

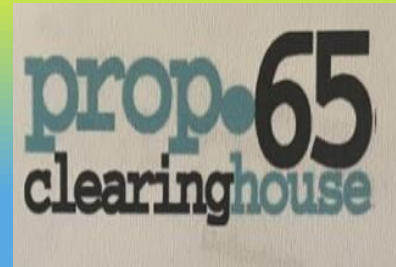
# ***Beech-Nut Lives On*** **Calculating Exposure in Food**

**2024 Prop 65 Conference**

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# ***The Regulations***

## 27 CCR § 25821 - Calculating Exposure in Food

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.

# ***Applying the Regulations when Calculating Exposure in Food***

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

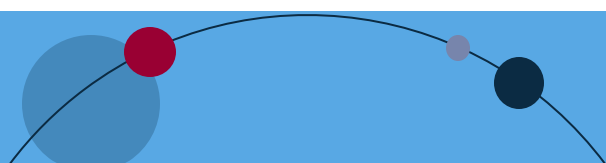
**Who are the “average users of the consumer product”?**

**What is a “per capita basis” and why can’t I 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?**



# ***The Beech-Nut Case***

## ***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 the defendants did not have a duty to provide a Proposition 65 warning for lead in baby food products where they demonstrated that the average consumer's reasonably anticipated rate of exposure to lead was below the Safe Harbor level. The *Beech-Nut* court heard from leading testifying experts and made these key findings:

**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 consumption. (*Id.* at 316).

# ***Response to Beech-Nut***

- In 2015, OEHHA produced “pre-regulatory discussion” document. It proposed prohibiting averaging test results across lots. Also proposed setting different MADLs based on frequency of duration.
  - ▶ It withdrew the document and issued no proposed regulatory changes.
- In 2015, a private enforcer petitioned OEHHA to issue new regulations on food assessment in response to *Beech-Nut*.
  - ▶ After public notice and comment OEHHA denied the petition.
- In 2018, OEHHA proposed regulations on calculating intake by the average consumer in food assessments, which would have prohibited the use of much of *Beech-Nut’s* methodology, including prohibiting use of geometric mean.
  - ▶ After public notice and comment OEHHA withdrew the proposal.

**Not a specific to *Beech-Nut*, but shows appellate court endorsing its methodology (blood lead modeling)**

- In 2018, an enforcer filed suit seeking an order compelling OEHHA to withdraw or lower the lead MADL.
  - ▶ The appellate court dismissed the case. and endorsed the 0.5 ug/day valuation and methodology relied on, holding that blood level monitoring is the “functional equivalent reproductive NOEL.”  
*Mateel Pacific Justice Foundation v. OEHHA* (2018) 24 Cal.App.5th 220.

There is currently no enacted or proposed regulation limiting or prohibiting the use of *Beech-Nut’s* methodology.



# ***Beech-Nut's Methodology On Trial***

## ***Beech-Nut Challenged in Three Recent Cases***

### **Consumer Advocacy Group v. Gulf Pacific Rice Co., Inc.**

Los Angeles County Superior Court, Case No. BC553427. Judgment, March 15, 2024 (on appeal).

>> *Brown Rice*

### **Consumer Advocacy Group v. Ross Dress for Less, Inc., (Badia Spices, Inc.)**

Los Angeles County Superior Court, Case No. 19STCV38610. Judgment, May 26, 2024 (on appeal).

>> *Turmeric*

### **Consumer Advocacy Group v. Gel Spice Co., Inc.**

Los Angeles County Superior Court, Case No. BC665798. Order of Dismissal, September 3, 2024.

>> *Turmeric plus six other spices*

# ***Applying Beech-Nut's Methodology***

***CAG v. Gulf Pacific Rice***

***CAG v. Ross Stores (Badia)***

## The Gulf Rice Case – the Arguments

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.

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

### Plaintiff argued

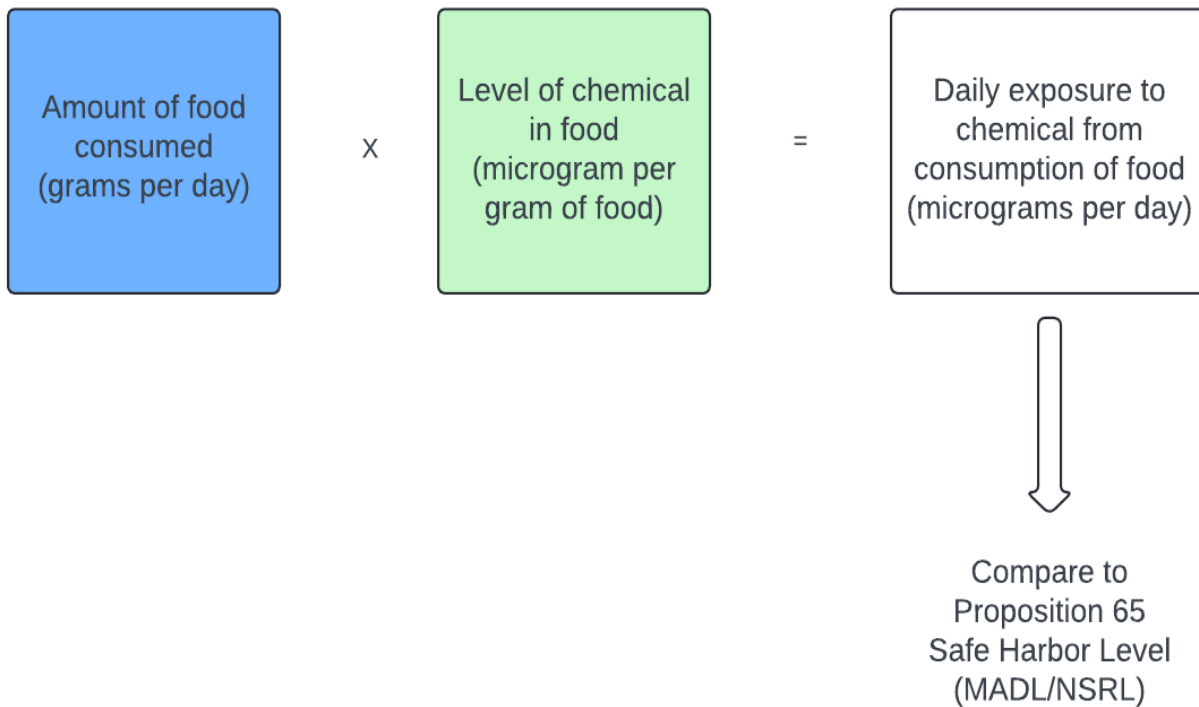
The geometric mean was not appropriate as it diluted the true level of lead

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.

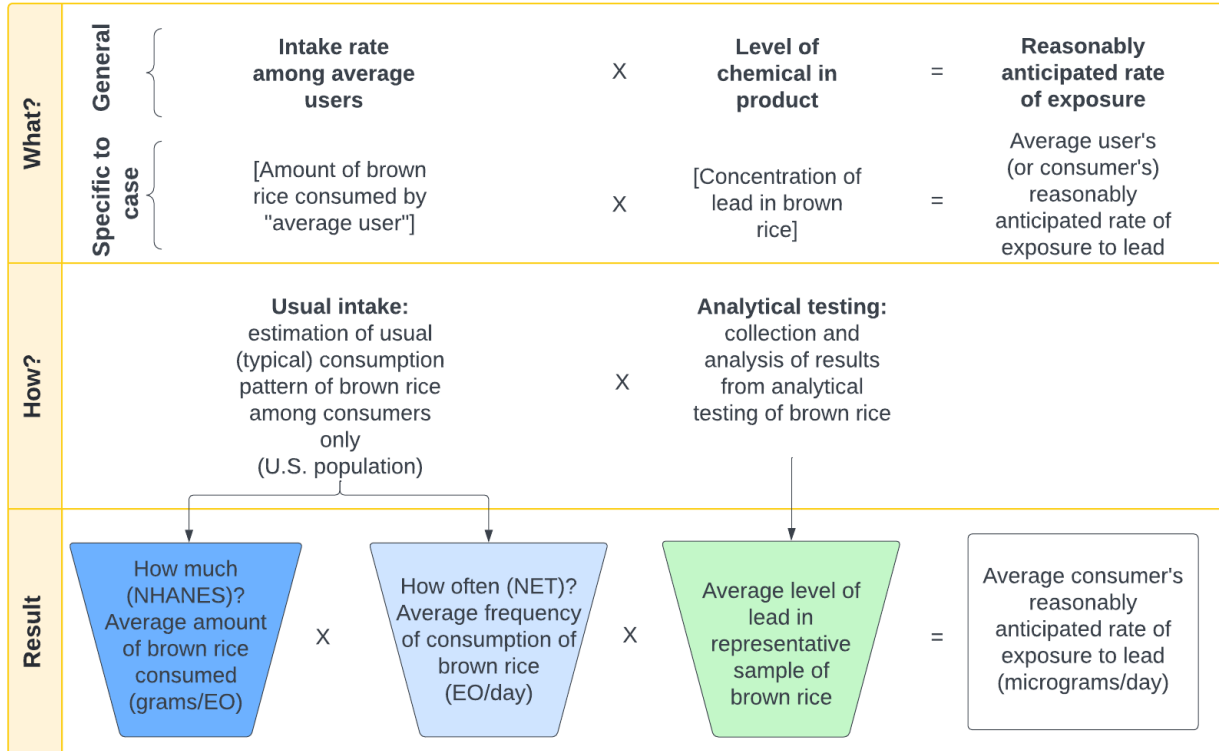
NHANES was not appropriate for consumption data because it was based on the data of all ethnicities and included non-Asians in its dataset.

## Dietary Exposure Calculation - Overview

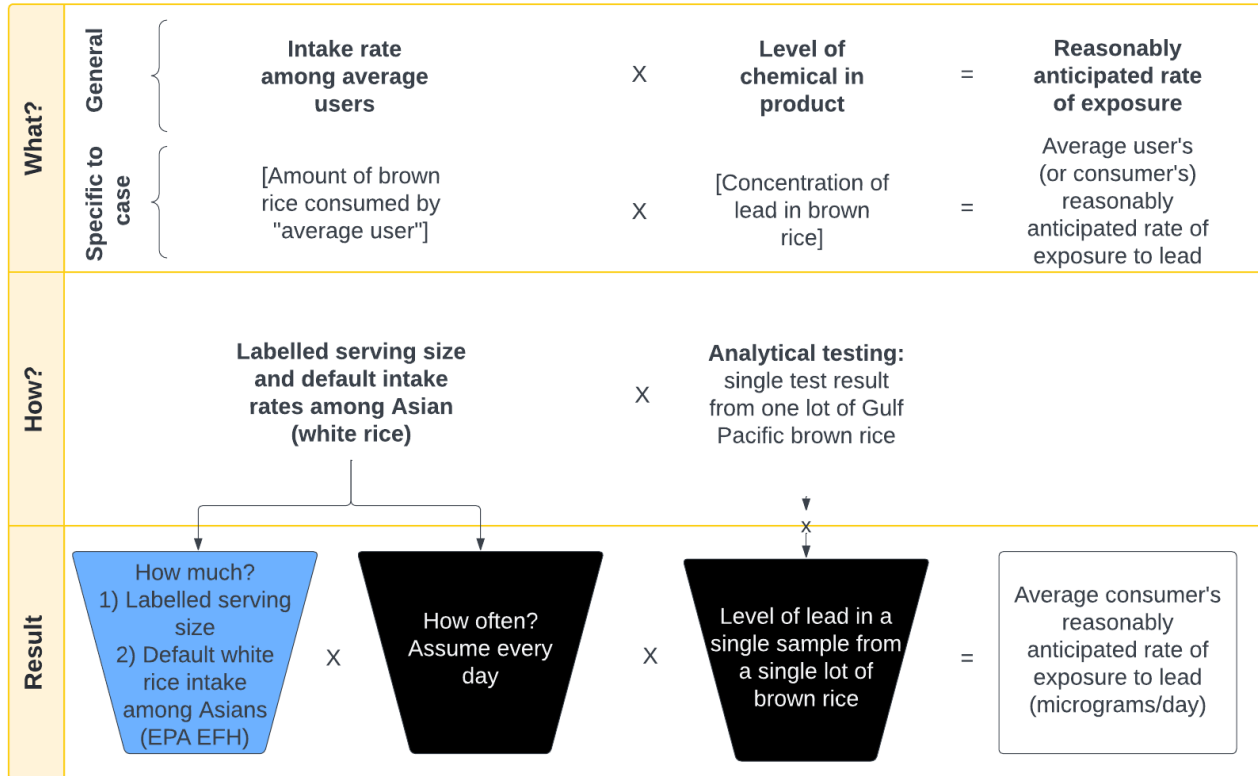


# The Gulf Pacific Rice Case – How Defendants Applied Beech-Nut

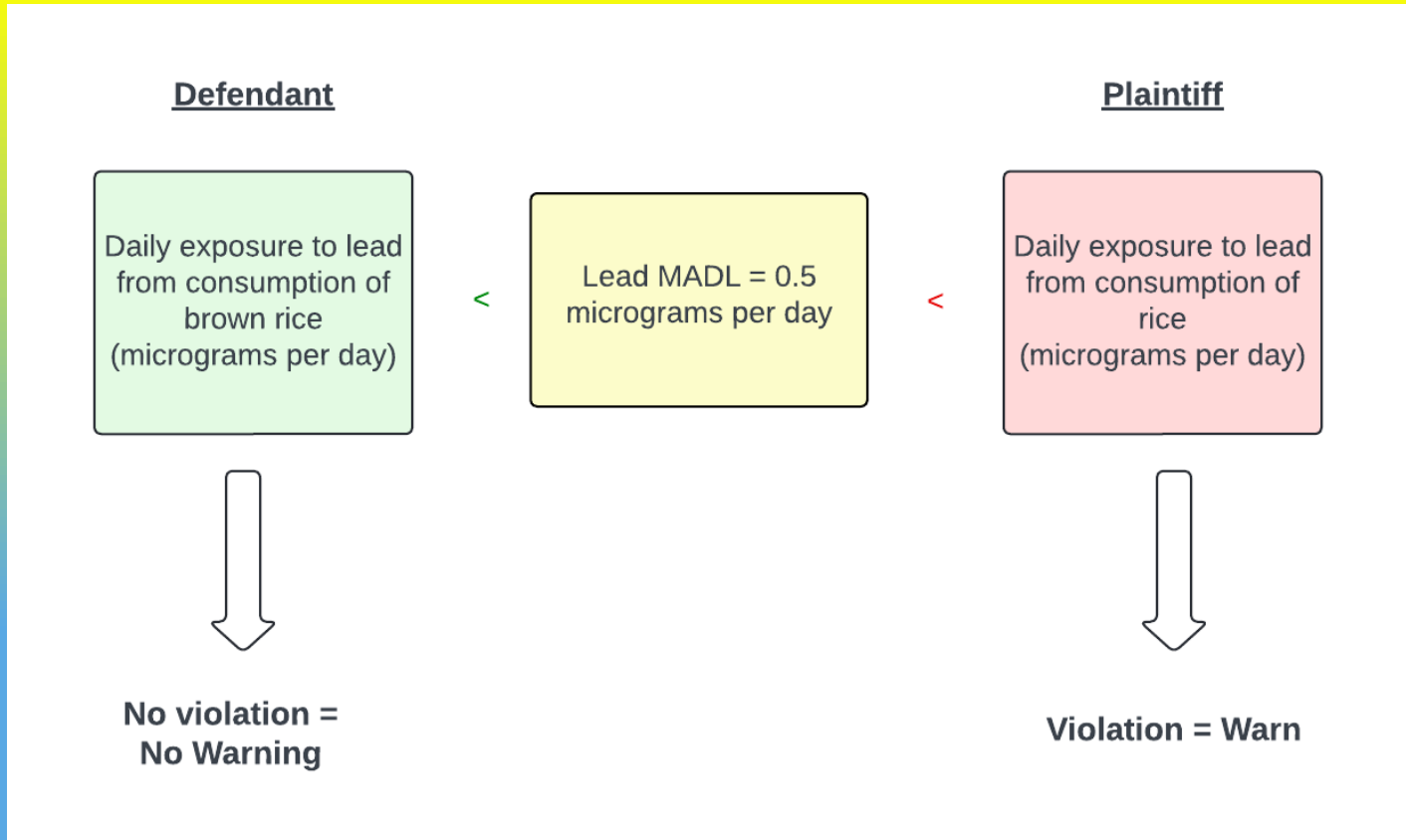
## Overview of dietary exposure assessment



# The Gulf Rice Case – Plaintiff's Non-Beech-Nut Exposure Assessment



# The Gulf Pacific Rice Case – Impact of differences in methodology and data sources





## The Badia Case – the Arguments

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 the best consumption data was from NHANES

### Plaintiff argued

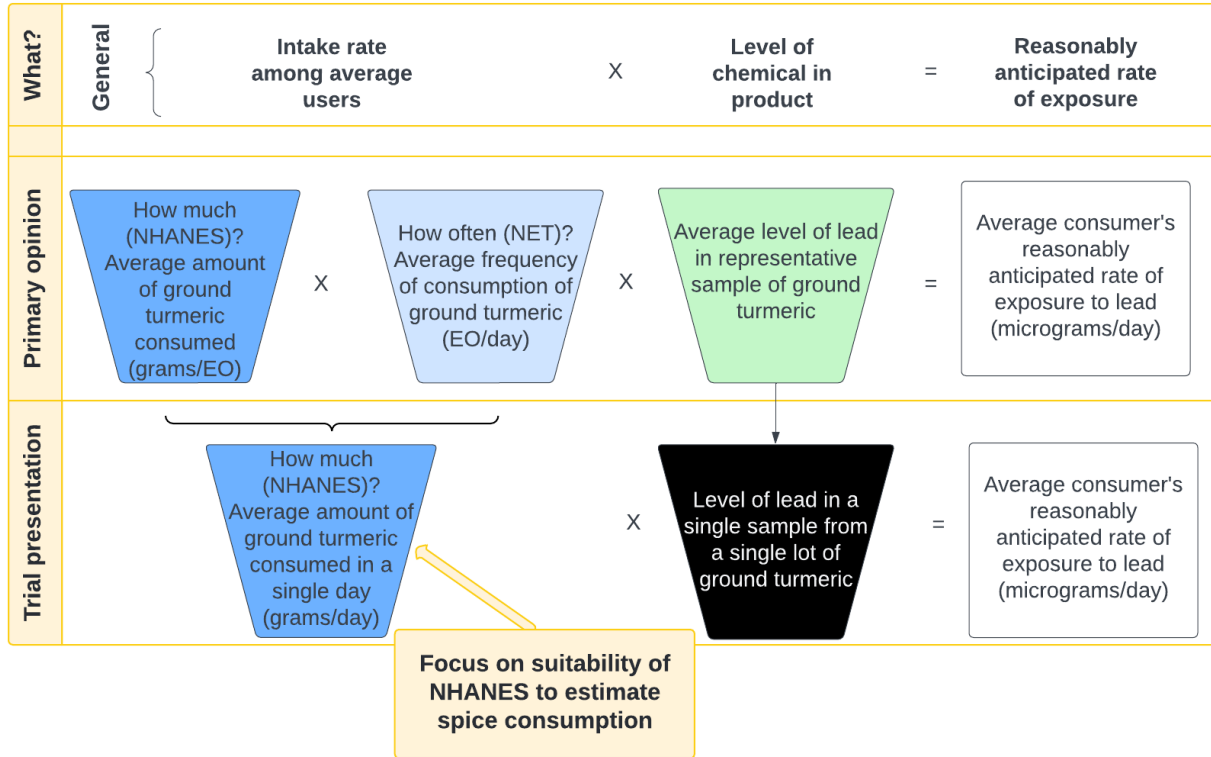
The geometric mean was not appropriate as it diluted the true level of lead.

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.

# The Badia Case – How Defendants Applied Beech-Nut



# ***Beech-Nut's Methodology***

***How Lead Behaves in Food***

***Sufficiency of Data***

***Averaging Exposure Over Time***

## ***How Lead Behaves in Food***

**In all three cases, plaintiff claimed that a single data point for lead in rice and spice was sufficient.**

**In the two cases where judgment entered – *Gulf* and *Badia* – the courts disagreed. They followed *Beech-Nut* and the unique way lead behaves in food**

**Estimates of lead exposure from food requires the use of multiple samples/data points:**

- **As stated by expert Dr. Barbara Peterson in *Beech-Nut*, the following factors should be considered:**
  - **Lead adheres to different parts of a food (e.g., rice vs. rice hull)**
  - **Lead is not homogenous within a food product**

## Sufficiency of Data

Plaintiff argued that 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.

**WHY? 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.)

## Averaging Exposure to Lead – One Day or More Than One?

The Beech-Nut court observed that experts on both sides agreed that there is (at least) an eight-week “window of susceptibility” to lead.

- **Notably, “eight weeks is the shortest period during which an exposure to lead would be expected to have an adverse reproductive effect.”**
- The NET survey cited by *Beech-Nut’s* food exposure expert Dr. Petersen established that the food products in question are eaten no more frequently than four times/month.
- *Beech-Nut’s* toxicology expert Dr. Barbara Beck demonstrated that blood lead levels among women of childbearing age and four-month old children associated with exposure at the Safe Harbor for lead (i.e., 0.5 micrograms per day) were greater than or equal to the blood lead levels associated with exposure to lead from consumption of the products at issue as estimated by Dr. Barbara Petersen (so, *the estimated consumption would not result in exposure over the MADL*).

The Court then concluded that since no warning would be required under the modeled NOEL standard, it would be “difficult to see why frequency of use should not be considered.”

## ***Averaging Lead Exposure Over Time***

**Using the *Beech-Nut* methodology, the defendants in the *Gulf* and *Badia* cases argued lead exposure should be calculated over more than one day.**

**Plaintiff's toxicologist argued that lead is a "weak teratogen" and that it has "acute" teratogenic effects and thus, per the regulations, can be treated as a teratogen  
= one day should be the time period for exposure.**

**The *Gulf* and *Badia* courts found defendants' experts more persuasive and rejected the single-day exposure analysis.**

# *Thoughts, Take Aways & Predictions*



# Questions ?

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