Asian Americans based on theory that "ethnic Asians" in CA ate more than the national average.

NHANES was not appropriate for consumption data because it was based on the data of all ethnicities and included non-Asians in its dataset.

The Badia Spices Case – *currently on appeal*

Case involved ground turmeric.

Defendant argued

Beech-Nut applied and that the appropriate method to calculate included using multiple test data points, averaging of the test result data, including across lots of the turmeric, and applying the geometric mean, were appropriate.

Defendant also relied on *Beech-Nut* to argue that NHANES was best consumption data.

Plaintiff argued

The geometric mean was not appropriate as it diluted the true level of lead.

Testing any other spice than that from the exact same lot was not appropriate as it would allow the defendant to "wash out" problematic test results.

NHANES does not accurately capture average use of spices.

Better method to calculate turmeric consumption is "disappearance" theory reviewing import records of turmeric.

Sufficiency of Data

Is one test result was enough?

The cases where judgment entered - *Gulf* and the *Badia* - relied on *Beech-Nut* in finding multiple data points were necessary for calculating food exposure. Both cases are on appeal.

Defendants Argued that multiple samples and data points are critical to paint an accurate and realistic estimate of lead intake due to:

- **Lead's ability to partition at different concentrations in various foodstuffs**
- **Consumers with high intakes of one type of food can skew overall estimates—the goal is to estimate intake for a *typical consumer***
- **The *Beech-Nut* case illustrated the power of combining databases to estimate exposure:**
  - **National Eating Trends (NET) survey (14-day food diaries from consumers around the U.S.)**
  - **The National Center for Health Statistics National Health and Nutrition Examination Survey (NHANES)(aka "What We Eat in America")(2-day food consump. data from around the U.S.)**

Plaintiffs' Perspective:

Regarding test results:

One test is enough to establish exposure -- *Lee v. Amazon.com, Inc.* (2022) 76 Cal.App.5th 200.

The burden of establishing a particular level for the exposure defense "shall be on the defendant." (Health & Saf. Code 25249.10 subd. (c).)

FDA, NY State Dept. of Agriculture & Markets, and others readily make inferences from a single problematic test.

Regarding the rate of consumption:

The regulations look for what was "reasonably anticipated".

Companies need to know whether or not they need to warn.

The point is to protect consumers, not to enrich experts.

Rate of Consumption – Default Framework

The Regulations look to what is *reasonably anticipated* and *appropriate:*

- **All provisions under Section 25821 subdivision (c) are termed "assumptions" by the regulations and are subject to the proviso "unless more specific and scientifically appropriate data are available."** (Cal. Code Regs. tit. 27 § 25821 subd. (c).)
- **The default framework of 25821(c)(2) provides an *illustrative example* of the sort of "general category" data that should be used in the absence of "more specific and scientifically appropriate" data.** (§ 25821 subd. (c)(2) ["data for use of a general category or categories of consumer products, ***such as*** the United States Department of Agriculture Home Economic Research Report . . ."].)
- Contained ~250 "general categories." ***Modern equivalent:*** FDA Reference Amounts Customarily Consumed (RACC).

The regulations do not require NHANES.

- **NHANES allowed where "more specific and scientifically appropriate data" – e.g. *Beech-Nut*.**
- **"Actual consumption" not required. (*Lee v. Amazon*.)**

Rate of Consumption – Subpopulations

Subpopulation analysis is required where: (1) a particular group of people are reasonably anticipated to be at greater risk, and (2) specific data substantiating that anticipation are available.

Section 25821(c) provides two complementary frameworks—termed "assumptions"

- **(c)(1)** incorporates everything under Section 25721(d), including the subpopulation provisions of Section 25721(d)(2). (See below.)
- **(c)(2)** provides the default framework discussed above.

Section 25721(d)(2) "For an exposure reasonably anticipated to affect a certain subpopulation of the general population in any geographic area, specific data (if available) relating to that subpopulation shall be used to determine the level of exposure."

Creates a two-pronged test. "Reasonably anticipated" and "specific data."

Where both conditions are met, need to assess if level of exposure exceeded threshold for warning.

Purpose, Importance, and Impact

Interpretation and application of the safe harbor defense is informed by the purpose of the law.

- **Enacted to require disclosure, "secure strict enforcement" of that requirement.** (See *Lee v. Amazon*, quoting Prop. 65 ballot pamphlet.)
- **In the absence of Prop. 65, market forces incentivize exposing consumers to toxins without telling them about it.** Making a product out of PVC dosed with phthalates (which make PVC more flexible) is often much cheaper and easier than using non-toxic alternatives. If they can be sold on equal footing, without disclosure….
- **Prop. 65 seeks to change that incentive structure, require disclosure.**

Undisclosed toxic exposures have massive economic costs.

- **Cumulative cost of toxic exposures is estimated* as high as 10% of global GDP.** *(higher incidence of various diseases, earlier disease onsets, reduced testosterone levels, links to incidence of autism etc. etc.)*
- **Proposition 65 has had "commerce transforming" effects, spurring innovation and safer products nationwide.**

References:

- *Source for 10% of Global GDP estimate:* Philippe Grandjean & Martine Bellanger, *Calculation of the disease burden associated with environmental chemical exposures: application of toxicological information in health economic estimation*, Journal of Environmental Health 16 Art. 123 (Dec. 5 2017), https://doi.org/10.1186/s12940-017-0340-3.

- *Source for "commerce transforming" quote*: Claudia Polsky & Megan Schwarzman, *The Hidden Success of a Conspicuous Law: Proposition 65 and the Reduction of Toxic Chemical Exposures*, 47 Ecology L.Q. 823, 833 (2020) (identifying "modes of action" by which Proposition 65 has "rendered facilities, foods, and consumer products safer than before").

- *Ballot pamphlet language referenced*: "The people of California find that hazardous chemicals pose a serious potential threat to their health and well-being, that state government agencies have failed to provide them with adequate protection, and that these failures have been serious enough to lead to investigations by federal agencies of the administration of California's toxic protection programs. The people therefore declare their rights: [¶] (a) To protect themselves and the water they drink against chemicals that cause cancer, birth defects, or other reproductive harm. [¶] (b) To be informed about exposures to chemicals that cause cancer, birth defects, or other reproductive harm. [¶] (c) To secure strict enforcement of the laws....."

Thank You !

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