



Prop 65 Food Cases: Trials, Trends & Take Aways

Panelists

Robert Boone, Partner, Maschoff Brennan

Jennifer Singh, Partner, Amin Wasserman Gurnani

Margaret Whittaker, Managing Director & Chief Toxicologist,
ToxServices LLC

Reuben Yeroushalmi, Principal, Yeroushalmi & Yeroushalmi

Jake Schulte, Attorney, Entorno Law

Moderator

Dennis Raglin, Shareholder, Carlton Fields, LLP

**The Prop 65 Clearinghouse
Annual Conference - 2026**

The *Pictsweet* Case



Overview of Dr. Steven Boomhower's Opinions

Basis for Listing Cadmium Under Prop 65

- Non-teratogenic developmental and male reproductive effects associated with protracted oral exposure (OEHHA, 1996)

The Appropriate Exposure Duration for Cadmium is 60+ Days

- Based on the relevant developmental and male reproductive effects that led to cadmium's listing

Evidence Does Not “Clearly Show” Teratogenic Effects from Oral Cadmium Exposure

- Malformations (*i.e.*, teratogenic effects) were not a consistent finding (OEHHA, 1996)

Assessing Exposure to Evaluate Compliance

“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).”

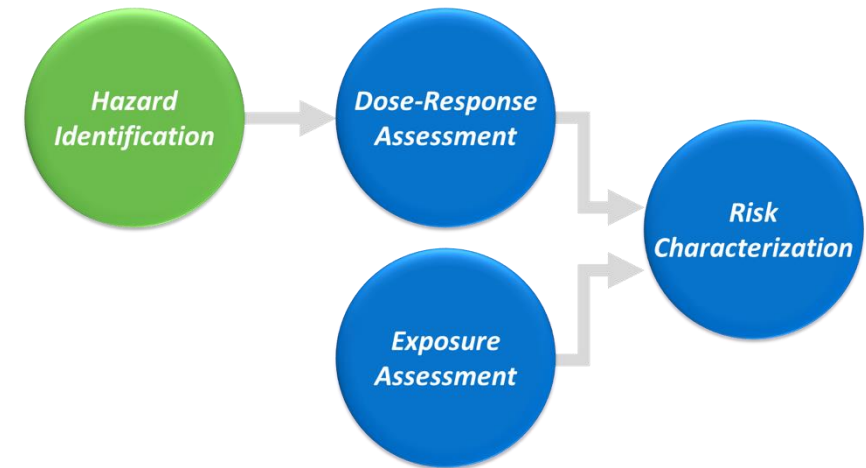
Office of Environmental Health Hazard Assessment (OEHHA)
27 CCR § 25821(b)

Criteria for Recommending Chemicals for Listing Under Prop 65

- The State's Qualified Experts use criteria described in OEHHA (1993), "Criteria for Recommending Chemicals for Listing as 'Known to the State to Cause Reproductive Toxicity'"
- The State's Qualified Experts base their recommendation on at least one of the following:
 - Sufficient evidence in **humans**
 - Limited evidence in **humans that is supported by experimental animal (mammalian)** data
 - Sufficient evidence in **experimental animals (mammals)**, such that extrapolation to humans is appropriate



OEHHA
California Office of Environmental
Health Hazard Assessment



Basis of Listing Cadmium Under Prop 65

- In 1997, cadmium was added to the Prop 65 list of reproductive toxicants based on a determination by the State's Qualified Experts
- Cadmium was listed for **developmental** effects and **male reproductive** effects; cadmium was not listed for female reproductive effects
- The State's Qualified Experts' determination to list cadmium was based on OEHHA (1996), a review of the scientific evidence on potentially adverse developmental and reproductive effects associated with cadmium



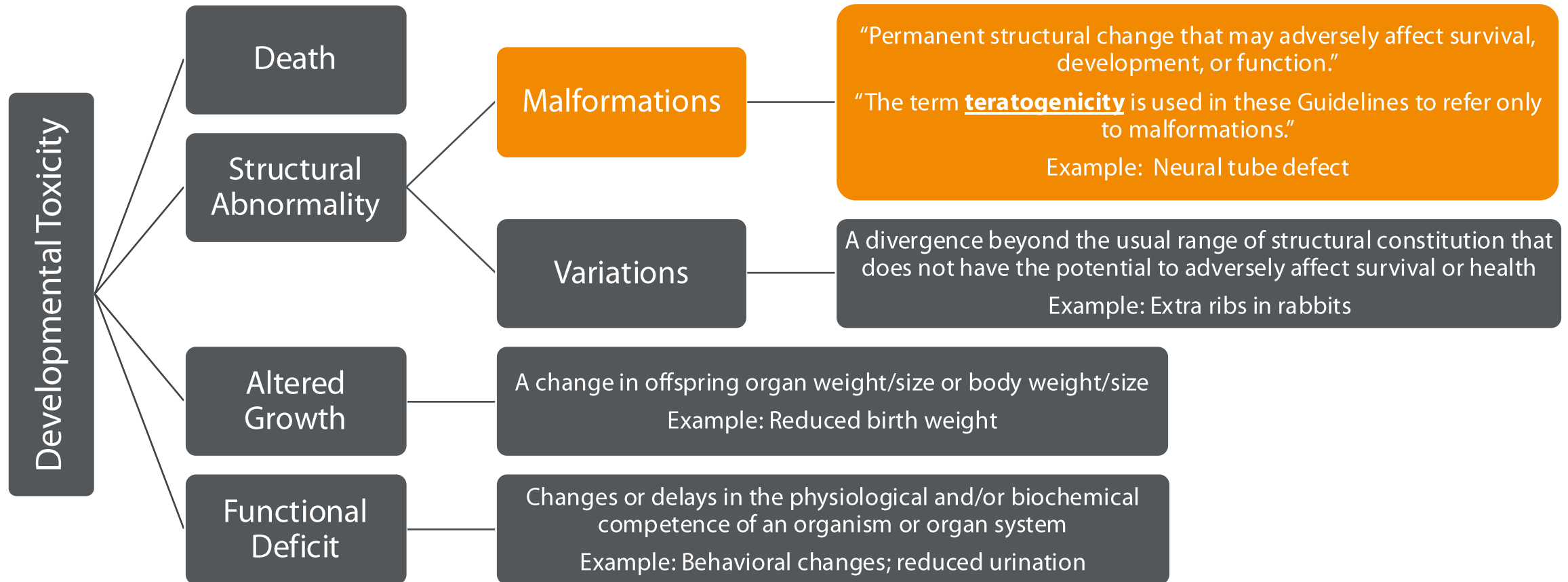
EVIDENCE ON DEVELOPMENTAL AND REPRODUCTIVE TOXICITY OF CADMIUM

Reproductive and Cancer Hazard Assessment Section (RCHAS)
Office of Environmental Health Hazard Assessment (OEHHA)
California Environmental Protection Agency (Cal/EPA)
October, 1996

- OEHHA (1996) indicated that the most consistent developmental and male reproductive effects associated with oral exposure to cadmium were associated with chronic or protracted exposure durations
 - “The most consistently observed effects of oral or inhalation exposure to Cd on the development of experimental animals are **reductions in fetal or birthweight**, followed by alterations in locomotor behavior” (p. 31)
 - “Overall, the most consistent effects on development, when Cd exposure is by a relevant route of exposure, are on **growth parameters**, followed by locomotor behavior” (p. 33)
 - “Sperm counts and motility have been shown to be depressed in Cd-exposed animals, but **only after long-term treatment**” (p. 60)
- None of the effects described above are teratogenic effects
 - “Malformations have been reported with Cd exposure, **but are not a consistent finding with relevant routes of exposure**” (p. 7)

What Developmental Effects Are “Teratogenic”?

- Although the definition of “teratogenicity” can vary across agencies, **OEHHA applies US EPA’s definition** described in its *Guidelines for Developmental Toxicity Risk Assessment*



Prop 65 & Food

Calculating Exposure





A Toxicologist's Take on Proposition 65 Food Intake

Prop65 Clearinghouse Conference

August 31, 2026

**Margaret H. Whittaker, Ph.D., M.P.H., C.Biol.,
F.R.S.B., E.R.T., D.A.B.T.**

**Managing Director and Chief Toxicologist
ToxServices LLC**

Toxic Antipasti



Listing chemicals on Prop 65, cadmium as an example



When is "average" not average?



Available tools and databases for estimating food intake



Resources for mastering food-related tools and databases (e.g., NHANES)

Assessing Prop 65 Contaminant Exposure from Foods

Proposition 65 and Foods: Key Points



- Foods commonly receive **Notices of Violation (NOVs)**



- On a typical month, foods receive **200-300** Prop 65 NOVs



- Powdered foods, pasta/noodles, fruits and vegetables, spices, snack foods, and seafoods **commonly receive NOV**s



- Heavy metals (lead, cadmium) and natural toxins (e.g., aflatoxin, ochratoxin A) are **common contaminants**

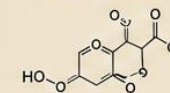
HEAVY METALS

Pb
Lead

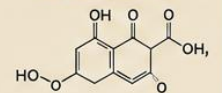
Cd
Cadmium

NATURAL TOXINS

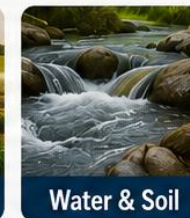
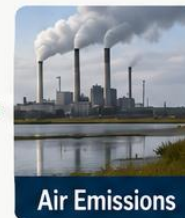
Aflatoxin



Ochratoxin A



- Many Prop65 chemicals are present as **low-level contaminants in the environment**



These contaminants can be present in the food supply at very low levels.

Prop 65 Listing Procedures and Basis of Cadmium's Prop 65 Listing

The Four Ways Chemicals Get Added to Proposition 65

Proposition 65 uses four statutory mechanisms to add chemicals to the list of chemicals known to cause cancer or reproductive toxicity.

1 LABOR CODE (LC)



Chemical is identified by reference to specified provisions of California Labor Code §6382.

EXAMPLE PATHWAY:

Chemicals identified by IARC as carcinogens under the applicable Labor Code criteria.

KEY PLAYER:

California Labor Code §6382 (e.g., IARC cancer classifications)

2 STATE'S QUALIFIED EXPERTS (SQE)



California's scientific expert committees determine that a chemical has been clearly shown to cause cancer or reproductive toxicity.

- **CIC** – Carcinogen Identification Committee (cancer)
- **DARTIC** – Developmental and Reproductive Toxicant Identification Committee (reproductive toxicity)

KEY PLAYERS:

CIC and DARTIC

3 AUTHORITY BODIES (AB)



A designated authoritative body formally identifies a chemical as causing cancer or reproductive toxicity.

DESIGNATED AUTHORITY BODIES:



U.S. EPA



FDA



NIOSH



NTP



IARC

4 FORMALLY REQUIRED (FR)



A state or federal agency formally requires the chemical to be labeled or identified as causing cancer or reproductive toxicity.

COMMON EXAMPLE:

FDA requires warnings on prescription drugs for cancer, birth defects, or other reproductive harm.

KEY PLAYERS:

State or Federal Agencies (e.g., FDA labeling requirements)

Cadmium is listed on Prop 65 due to Developmental toxicity (May 1, 1997), Male reproductive toxicity (5/1/1997), and Cancer (10/1/1997)

EVIDENCE ON DEVELOPMENTAL AND REPRODUCTIVE TOXICITY OF CADMIUM

Reproductive and Cancer Hazard Assessment Section (RCHAS)
Office of Environmental Health Hazard Assessment (OEHHA)
California Environmental Protection Agency (Cal/EPA)
October, 1996

When is "average" not average?

Prop 65 Food Exposure Assessment – 27 CCR §25821

Two critical items must be considered in food exposure assessments

1 WHO is the average based on?



Average users of the specific food
(e.g., "spinach eaters")

- ✓ Exposure should be calculated using the reasonably anticipated rate of intake for average users of a specific food
- ✗ **NOT** a per capita basis for the general population

2 WHAT exposure period matters?



The reasonably anticipated rate of exposure shall be based on "the pattern and duration of exposure that is relevant to the reproductive effect" associated with a Prop 65 chemical.



WHY THIS MATTERS: For Prop 65 chemicals that may cause an adverse effect such as **developmental toxicity** following a **short duration** of exposure, long-term averaging may not adequately characterize the relevant exposure.

AVERAGE EXPOSURE IS NOT NECESSARILY "AVERAGE AMOUNT EATEN ON AN EATING DAY"

AMOUNT PER EATING OCCASION (EO)



100
grams/EO

Exposure when food is consumed



AVERAGE FREQUENCY



1/7
days

Consumed 1 day per week



TIME-AVERAGED INTAKE



14.3
grams/day

$100 \text{ grams} \times 1 \text{ day}/7 \text{ days}$

$$100 \text{ g} \times 1/7 = 14.3 \text{ g/day}$$

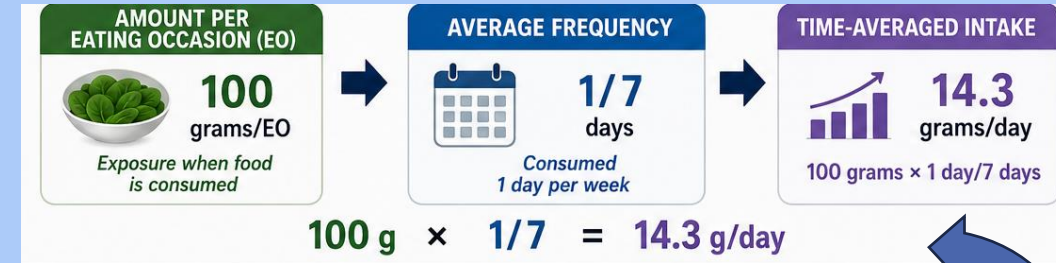
CASE EXAMPLE

PICTSWEET SPINACH CASE



Court recognized that exposure assessments should reflect actual consumption patterns rather than assuming a full serving every day.

Prop 65 Average Intake: Cadmium as Example



- Cd's MADL is 4.1 µg/day (oral tox study in rats)
- If someone eats 100 g spinach per day, containing 0.125 ppm Cd (0.125 µg/g), a person ingests 12.5 µg Cd (100 g x 0.125 µg/g)
 - Does the 12.5 µg Cd intake indicate that the 4.1 ug/day Cd MADL is exceeded? **No.**
- Averaging is important...the average person doesn't eat spinach every day
 - Beech-Nut accepted use of geometric mean to characterize skewed consumption data
- 27 CCR 25821 states that the pattern and duration of exposure must be assessed
 - Cd may be developmentally toxic over a short period of time
 - But these short-term toxicity studies almost all involved injection route
 - The relevant route of exposure (as mentioned in the Pictsweet NOV) is the oral route, so the hazard flagged by injection route exposure is unlikely to pose a risk to consumers

The primary route of exposure has been through ingestion.

Available Tools to Estimate Food Intake

- CDC's National Health and Nutrition Examination Survey (NHANES) is primary database
 - NHANES estimate grams food/Eating Occasion (EO), based on self-reported 24 hour recall survey responses
- NHANES' Food Frequency Questionnaire (FFQ) estimates frequency of EOs
- Daily food consumption is then derived by multiplying grams food/EO x EO/day

 Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

National Center for Health Statistics

CDC

 National Health and Nutrition Examination Survey

About NHANES

Latest Data Releases

Questionnaires, Datasets, and Related Documentation

Survey Participants

Biospecimen Program

New Content and Proposal Guidelines

Survey Results and Products

Tutorials

Listserv

Information for Health Professionals



National Health and Nutrition Examination Survey

NHANES August 2021-August 2022

[Print](#)

After suspension of NHANES field operations in March 2020 due to the COVID-19 pandemic, the 2-year cycle in August 2021. The August 2021-August 2023 nationally representative sample design and modified questionnaires, and examination procedures and analytic guidance and the [Plan and Operations Report](#) for additional information.

Data, Documentation, Codebooks

 Demographics Data

 Dietary Data

 Examination Data

 Laboratory Data

 Questionnaire Data

 Limited Access Data



National Health and Nutrition Examination Survey

August 2021-August 2023 Dietary Data - Continuous NHANES

[Print](#)

- [NHANES August 2021-August 2023 Dietary Variable List](#)
- [Questionnaire Instruments](#)
- [Exam Procedure Manuals](#)
- [Measuring Guides for the Dietary Recall Interview](#)
- [What We Eat in America, Dietary Data: Impact of Mode Change](#)
- [Dietary Supplement Data Collection Mode Changes](#)
- [Brief Overview of Sample Design, Nonresponse Bias Assessment, and Analytic Guidelines](#)
- [SAS Universal Viewer](#)
- [Data User Agreement](#)

Data File Name	Doc File	Data File	Date Published
Dietary Interview - Individual Foods, First Day	DR1IFF_L.Doc	DR1IFF_L.Data [XPT - 64.2 MB]	October 2024
Dietary Interview - Individual Foods, Second Day	DR2IFF_L.Doc	DR2IFF_L.Data [XPT - 56.4 MB]	October 2024

National Health and Nutrition Examination Survey

2005-2006 Data Documentation, Codebook, and Frequencies

Food Frequency Questionnaire - Raw Questionnaire Responses (FFQRAW_D)

Data File: FFQRAW_D.xpt

First Published: September 2008

Last Revised: NA

Component Description

A food frequency questionnaire (FFQ) (previously referred to as the NHANES Food Propensity Questionnaire or "FPQ"), was added to NHANES 2003-2004 to ascertain information on food and food group consumption patterns during the past year. The same FFQ instrument was used during NHANES 2005-2006.

When is NHANES Not the Best Database to Estimate Food Consumption?

- Certain food categories are poorly represented in NHANES
 - Spices are an example of a food that is not well indexed in NHANES
 - Dietary intake estimates based on a limited number of respondents may not be representative of an entire population of consumers of a certain food stuff
- Often, commercially available food consumption databases are based on NHANES data, so not always best option if NHANES falls short
- Dietary consumption can be estimated using surveys (e.g., Masri et al. 2025)



Resources to Learn More

- Please contact me if you'd like a complementary Standard Operating Procedure (SOP) that pertains to the use of NHANES and related databases to estimate dietary exposure!
(mwhittaker@toxservices.com)

Gulf Pacific Rice

Badia Spices

Gel Spice



The Regulations on NHANES



Under the regulations, “exposure shall be based on...data” such as NHANES “where...available”

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.

27 Cal. Code Regs § 25821(c)(2)

[The United States Dept of Agriculture Home Economic Research Report is the predecessor to NHANES]

The Courts on NHANES



The key appellate case ruling on exposure from foods under Prop 65 is *Beech-Nut*, which affirmed the trial court's endorsement of the assessment methodology utilizing NHANES to determine the average intake of **baby food**.

Three recent trial courts have followed the *Beech-Nut* rubric, upholding that NHANES is the superior data source for determining average consumption, and supporting use of the geometric mean when averaging intake.

For rice – *Consumer Advocacy Group, Inc. v. Gulf Pacific Rice Co.* (Cal. Super. Ct. 2024, No. BC553427)

For turmeric – *Consumer Advocacy Group, Inc. v. Badia Spices, Inc.* (Cal. Super. Ct. 2024, No. 19STCV38610)

For spinach – *Chemical Toxin Working Group v. The Pictsweet Company* (Cal Super. Ct. 2024, 24STCV08902)

A fourth case, also involving **spices**, *Consumer Advocacy Group, Inc. v. Gel Spice Co. Inc.* (Cal. Super. Ct. 2024, No. BC665798), was dismissed before ruling on exposure, but the court's rulings throughout recognize the importance of averaging consumption for the general population and reject plaintiff's proposed alternative methodologies.

ELF v. Beech-Nut

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

“naturally occurring” defense was applicable to their products. The court concluded, however, that warnings were not required as each of their products was at or below the regulatory safe harbor exposure level. The court found the expert testimony and analysis presented by defendants to be “far more persuasive” than ELF’s analysis. For example, the court rejected Burton-Freeman’s use of the 85th percentile of the NHANES database “as a proxy for amounts consumed by average users,” instead accepting Petersen’s average consumption per day calculations based on the geometric mean.

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

NHANES is the
“best available
data base”

determining whether that standard has been met in this case.” In sum, on the record here, we cannot conclude that the trial court erred in accepting defendants’ experts’ opinions that the products qualify for the exemption under the safe harbor defense of Regulation 25801, subdivision (b)(2).

DISPOSITION

The judgment is affirmed.

CAG v. Gulf Pacific Rice Co, Inc.

19 99. Data from the U.S. Center for Disease Control and Prevention's National Center for
20 Health Statistics' National Health and & Nutrition Examination Survey ("NHANES") is
21 the most robust and reliable source of consumer use data for consumer use of rice.
22 100. NHANES data is designed to be representative of the entire population in the
23 United States, and to capture how often foods are consumed, when they are consumed and
24 how much is consumed, NHANES data is publicly available and is frequently used by
25 state and federal regulators, including OEHHA for food consumption analysis.

5 122. The U.S. Centers for Disease Control and Prevention's National Center for Health
6 Statistics' National Health & Nutrition Examination Survey ("NHANES") is appropriate to
7 be used to determine consumer use data for consumption of the rice product at issue.

8 123. NHANES includes data concerning all consumers of rice, including Asians.
9 NHANES measures consumption rates of the average consumer, which by its very
10 definition includes all ages, genders, races, frequent eaters, and infrequent eaters.

11 124. A valid food exposure assessment pursuant to Proposition 65 regulations and the
12 NHANES database requires consumption data from all ethnicities who consume the food,
13 as well as data from men, women and children.

14 125. Pursuant to Proposition 65 regulations, using NHANES for calculating lead
15 exposure in this case provides for the inclusion of all consumers of the food, and is not
16 limited to any specific subpopulation, ethnicity, gender or other subcategory.

NHANES "is the most
robust and reliable
source of consumer use
data for consumer use
of rice."

CAG v. Badia

3 176. The Court, having considered the evidence submitted by both Parties,
4 concludes that NHANES is the appropriate source to use for obtaining food consumption
5 data, and is the appropriate source for obtaining consumption data relating to ground
6 turmeric, the spice at issue in this case. It further finds that NHANES is superior to the
7 alternative sources and consumption calculation methods proposed by CAG's experts.

NHANES is "a better
source for food
consumption data,
including turmeric..."

NHANES is
"superior to the
alternative
sources"

1 198. In sum, the Court concludes that NHANES is a better source for food
2 consumption data, including turmeric, than Dr. DeSantis's import/export theory. It
3 further finds based on the above, and pursuant to *Sargon Enterprises v. University of*
4 *Southern California* (2012) 55 Cal.4th 747 and Evid Code §§ 720(a), 801 and 803, the
5 Court concludes that Dr. DeSantis's testimony is speculative, irrelevant and not
6 supported by the evidence. Therefore, the testimony is inadmissible.

CTWG v. Pictsweet



15 data are available." (27 CCR §25821(c)(2).) To determine amount per EO, Dr. Scrafford
16 used the USDA's National Health and Nutrition Examination Survey, or NHANES, which
17 she testified is the successor to the USDA report identified in the regulations. NHANES is
18 a robust and reliable source of consumer use data, it is representative of the entire
19 population, it is publicly available, and it is frequently used by state and federal regulators,
20 including OEHHA. (March 12, 2026, R.T. 41:1–44:8.) To determine EO per day, Dr.
21 Scrafford relied on the 14-day National Eating Trends survey, or NET, from Circana, Inc.
22 (*Id.*, 72:12–73:14.)

26 Based on the evidence and credibility of witnesses, the court concludes that Pictsweet
27 met its burden of proof by preponderance of the evidence to establish that the Level of
28 Exposure to cadmium from the Product does not exceed the MADL of 4.1 µg/day. Based

33

STATEMENT OF DECISION

1 on the totality of evidence presented, the court concludes that Pictsweet has met its burden
2 of proof by preponderance of evidence to establish that it was in compliance Prop 65 at
3 the time the Product was purchased, and that the Product did not and does not require
4 Prop 65 warnings. Therefore, a complete defense to CTWG's claim has been established
5 and defendants are entitled to judgment in their favor.

The Courts on Alternative Surveys



Although a properly designed and validated survey commissioned from a reputable source that is representative of the average consumer may provide reliable food consumption data for Proposition 65 evaluation, surveys alternative to NHANES have been rejected as unreliable by at least two trial courts:

In CAG v. Gulf Pacific Rice Co. (Cal. Super. Ct. 2024, No. BC553427) the Court rejected plaintiff's alternative consumption surveys, ruling that: "using NHANES for calculating lead exposure in this case provides for the inclusion of all consumers of the foods, and is not limited to any specific subpopulation, ethnicity, gender or other subcategory.... An assessment that uses data from just one ethnicity is not a valid, representative sample." (quoting Statement of Decision.)

In CAG v. Badia Spices, Inc. (Cal. Super. Ct. 2024, No. 19STCV38610) the plaintiff's expert relied on surveys that the court deemed deficient and unreliable, and the experts' opinions relying on those surveys were deemed inadmissible and stricken under *Sargon Enterprises v. University of Southern California* (2012) 55 Cal.4th 747 and Evid Code § § 720(a), 801 and 803. (citing Amended Final Judgment.)