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Recent Proposition 65 Decision Gives Guidance to Food, Beverage and Consumer Goods Companies

While the California Senate continues to deliberate reforming the Safe Drinking Water and Toxic Enforcement Act, commonly known as Proposition 65 (Prop. 65), on July15, 2013, Alameda Superior Court Judge Brick issued an important and comprehensive decision in *Environmental Law Foundation v. Beech-Nut Corporation et al.* Judgment for the defendants was entered on August 7, 2013. Judge Brick held that food and beverage companies can average exposure over time when determining whether the level of toxic substances in products goes above the threshold level, requiring a warning. Judge Brick's decision will give food, beverage and other consumer goods companies that do business in California helpful guidance in complying with Prop. 65's labeling requirements.

Under Prop. 65, the Governor of California has established a list of chemicals that are known to cause cancer, birth defects or other reproductive harm (the so-called Proposition 65 List). Among other requirements, entities with more than 10 employees that do business in California (including entities located outside of California) are required to provide a clear and reasonable warning before knowingly exposing persons to any chemicals on the Proposition 65 List. If businesses do not comply, the California Attorney General, City Attorney or private enforcers, such as the plaintiff in this case, Environmental Law Foundation (ELF), may bring an enforcement action "in the public interest." Prop. 65 lawsuits have involved a range of consumer products, foods and beverages and have cost companies hundreds of millions of dollars in defense costs.

Since most Prop. 65 cases settle before trial, the *Beech-Nut Corporation* litigation is a rare opportunity to get insight into the three major defenses to such lawsuits and the methodology by which the court determined that the defendants in this case are not obligated to provide Prop. 65 warnings.

Background of *Beech-Nut* Litigation

The *Beech-Nut* complaint named 34 defendants, including several US and non-US food growers, food manufacturing and packaging companies and food retailers that manufacture and/or distribute certain packaged fruit and vegetable products (collectively, the Products). ELF alleged that the Products contain concentrations of lead above the Prop 65 labeling threshold, without providing a warning to consumers.

The defendants argued that they were not subject to Prop. 65's labeling requirements because (1) the lead concentrations were under the labeling threshold (i.e., the safe harbor) if consumption were averaged over time and not measured on a daily basis; (2) the labeling requirements were preempted by the federal Nutritional Labeling and Education Act, and by the federal policy of promoting a diet rich in fruits and vegetables; and (3) that warnings were not required because the toxins occurred naturally in the Products.

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Court Permits Averaging Exposure

In a significant victory for the defendants, the court agreed that it was appropriate to average consumption over time in determining whether exposure fell below the so-called safe harbor limits. No Prop. 65 warning is required if the defendant can establish that the exposure will have no observable effect assuming exposure at 1,000 times the level in question for substances known to the state to cause reproductive toxicity. The defendants argued that the amount of average exposure to lead was well below 1/1,000 of the amount known to cause reproductive toxicity.

The defendants' expert used the following methodology to calculate exposure:

- **Step 1:** Averaged the results of all tests of the Products, conducted by both plaintiff and defendants.
- **Step 2:** Averaged the consumption data about the Products, which she retrieved from the National Health and Nutrition Examination Survey database (NHANES).
- **Step 3:** Determined the frequency with which average users consumed each of the Products using the National Eating Trends (NET) database which has been retaining dietary information from surveyed respondents over a 14-day period.[1]
- **Step 4:** Multiplied the results of steps 1, 2 and 3.
- **Step 5:** Compared the result of step 4 to the 0.5 microgram/day standard as a reproductive toxin (whereas the standard is 15 micrograms/day as a carcinogen).

The plaintiff argued that it was improper for the court to average the test results in step 1 because, among other things, doing so would mask higher exposure for some individuals. The court found defendants' expert arguments for averaging compelling given that test results for food products will vary even from test to test despite using the same container, package, bottle or jar. The court held that such averaging was thus "scientifically necessary."

Next, plaintiff objected to using "geometric mean" as opposed to "arithmetic mean" for averaging the test results and consumption data. While an arithmetic mean simply adds the individual data points and divides the sum by the number of data points that were added, a geometric mean ignores individual high or low figures that might otherwise skew a mean. The court held that using a geometric mean was more appropriate because the data log was normally distributed, making a geometric mean more likely to reflect a true average exposure.

Plaintiff further argued that consumption data from the NHANES database should be assumed to reflect the amounts of the Products consumed on a daily basis and that the court should not assume less frequent consumption. Plaintiff relied primarily on the testimony of a government witness from the Office of Environmental Health Hazard Assessment (OEHHA), which is tasked with administering the Prop. 65 program. The witness testified that it is OEHHA's policy to permit taking frequency of exposure into account for lead when a defendant seeks to establish a defense under section 25801(b)(1) but not when the defense is brought under 25801(b)(2)[2], as was here. The court, however, did not give deference to this policy because it was not an official OEHHA regulation and because this policy would not further the legislative objectives of Prop. 65. Thus, the court held that the consideration of frequency of consumption was appropriate in assessing exposure.

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[1] The NET database is maintained by NPD Group, a market research and advisory firm.

[2] H&SC 25801(b) provides: A level of exposure to a listed chemical shall be deemed to have no observable effect, assuming exposure at one thousand times that level, provided that the level is determined: (1) By means of an assessment that meets the standards described in Section 25803 to determine the maximum dose level having no observable effect, and dividing that level by one thousand (1,000) to arrive at the maximum allowable dose level, or (2) By application of a specific regulatory level for the chemical in question as provided in Section 25805.

Finally, plaintiff objected to using a 14-day average for ordinary consumption. Three experts testified that a 14-day averaging period constitutes a conservative way to determine the "rate of intake or exposure" in light of the pharmacokinetics of lead, which include the following: the half-life of lead in the blood is 30 days or more and the window of susceptibility (when exposure can cause harmful effects) is at least one trimester of pregnancy. The court was persuaded by this testimony.

No Federal Preemption Because of a Lack of Evidence Supporting a Conflict

Defendants argued that Prop. 65 warnings conflict with (1) Congress's promotion of the US Department of Agriculture's programs encouraging the consumption of fruits and vegetables and (2) the regulatory scheme for labeling foods under the Nutritional Labeling and Education Act.

With regard to the first point, the court found that there was no express preemption (no act of Congress or any field that Congress intended to occupy that was in direct conflict with Prop. 65). Although the court seemed persuaded that the federal government was promoting the consumption of fruits and vegetables, the defendants' argument for preemption failed because they lacked evidence establishing that Prop. 65 warnings on the Products would discourage consumers from eating fruits and vegetables. The court noted that the expert testimony by defendants on this topic was insufficient because their expert was not a psychologist or an expert in how consumers react to warnings. The court elaborated in a footnote that defendants did originally designate a consumer behavior expert, who was later withdrawn. This final point suggests that perhaps persuasive expert testimony in this area might have convinced the court of a federal preemption defense.

As for the second point regarding the regulatory scheme for labeling, the court found that defendants could point to no FDA regulation or other federal policy that requires prior federal approval of labels for food products, as opposed to drugs.

Insufficient Evidence to Establish a Naturally Occurring Defense

Under the naturally occurring defense, there would be no "exposure" to a listed chemical under the Act as long as the person responsible for the exposure can show that the chemical is naturally occurring in the food.[3] A chemical is considered "naturally occurring" if it is (1) 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 that is naturally present in the environment in which the food is raised, grown or obtained, and (2) the presence of the chemical is not the result of any known human activity.

Defendants presented evidence that a vast majority of the lead taken up by the roots of the plants and transmitted into the fruit is naturally present in the soil. They justified this conclusion by claiming that almost no anthropogenic lead exists in soil below the depth of 30 centimeters, where most plant roots are located. From this, the court concluded that although a predominant amount of the lead in

[3] The naturally occurring defense is only available if the presence of the chemical is not avoidable by good agricultural and manufacturing practices, and by the use of quality control measures to reduce the chemical to the "lowest level currently feasible." The court provided some guidance on this requirement: The court rejected plaintiff's argument that compliance with the Codex Alimentarius Commission's *Code of Practice for the Prevention and Reduction of Lead Contamination in Foods* is necessary to satisfy the foregoing requirement. The court also rejected defendants' expert opinion that compliance with the FDA's 50 parts per billion (ppb) acceptable guideline for grape juice should establish that the level of lead in the Products was at the lowest level currently feasible.

the Products may in fact be due to the natural levels present in the soil, defendants could not establish that the naturally occurring lead was the *sole* source of the lead present. The requirement that the naturally occurring source be the *sole* contributor is not ambiguous and thus must be strictly adhered.

The court recognized that an alternative to establishing that the chemical's presence is solely the result of the environment is to demonstrate the portion of the Products that are geogenic (i.e., naturally occurring in the soil) and not count that portion toward the exposure analysis under the Act. Defendants, however, were unable to present any proof differentiating the proportions of lead in the Products that were geogenic versus anthropogenic.

Conclusion

Judge Brick's final decision adopting averaging in determining whether the safe harbor limits are satisfied may represent a substantial victory for food, beverage and consumer goods manufacturers doing business in California. Companies with products with safe levels of trace chemicals may now have a valuable defense in their arsenal when faced with "shakedown" lawsuits, if Judge Brick's opinion and end ruling are not overturned on appeal. While defendants failed to prevail on their naturally-occurring defense, Judge Brick's decision provides substantial guidance to defendants who may need to rely on it in the future.

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