Proposition 65
Acrylamide & Furfuryl Alcohol

Martin J. Hahn

May 2, 2018
Agenda

• Proposition 65 101
• Acrylamide
• Furfuryl alcohol
• Questions and Answers
California’s Proposition 65

- State law adopted in 1986
- Requires the state to revise and republish at least once per year the list of chemicals known to the State to cause cancer or reproductive toxicity
- Over 900 chemicals listed
- Consumer right-to-know: requires a warning/notice in instances when a product contains a listed chemical
California’s Proposition 65

• Proposition 65 is not a safety statute
• Office of Environmental Health Hazard Assessment (OEHHA)
• Proposition 65 involves conditions under which California residents must be warned
  – Retail exposure
  – Internet sales
Proposition 65 Warning for Foods

**WARNING**: Consuming this product can expose you to chemicals including acrylamide, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov/food.
Enforcement

- State can sue to enforce warning requirements
- Bounty hunter provision allows private parties to bring a law suit (and get paid)
- Violations of Proposition 65 are subject to civil penalties of up to $2,500 per day per violation; 25% of any assessed penalty goes to a successful plaintiff
- Lawsuits usually result in consent decree settlements
Consent Decree Settlements

- Civil penalties and attorneys fees
- Target listed chemical levels
- Specified warning language
- Agreement between plaintiffs or the state and individual companies
- Many contain “opt-in” provisions
- Require annual monitoring to document compliance
Defense - Naturally Occurring Exemption

• Prop 65 Excludes Naturally Occurring Substances:
  Must be naturally present in the environment with no intervention by man (including processing)...company bears burden of proof

• 27 CCR § 25501
What is Naturally Occurring?

- Lead in calcium supplements, ginger, shellfish, and other foods?
- Mercury in tuna?
- Acrylamide or furfuryl alcohol that form during cooking?
Defense--Safe Harbor Exemption

- Warning is not required if within a safe harbor:
  - OEHHA publishes many safe harbors
  - Company can calculate safe harbor but bears risk OEHHA would disagree
- Safe harbor is reported in micrograms per day
Defense - Safe Harbor Exemption

- Safe harbors can be established by OEHHA or industry
- For carcinogens, the risk level which represents no significant risk is less than a 1 in 100,000 increase in risk of cancer over 70 years, except where sound considerations of public health support an alternative level, as, for example:
  - “where chemicals in food are produced by cooking necessary to render the food palatable or to avoid microbiological contamination”
- 27 CCR 25703(b)(1)
Keep Your Eye on Coffee

• Coffee industry being sued for failing to warn of acrylamide
• Industry is arguing an acrylamide forms due to food safety so 1:100,000 does not apply
• Court disagreed.....
Acrylamide

- Acrylamide has been on Prop 65 list since 1990
- In 2002, Swedish scientists discovered acrylamide in food
- Acrylamide forms as part of Maillard reaction—asparagine and sugar—at high temperatures
Levels of Acrylamide in Foods Reported by FDA

- FDA website contains a list of acrylamide levels in foods 2002-2006
  - Salted Almonds 236 ppb
  - Smoked Almonds 457 ppb
  - Salted Almonds 249 ppb
  - Salted Cashews ND
  - Salted Peanuts ND
  - Party Peanuts ND

https://www.fda.gov/Food/FoodborneIllnessContaminants/ChemicalContaminants/ucm053549.htm
Prop 65 Safe Harbors for Acrylamide

- 0.2 ug/day (cancer)
- 140 ug/day (reproductive toxicity)
- How do you convert ug/day into ppb to determine the level that can be in your food?
- You need to conduct an intake assessment
Do the Math

- Courts Recognize
  - Use of Geometric Mean (from NHANES)
  - Adjusted for food frequency (remember 70 year life exposure)
  - Use of rounded values
Converting the “Safe Harbor” to ppb in Product

• Assumptions:
  – Geometric mean for nut intake is 20 grams
  – Food frequency is every 10 days
  – Safe harbor is 0.2 ug

• MATH:
  \[ X \text{ ug/kg} \times 0.020\text{kg chips/day} \times \frac{1\text{ consumption/every 10 days}}{0.2 \text{ ug per day}} = X = 100 \text{ ug/kg or 100 ppb}\]

**Purely hypothetical number**
Acrylamide “Negotiated Safe Harbors”

- There are multiple consent decrees for acrylamide in savory snacks
- Most consent decrees set the “safe harbor” at 281 ppb (some are set at 275 ppb)
- Consent decrees cover:
  - Cereals
  - Potato chips
  - Tortilla chips, taco shells
  - Pretzels
  - Baked Snacks
  - Popcorn
  - Pork rinds
  - Puff extruded corn products
- Different safe harbor of 490 ppb is set for potato crisp-type products
Recent Activity

• 2016-17 we saw an uptick in acrylamide notices with about 100 filed within past year
  – Targeting primarily food retailers and manufacturers of savory snacks
  – Targeting savory snacks that have not been included in other consent decrees
  – Center for Environmental Health (CEH) has filed many of them
Furfuryl Alcohol

- OEHHA listed furfuryl alcohol under Proposition 65 on September 30, 2016, as a chemical known to the state to cause cancer for purposes of Proposition 65
- Sometimes intentionally added to foods as a flavoring
- Formed during heat processing – Maillard reaction
Furfuryl Alcohol

• The compliance date for Proposition 65 warning regarding furfuryl alcohol – containing products was September 30, 2017

• OEHHA has not established a safe harbor for furfuryl alcohol

• One conservative furfuryl alcohol “safe harbor” is 9.5 µg/day (cancer)

• An alternative risk level for furfuryl alcohol in foods higher than 9.5 µg/day (cancer) may also be developed
Converting the “Safe Harbor” to ppb in Product

- **Assumptions:**
  - Geometric mean for nut intake is 20 grams
  - Food frequency is every 10 days
  - Safe harbor is 9.5 ug

- **MATH:**
  \[ X \text{ ug/kg} \times 0.020 \text{ kg chips/day} \times 1 \text{ consumption/every 10 days} = 9.5 \text{ ug per day} \]

  \[ X = 4750 \text{ ug/kg or 4750 ppb}** \]

**Purely hypothetical number**
Recent Activity

- At least six 60-day notices have been filed on furfuryl alcohol since the compliance date
  - Targeting primarily food retailers and manufacturers of potato based snacks and pretzels
  - Center for Environmental Health (CEH) has filed four of the six
What to Do?
What to Do?

- Information is key
  - What levels of acrylamide or furfuryl alcohol form in your product?
  - What mitigation measures are available, if any, to reduce?
  - Have you done an intake assessment for the Prop 65 analysis
- While the issue impacts the industry, individual company results could vary depending on product and process
Additional Challenges

• Importance of using a validated analytical method
  – No AOAC method for furfuryl alcohol or acrylamide
  – FDA has published a method for acrylamide: coffee court rejected industry data for using a different method

• Currently, courts allow averaging, which supports collecting multiple data points
Warnings

• WARNING: Each company must consult with its own counsel to determine whether a warning is advisable, the level that would trigger the warning, and the language that should be used

• Labels and in-store signs are among the options
New California Regulation on Warnings

• On August 30, 2016, the OEHHA approved the adoption of amendments to Article 6, Clear and Reasonable Warnings
• Businesses have the option of continuing to comply with the current version of the regulations until August 30, 2018, or comply with these new regulations in advance of the effective date
• Requires warning to identify the name of one or more of the listed substances
• Provides options
  1. Label
  2. Providing specific written notice to the agent or retailer
  3. Private Contract with Retailers
New California Regulation on Warnings

• In practice, for a food product that may expose consumers to both listed carcinogens and reproductive toxicants, that the following warning content is deemed compliant by OEHHA:

• “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 and [name of one or more chemicals], which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov/food.”

• When the warning is provided on the food product label, it must be set off from other surrounding information, enclosed in a box and comply with the content requirements
What To Do If You Receive a Demand Letter?

- Bounty hunters are required to give companies notice of alleged violation
- Collect the facts
  - Do your products have furfuryl alcohol or acrylamide?
  - What levels?
- Work with legal counsel to develop best possible strategy
  - How do your numbers compare with safe harbor?
  - Is it worthwhile to support the development of an alternative risk level?
A Word on Glyphosate

• Feb 28, 2018 federal District Court grants motion for preliminary injunction precluding California from requiring glyphosate cancer warning

• Will it survive appeal?
Questions?

Martin J. Hahn
Partner
Martin.Hahn@hoganlovells.com
(202) 637-5926