

# interactive dialogue

The “**Prop 65 Risks for Food & Beverage Industry**”  
webinar will begin at 12:00 pm CT

To listen to the audio portion of the webinar, please dial  
1-800-536-9136, access code: 9038709#.

- A sign-in sheet and materials were attached to the program reminder email sent Tuesday, January 29, 2019.

- To submit a question before or during the webinar, please use the chat pane on the left-hand side of your screen.
- A replay of this webinar will be available upon request.



# interactive dialogue

## Prop 65 Risks for Food & Beverage Industry

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# a brave new format

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# Prop 65 – Legislative Background



## Brief Background on the Law (Cal. Health & Safety Code § 25249.5)

- **The Unusual Predicate:** Use of chemicals in products not prohibited, but a warning label is required.
- **Cancer and Reproductive Harm:** Dual focus of the law.
- **A Growing List:** 30 chemicals in 1987, over 900 today.
- **The Penalty (\$2,500):** Each exposure a separate violation.
- **A Thriving Cottage Industry:** A significant number of lawsuits continue to be filed by individuals and entities in the public interest.
- **“Safe Harbor” Concepts**
  - MADL (Maximum Allowable Dose Level) for reproductive toxins: identifies the exposure level and divides that figure by 1,000 to establish a margin.
  - NSRL (No Significant Risk Level) cancer: a safe harbor based on one cancer out of 100,000 exposed for a 70-year period.
- **Burden Shifting:** Once the presence of a chemical or carcinogen is established, burden shifts to defendant to show no warning required.
- **Transparency into Settlements:** Court approval required, Attorney General notification, amounts reported to the OEHHA, a searchable database.

# Prop 65 – Regulatory Developments



- **OEHHA's Concerns and Objectives**
  - Over-warning phenomenon
  - New methods and content for warnings including greater specificity as to the nature of the exposure
  - Apportioning responsibility among parties in the distribution chain
- **New Regulations Became Effective August 30, 2018**
  - **Methods and Contents of Warnings (§ 25601\*)—The New “Safe Harbors”**
    - Not required to use the warning methods but will be deemed a “safe harbor” to liability.
    - Two warning schemes: on-product warning labels vs. other warnings (e.g., packaging, website and catalogues)
    - Specificity required for all warnings, except on-product labels
  - **Apportionment of Liability (§ 25600.2)**
    - Product manufacturers, producers, packagers, importers, suppliers or distributors primarily responsibility for warning
    - Retailer following reasonable directives of manufacturer now has certain “safe harbors”
    - Agreements between the parties in the distribution chain
  - **Industry Specific Safe Harbors Including Food and Beverage**

“Section” refers to Title 27, Article 6, California Code of Regulations.

# Prop 65 – New Warning Regulations Applicable to Food & Beverage

## Food Exposure Warnings

- Methods of Transmission (§ 25607.1)
  - Food product label warnings must be set off from other information in a box (§ 25607.1(a))
  - If another language used on a sign, label or shelf tag, the warning must also be provided in that language. (§ 25607.1(b))
- Content Requirements (§ 25607.2)
  - **“WARNING”** in bold and all caps
  - Identification of at least one chemical and/or carcinogen
  - Explicit reference to OEHHA Prop 65 website



### **WARNING**

“Consuming this product can expose you to chemicals, including [name of one or more chemicals], which [is/are] known to the State of California to cause cancer. For more information to [www.P65Warnings.ca.gov/food](http://www.P65Warnings.ca.gov/food)”

# Prop 65 – New Warning Regulations Applicable to Food & Beverage



## Food and Non-Alcoholic Beverage Exposure Warnings for Restaurants

### – Methods of Transmission (§ 25607.5)

- At least one of the following:
  - 8½ x 11 in. sign, 28-point or larger type, readable and conspicuous to customers as they enter each public entrance to the restaurant or facility;
  - 5x5 in. or larger notice/sign, 20-point or larger type, placed at each point of sale so as to assure that it is readable and conspicuous; and/or
  - Warning on any menu or list describing food or non-alcoholic beverage offerings, type size no smaller than the largest used for the names of general menu items;
- Provided in English and in any other language used on other signage or menus

### – Content (§ 25607.6)

- **“WARNING”** in bold and all caps
- The words, “Certain foods and beverages sold or served here can expose you to chemicals including acrylamide in many fried or baked foods, and mercury in fish, which are known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to [www.P65Warnings.ca.gov/restaurant](http://www.P65Warnings.ca.gov/restaurant).”

# Prop 65 – New Warning Regulations Applicable to Food & Beverage



## Alcoholic Beverage Exposure Warnings

### – Methods of Transmission (§ 25607.3)

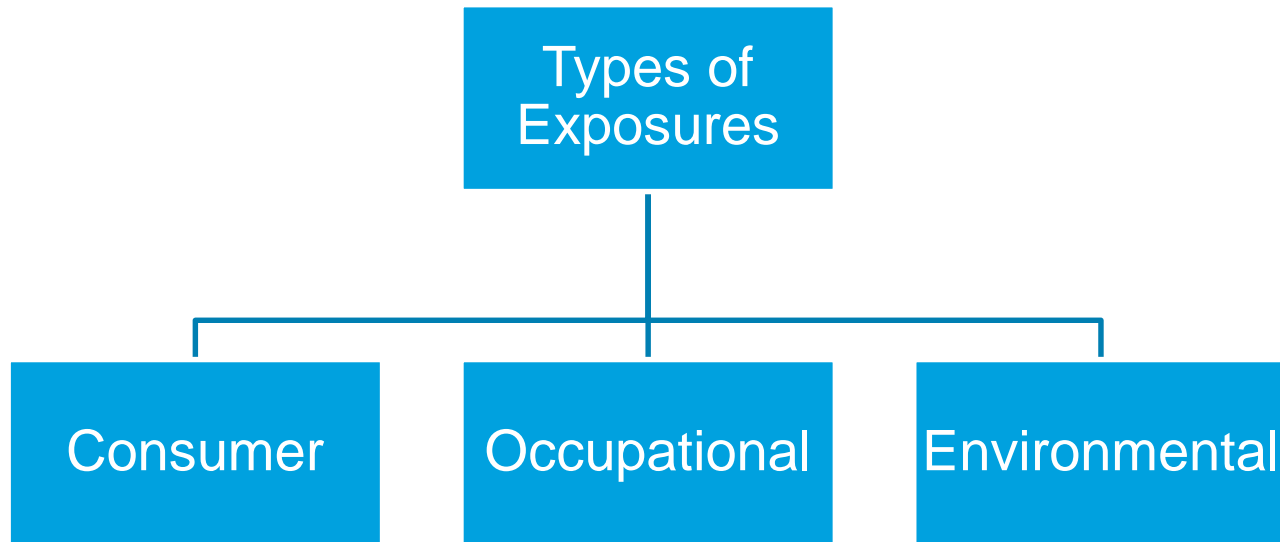
- At least one of the following:
  - 8.5 x 11 in. sign, 22-point or larger type, placed at eye level so as to be readable and conspicuous to customers upon entrance to areas where alcoholic beverages are served
  - 5x5 in. or larger sign, 20-point or larger type, displaying “boxed” WARNING, placed at each retail point of sale or display to assure it is readable and conspicuous
  - For on-premises consumption, warning to be provided on menu or list identifying alcoholic beverages served; or if no such menu/list, on the menu or list for food and other beverages sold on premises
  - For sale/distribution to CA purchasers through package delivery services, incorporation of the warning message on or in the shipping container or delivery package, in type size no smaller than largest type for other consumer information on the product
- Provided in English and any other language used for labeling or advertising the product on premises

### – Content (§ 25607.4)

- “**WARNING**” in all caps and bold print
- The words, “Drinking distilled spirits, beer, coolers, wine and other alcoholic beverages may increase cancer risk, and, during pregnancy, can cause birth defects. For more information go to [www.P65Warnings.ca.gov/alcohol](http://www.P65Warnings.ca.gov/alcohol).”



# Prop 65 – Warning Obligation Arises From Exposures



# Prop 65 – The Ingredient Catch-22

**Ingredient manufacturers of bulk-sold ingredients must warn, but dependent upon the concentration or manner of use**



- How can a manufacturer comply with the warning requirement where the need for a warning depends on the concentration or the manner of use of the listed chemical in the final product?
- How can a manufacturer assess consumer use?

# Prop 65 – Naturally Occurring Exemption

**Consumption ≠ ‘exposure’ to listed chemical contained in a food, “if the person responsible for the exposure can show that the chemical is naturally occurring in the food.” § 25501(a).**

- “[A] chemical is ‘**naturally occurring**’ if it is 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 which is **naturally present in the environment in which the food is raised, or grown, or obtained.**” § 25501(b).
- Several limitations:
  - The chemical cannot result from any known human activity (e.g., addition of chemical fertilizers)
  - The chemical must have been unavoidable despite good agricultural or manufacturing processes
  - The chemical is not present above the “lowest level currently feasible”



## Arsenic in Rice

- Arsenic is a Prop 65 list chemical
- While not a natural component of rice, environmental factors have led to presence of arsenic in rice grown in certain regions
- OEHHA has identified exemption levels for inorganic arsenic in rice (§ 25501.1(a) (adopted Aug. 9, 2018))

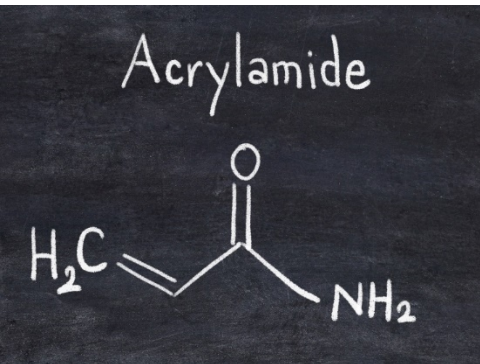
# New York CLE Code



**“We have some NY lawyers participating today. In accordance with NY CLE Rules, the New York Verification Code for this program is**

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# Prop 65 – The Big Five



- **Acrylamide**

- A chemical compound with the chemical formula  $C_3H_5NO$
- Naturally occurring in the process of baking, frying or roasting plant-based foods
- MADL = 140 micrograms per day
- Food Focus
  - The Coffee Saga. Significant loss for industry in Los Angeles Superior Court followed by an OEHHA walk-back late in the year. Ultimate result: Prop 65 warnings not required for coffee.
  - French fry, potato chip/KFC vs. coffee
  - FDA Guidance provides information to help growers, manufacturers, and food service operators reduce acrylamide levels in certain foods.
- Aug. 29, 2018 letter from FDA to OEHHA regarding acrylamide warnings for foods such as coffee and whole-grain cereals, raised concerns that such warnings were misleading to consumers, ignored the health benefits of those foods, and might encourage consumers to alter their diets in ways that may not benefit their health



# Prop 65 – The Big Five



- **Glyphosate**

- Chemical used in herbicides such as Roundup
- Trace amounts of glyphosate can found in soy, corn and corn oil, nuts, beets, beet sugar, carrots, grains
- Concerns raised in Europe in 2015--“*probably* carcinogenic in humans”
- Listed on Prop 65 List in 2017 (met the “*known* to the State of California to cause cancer” standard)
- NSRL = 1100 micrograms per day
- \$289 million personal injury verdict in San Francisco in August 2018 brought attention and a wave of lawsuits (Bayer, which acquired Monsanto, reported 8,000 pending lawsuits as of August 2018)
- Parallel lawsuits with mixed results:
  - *Monsanto Co. v. Office of Environmental Health Hazard Assessment* (“OEHHA”), No. 16-CE CG 00183 (Fresno County Superior Court),
    - Argument improper delegation “authoritative body” International Agency for Research on Cancer, forced speech
    - Challenges unsuccessful at trial court, Court of Appeal and review denied by Cal. Supreme Court
  - *National Association of Wheat Growers et al v. Lauren Zeise, director of OEHHA, et al, U.S. District Court, Eastern District of California, No. 17-at-01224.*
    - Adopted the force speech argument

# Prop 65 – The Big Five

## Bisphenol A (BPA)



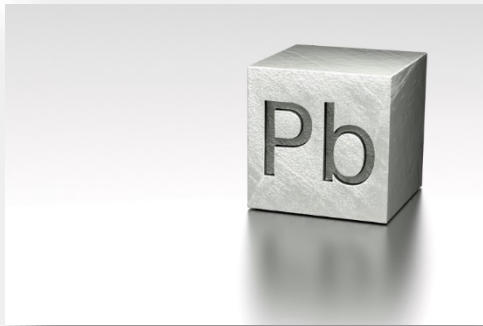
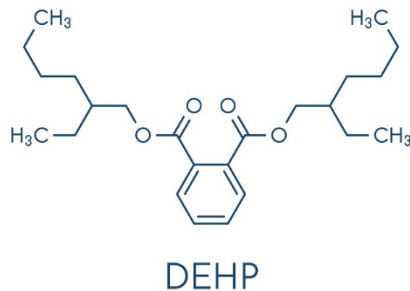
- Widely used chemical, including in some protective coatings, such as linings that prevent rust, corrosion, and contamination in metal food and drink cans, jar lids and bottle caps
- **Safe Harbor (§ 25607.30):** Applicable to “canned and bottled foods and beverages” which means “foods and beverages packaged in hermetically sealed, durable metal or glass containers, including, but not limited to, those containing fruits, vegetables, soups, pasta products, milk, soda, and alcoholic beverages.”

### Two Options:

1. Product Label: “WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm” (§ 25607.30(a)(1)(A))
2. Point of Sale Warnings: Must provide written notice and the signs at no costs. (§§ 25607.30(a)(1)(B); 25607.31)

“Many food and beverage cans have linings containing bisphenol A (BPA), a chemical known to the State of California to cause harm to the female reproductive system. Jar lids and bottle caps may also contain BPA. You can be exposed to BPA when you consume foods or beverages packaged in these containers. For more information go to:  
[www.P65Warnings.ca.gov/BPA](http://www.P65Warnings.ca.gov/BPA).”

# Prop 65 – The Big Five



- **DEHP (Di(2-ethylhexyl)phthalate):**
  - “DEHP belongs to a family of chemicals called phthalates, which are added to some plastics to make them flexible.” OEHHA Website
  - Virtually eliminated from most food packaging, but may be detected in food that has come into contact with certain plastic during processing and packaging
- **Lead:** An “oldie but goodie” in Prop 65.
  - OEHHA Warns that lead has been found in “[s]ome candies and spices from Mexico and Asia, some balsamic vinegars, some brightly colored traditional remedies such as Azarcon and Greta, and some dietary supplements”
  - Naturally occurring is not a defense

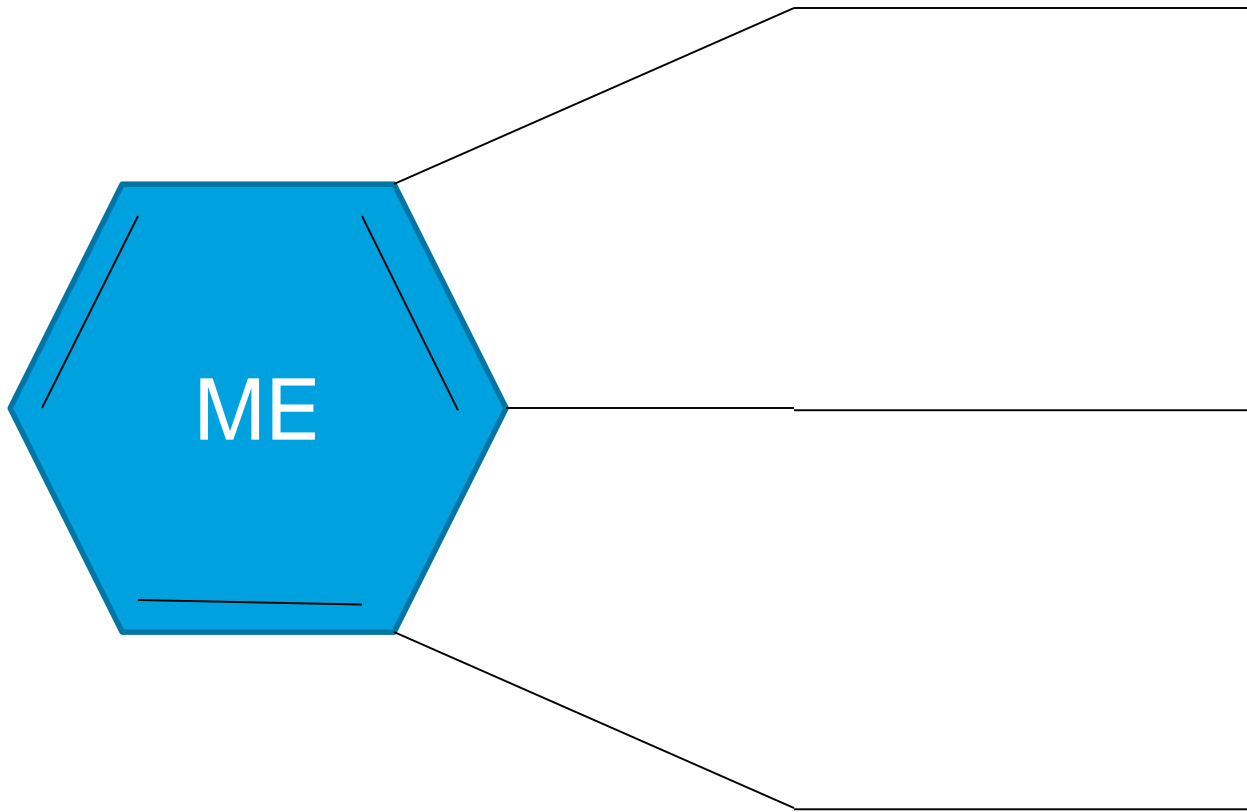


# The Future of Prop 65

- **The FDA's Shot Across California's Bow**
- **California Will Continue to Look to European Regulators**
- **Growing Consensus for Uniform Standards Over Patchwork of State Regulations**
- **Laws Similar to California's Prop 65 are Sprouting up in Other Jurisdictions**
- **Preemption Options to the FDA and Congress**
- **Courts More Sympathetic to Responsible Defendants, Questioning Junk Science**



# What to do next?



# who wants more credit? CLE credit, that is...

Complete the sign in sheet included in the reminder email (sent yesterday) and return to [hubble.michelle@dorsey.com](mailto:hubble.michelle@dorsey.com).

We will send CLE Certificates to those who return the form.

# questions?



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