



FDLI Food Advertising, Labeling, and Litigation Conference

Key Developments in California's Prop 65 and Beyond

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Prop 65 Developments

- Averaging Regulations
- Glyphosate
- Acrylamide
- Furfuryl Alcohol
- Marijuana
- Nickel (soluble compounds)
- New York Consumer Right to Know Act
- Synthetic Food Dyes



Averaging Regulations

- Amendments to 27 CCR § 25821 (MADL Defense) –
CURRENT LAW
 - MADL Defense = **Level In Question** x1000 < NOEL
 - OEHHA's: "**level of exposure** . . . determined by multiplying the **level in question** (concentration of a chemical in a given medium) times the . . . **rate of exposure** . . . using the reasonably anticipated rate of **intake or exposure for average users** of the consumer product."
 - **Level of Exposure**= **Concentration** x **rate of exposure**

Averaging Regulations

- Amendments to 27 CCR § 25821 (MADL Defense) – PROPOSED CHANGES
- **Change 1:** No averaging test results across manufacturers, producers, or facilities.
 - Diminishes value of industrywide or academic surveys
 - Increases value of facility-specific COAs.
- **Change 2:** “Average rate” means arithmetic mean, not geometric mean.
 - Not adopted but would have partially overturned *E.L.F. v. Beech-Nut*.
 - In general, would have resulted in higher consumption rates

Averaging Regulations

- Lead MADL
 - OEHHA dropped its effort to lower the lead MADL; still at 0.5 mcg/day
- Averaging Over Time
 - OEHHA dropped its effort to restrict reproductive toxicants to a one-day period
 - But OEHHA has still stated that its lead MADL uses a one-day period
- Arithmetic Mean
 - OEHHA dropped its proposal to restrict “average” to arithmetic and not geometric mean
 - But OEHHA proposal said it was “clarifying” its original intent, which a court may honor
- Lot Averaging
 - OEHHA dropped its proposal to restrict averaging of concentrations across lots (foods)

Glyphosate



- Added to Prop 65 list in 2017
 - Per IARC: “probably carcinogenic to humans”
 - *Monsanto v. OEHHA* (Cal. Ct. App. 2018)
- *Wheat Growers v. Becerra* (E.D. Cal. 2018)
 - Enjoined the California AG from enforcing Prop 65’s warning requirement as to glyphosate
 - Government must prove that the compelled statement is factual and non-controversial
 - Summary judgment briefing underway

Glyphosate: US EPA Statement

- “Given EPA’s determination that glyphosate is ‘not likely to be carcinogenic to humans,’ EPA considers the Proposition 65 warning language based on the chemical glyphosate to constitute a false and misleading statement.”
 - FIFRA section 3(c)(5)(B)
- EPA Administrator Wheeler: "It is irresponsible to require labels on products that are inaccurate when EPA knows the product does not pose a cancer risk. We will not allow California’s flawed program to dictate federal policy.”



Glyphosate: OEHHA Response

- “OEHHA objects to US EPA’s characterization of any warning concerning glyphosate’s carcinogenicity as ‘a false claim’.”
- “It is disrespectful of the scientific process for US EPA to categorically dismiss any warnings based on IARC’s determinations as false.”
- “California law does not ‘dictate federal policy.’ Proposition 65 does not require US EPA to take any action on glyphosate or any other listed chemical.”



Acrylamide: Litigation

- 200+ Companies
- 7 Bounty Hunters plus the AG
 - Fries/Chips
 - Coffee
 - Cereal
 - Snack Foods
 - Hash Browns
 - Olives
 - Cookies
 - Toast
- 2003-present



Acrylamide: Science

- NSRL = 0.2 mcg/day; old OEHHA proposal to increase to 1.0
- Coffee testimony of at least 1.8 mcg/day, if not infinite
- OEHHA does not “know” that acrylamide causes cancer in humans
- Lipworth (2012) :
 - ... we found no consistent or credible evidence that dietary acrylamide increases the risk of any type of cancer in humans, either overall or among nonsmokers.
 - In conclusion, epidemiologic studies of dietary acrylamide intake have failed to demonstrate an increased risk of cancer.
 - ... the sporadically and slightly increased and decreased risk of cancer reported in more than two dozen papers suggests . . . a true null association. . . .

Acrylamide: Coffee



- *CERT v. Starbucks* litigation (L.A. Superior)
- Coffee Regulation
 - OEHHA regulation adopted June 2019; effective October 1, 2019
 - First time OEHHA has adopted such a regulation for any product or chemical
 - Litigation continues over validity of regulation and pending enforcement action

§ 25704. Exposures to Listed Chemicals in Coffee Posing No Significant Risk

Exposures to chemicals in coffee, listed on or before March 15, 2019 as known to the state to cause cancer, that are created by and inherent in the processes of roasting coffee beans or brewing coffee do not pose a significant risk of cancer.

Acrylamide: Preemption

- *Sowinski v. Post Foods (Cal. Ct. App. 2018)*
 - Prop 65 warnings for acrylamide in breakfast cereal are preempted because they conflict with the FDA's longstanding policy encouraging consumption of whole grains and breakfast cereal
 - Decision cannot be cited as precedent thanks to concerted effort by activists and the California AG to have it depublished
 - Decision was very much based on facts and FDA statements over the years
 - Nevertheless a recognition of FDA's power should it choose to exert itself



Furfuryl Alcohol

- Listing effective September 30, 2017
 - Based on one inhalation study
- Created by heat processing plus sugar
- May be found in most heat-processed foods
- Analytical methods are being developed
 - Easy to detect (bounty hunter's burden)
 - Hard to quantify (business's burden)
- OEHHA open to a safe harbor NSRL, with a numeric factor under the cooking provision

Furfuryl Alcohol: Litigation

- 2017 CEH notices on beef and poultry jerky
 - Withdrawn in light of FMIA and PPIA preemption
- 2017 CEH notices on BBQ and jalapeno chips
 - Not proceeding, probably based on analytical method issues
- 2017 and 2019 Embry notices on pretzels and bread
 - Nov 2017 notice on potato bread
 - March 2019 notices on pretzels
 - March 2019 notice on hamburger buns



Marijuana

- Marijuana smoke has been listed since 2009 as a carcinogen
- On March 15, 2019, OEHHA requested information on reproductive toxicity of four chemicals:
 - Cannabis (marijuana)
 - Marijuana (cannabis) smoke
 - Cannabis extracts
 - Δ -9-Tetrahydrocannabinol (THC)
- Submission period closed April 29, 2019
- OEHHA will develop the Hazard Identification Materials for submission to the DART-IC at a later date



Nickel (soluble compounds)

- OEHHA listed “nickel (soluble compounds)” as a reproductive toxin on October 26, 2018 based on DARTIC determination
 - Ambiguous discussion at DARTIC meeting
- OEHHA further defined the listing as “compounds of nickel with solubility in water of greater than 0.1 moles per liter (mol/L) at 20 degrees Celsius” (May 2, 2019)
 - Certainly includes nickel sulfate and nickel chloride
 - Other compounds?
 - Analytical methods not readily available
- Listing effective October 26, 2019



NY Consumer Right to Know Act

- NY Dept. of Envir. Conservation, NY Dept. of Health and NY Dept. of State
- Assessing on-package labeling and develop regulations establishing a labeling requirement
- Designate products
- Develop a list of carcinogens and other chemicals
- Enforcement?

Synthetic Food Dye Risk Assessment

- SB504 (2017) would have required labeling of foods containing synthetic food dyes
 - Watered down to a study bill
 - Appropriations rider directing OEHHA to undertake study
- OEHHA request for information (October 22, 2018 to February 19, 2019)
- OEHHA scientific symposium (September 19-20, 2019)
 - “to discuss the potential neurobehavioral effects in children”
 - “risk assessment of the potential impacts of synthetic food dyes, in particular those that are FDA batch-certified”
 - Focus on “the potential neurobehavioral and other neurological toxicity in children”

Synthetic Food Dye Risk Assessment

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|-------------------|----------------|
| FD&C Blue No. 1 | CAS 3844-45-9 |
| FD&C Blue No. 2 | CAS 860-22-0 |
| FD&C Green No.3 | CAS 2353-45-9 |
| Orange B | CAS 53060-70-1 |
| Citrus Red No. 2 | CAS 6358-53-8 |
| FD&C Red No. 3 | CAS 16423-68-0 |
| FD&C Red No. 40 | CAS 25956-17-6 |
| FD&C Yellow No. 5 | CAS 1934-21-0 |
| FD&C Yellow No. 6 | CAS 2783-94-0 |





QUESTIONS



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